ICSI Institute for Clinical Systems Improvement

## Health Care Protocol

# Perioperative Protocol

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# Evidence Grading

## Literature Search

Literature search terms for the current revision of this document include smoking as a risk factor for SSI, malnutrition as a risk factor for SSI, nicotine and wound healing. Literature search terms used for this revision are below and include literature from 2011 through 2013.

## GRADE Methodology

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include:

- developed by a widely representative group of international guideline developers;
- explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings;
- clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations;
- clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers;
- explicit acknowledgement of values and preferences; and
- explicit evaluation of the importance of outcomes of alternative management strategies.

**This document is in transition to the GRADE methodology**

Transition steps incorporating GRADE methodology for this document include the following:

- Priority placed upon available Systematic Reviews in literature searches.
- All existing Class A (RCTs) studies have been considered as high quality evidence unless specified differently by a work group member.
- All existing Class B, C and D studies have been considered as low quality evidence unless specified differently by a work group member.
- All existing Class M and R studies are identified by study design versus assigning a quality of evidence. Refer to Crosswalk between ICSI Evidence Grading System and GRADE.
- All new literature considered by the work group for this revision has been assessed using GRADE methodology.

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| Category | Quality Definitions | Strong Recommendation | Weak Recommendation |
|---|---|---|---|
| **High Quality Evidence** | Further research is very unlikely to change our confidence in the estimate of effect. | The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients. | The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences. |
| **Moderate Quality Evidence** | Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. | The work group is confident that the benefits outweigh the risks but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients. | The work group recognizes that there is a balance between harms and benefits, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances. |
| **Low Quality Evidence** | Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain. | The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available. | The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms. |

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# Recommendations Table

The following table is a list of evidence-based recommendations for the Perioperative protocol.

Note: Other recommendation language may appear throughout the document as a result of work group consensus but is not included in this evidence-based recommendations table.

| Topic | Quality of Evidence | Recommendations | Strength of Recommendation | Annotation Number | Relevant Resources |
|---|---|---|---|---|---|
| Preoperative basic health assessment | Low | A preoperative basic health assessment must be completed for all patients undergoing a diagnostic or therapeutic procedure. | Strong | 1 | *Committee on Standards and Practice Parameters, 2012; Roizen, 1987* |
| Electrocardiogram | Low | Perform electrocardiogram for all patients age 65 and over within one year prior to procedure. | Weak | 1.21 | *Correll, 2009* |
| | High | Electrocardiograms are not indicated, regardless of age, for those patients having cataract surgery. | Strong | 1.21 | *Schein, 2000* |
| | High | Preoperative electrocardiograms are not recommended for patients undergoing other minimal risk procedures, unless medical history/assessment indicate high-risk patient. | Strong | 1.21 | *Schein, 2000* |
| Hemoglobin | Low | The reason to obtain a preoperative hemoglobin should be based on the patient's underlying medical condition and the planned procedure. | Strong | 1.22 | *Wasserman, 1964* |
| Beta-Blocker | High | All surgical patients should be assessed for cardiac risk factors. | Strong | 2.11 | *Fleisher, 2007* |
| | High | Beta-blocker therapy should be continued perioperatively in patients currently taking beta-blockers. | Strong | 2.11 | *Fleisher, 2007* |
| | Low | Initiation of beta-blocker therapy should be considered for patients undergoing vascular surgery with high cardiac risk (CAD, positive stress test or presence of more than one clinical risk factor). | Strong | 2.11 | *Fleisher, 2007* |
| | Low | Initiation of beta-blocker therapy should be considered in all patients undergoing intermediate-risk surgery with CAD or high cardiac risk (defined by the presence of more than one clinical risk factor). | Strong | 2.11 | *Fleischmann, 2009* |
| | High | Beta-blocker therapy should be initiated one to two weeks prior to surgery if possible, and titrated to goal heart rate 60-80 bpm. | Strong | 2.11 | *Fleischmann, 2009* |
| | High | Beta-blockers should be continued postoperative for at least 30 days (longer if beta-blocker was taken prior to surgical procedure). | Strong | 2.11 | *Fleischmann, 2009* |

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| Topic | Quality of Evidence | Recommendations | Strength of Recommendation | Annotation Number | Relevant Resources |
|---|---|---|---|---|---|
| Statin Therapy | Low | All surgical patients should undergo assessment of cardiac risk factors. | Strong | 2.12 | *Fleisher, 2007* |
| | Low | Statin therapy for patients currently taking statins should be continued perioperatively. | Strong | 2.12 | *Fleisher, 2007* |
| | Low | Initiation of perioperative statin therapy in patients undergoing vascular or intermediate-risk procedures should be considered. | Strong | 2.12 | *Fleisher, 2007* |
| Anticoagulation and blood disorders | Low | If clinical circumstances suggest a potential bleeding problem, clinician should perform coagulation studies. | Strong | 2.13 | *Asaf, 2001* |
| Coronary stent | Low | Surgery should be avoided for at least four weeks after bare-metal stent implantation. | Strong | 2.131 | *Douketis, 2012; Holmes, 2010; Grines, 2007* |
| | | Surgery should be avoided for one year after drug-eluting stent implantation. | Strong | 2.131 | |
| | | If surgery cannot be avoided during the above time periods, dual anti-platelet therapy should be continued perioperatively unless strongly contraindicated (i.e., procedures associated with high risk for clinically significant bleeding, such as intracranial surgery). | Strong | 2.131 | |
| | | If deemed necessary to discontinue clopidogrel/prasugrel/ticlopidine preoperatively, aspirin should be continued, if at all possible, in the perioperative period in order to decrease cardiac risk. | Strong | 2.131 | |
| Sleep apnea | Moderate | Clinicians should remind patients who have been formally diagnosed with obstructive sleep apnea and have an oral applicance or continuous positive airway pressure equipment to bring their appliance or equipment with them on the operative day. | Strong | 2.2 | *Farney, 2011; Vasu, 2010; Abrishami, 2010; Gupta, 2001* |
| | Low | Clinicians should screen patients for sleep apnea or sleep apnea symptoms and communicate to surgical team. | Strong | 2.2 | |

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| Topic | Quality of Evidence | Recommendations | Strength of Recommendation | Annotation Number | Relevant Resources |
|---|---|---|---|---|---|
| Diabetes | Low | Individual patient evaluation and instruction should occur prior to surgery to avoid extremes in glucose levels. | Strong | 2.3 | *Mercado, 2003* |
| | | Doses of long-acting insulins (glargine, NPH, etc.) may be decreased by up to 50% preoperatively. | Strong | | |
| | | Oral diabetic agents should be held preoperatively. | Strong | | |
| | | Short-acting, sliding scale insulin should be used to treat high blood glucose values in patients holding their normal anti-diabetic medications. | Strong | | |
| | Low | GLP-1 agonists (exenatide, liraglutide, pramlintide) should be held perioperatively. | Strong | 2.3 | *Meneghini, 2009* |
| | Low | DPP-4 inhibitors (sitagliptin) can be continued peri-operatively, if patient desires. | Strong | 2.3 | *Meneghini, 2009* |
| Glycemic control | High | Glycemic control should be directed at achieving blood glucose levels between 140 and 180 mg/dL and not be directed at more intensive goal targets (80-110 mg/dL). | Strong | 2.31 | *Kansagara, 2011; NICE SUGAR Study Investigators, 2009; Van den Berghe, 2009; Griesdale, 2009* |
| Drugs to continue | Low | Clinicians should complete a thorough medication review (including all prescription, non-prescription, and herbal or "natural" medications) with the patient at least one week before surgery if at all possible. | Strong | 2.41 | *Winchester, 2010; Levin, 2009; Comfere, 2005; Pass, 2004; Mercado, 2003; Ang-Lee, 2001* |
| | Low | Medications contributing to the patient's current state of medical homeostasis should be continued (i.e., neuro/psych medications, anti-arrhythmic agents, HIV medications, statins, anti-hypertensives) with the exception of the medication groups listed in drugs to stop. | Strong | 2.41 | |

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| Topic | Quality of Evidence | Recommendations | Strength of Recommendation | Annotation Number | Relevant Resources |
|---|---|---|---|---|---|
| Drugs to stop | Low | Medications that do not contribute to the medical homeostasis of the patient should be discontinued in preparation for surgery (i.e., non-prescription medications, herbal or natural medications, and over-the-counter supplements). | Weak | 2.42 | *Levin, 2009; Pass, 2004; Mercado, 2003; Ang-Lee, 2001* |
| | | Medications that may increase risk of adverse outcomes perioperatively should generally be discontinued according to pharmacokinetic principles (i.e., NSAIDS, ACEI [angiotensin converting enzyme inhibitor]), ARB [angiotensin receptor blocker], diabetes medications, anticoagulants, osteoporosis agents, hormone therapy). | Weak | 2.42 | |
| | | Inadvertent administration of medications the night before or morning of surgery is not typically an indication for cancellation of surgical procedures. | Weak | 2.42 | |
| Nicotine cessation | Low | Patients should be strongly encouraged always to quit nicotine use. | Strong | 2.5 | *Myers, 2011* |
| Antibiotic management | Low | Clinicians should assess patients for known drug allergies. | Strong | 3 | *Medical Letter Treatment Guidelines, 2006; Bratzler, 2005a; Bratzler, 2005b; Prokuski, 2005* |
| | Low | Clinicians should administer appropriate prophylactic antibiotic for procedure within one hour prior to surgical incision or two hours for vancomycin/fluoroquinolones. | Strong | 3 | *Medical Letter Treatment Guidelines, 2006; Bratzler, 2005a; Bratzler, 2005b; Prokuski, 2005* |
| | Low | Prophylactic antibiotics should be discontinued within 24 hours after surgery end-time for all non-cardiac procedures. | Strong | 3 | *Medical Letter Treatment Guidelines, 2006; Bratzler, 2005a; Bratzler, 2005b; Prokuski, 2005* |
| | Low | Prophylactic antibiotic should be discontinued within 48 hours after surgery end-time for all coronary artery bypass graft (CABG)/cardiac procedures. | Strong | 3 | *Mertz, 2011* |

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| Topic | Quality of Evidence | Recommendations | Strength of Recommendation | Annotation Number | Relevant Resources |
|---|---|---|---|---|---|
| Prevention of endocarditis | Low | Patients diagnosed with certain cardiac conditions and undergoing specified procedures should receive appropriate antibiotic prophylaxis. | Strong | 3.21 | *Wilson, 2008* |
| Procedures in patients with previous total joint replacement | Low | Patients with prosthetic joints should not receive prophylaxis to prevent infected joint prosthesis. | Strong | 3.3 | *Fleisher, 2007* |
| Preventing fires in the OR/procedure room | Low | Each organization should have an OR prevention fire policy structured to fit the physical environment of the OR suites. | Strong | 17.2 | *Nishiyama, 2010; AORN, 2007* |
| | Low | The policy should be reviewed each year after the fire drill practice and updated with any needed changes. | Strong | 17.2 | *Nishiyama, 2010; AORN, 2007* |
| | Low | Each organization should have a comprehensive fire drill at least once a year. This should include different fire scenarios each year. | Strong | 17.2 | *Nishiyama, 2010; AORN, 2007* |
| | Low | All members of the perioperative team and support services in the surgical environments should participate in the drill. | Strong | 17.2 | *Nishiyama, 2010; AORN, 2007* |
| | Low | Local fire department members and organizational life safety representation should participate in the fire drill. | Strong | 17.2 | *Nishiyama, 2010; AORN, 2007* |

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# Foreword

## Introduction

This protocol describes the recommended actions to be taken throughout the perioperative period (preoperative, intraoperative and postoperative) in order to make operative procedures as safe as possible through systematization, protocols and providing metrics to measure and strive to improve. The purpose is to mitigate the risk of "never events" such as wrong site, patient or procedure and unintentional foreign body retention, as well as minimization of the risks of other complications and events such as surgical site infection, hypothermia and environmental mishaps, and provide guidance in other important areas such as medication management, patient evaluation and overall risk mitigation. Whenever possible, it has been crafted on an evidentiary basis, with the caveat that some recommendations do not have strong evidence within the literature but are thought by the work group to deserve strong recommendations regardless. The protocol also recommends metrics to be followed so that implementation of the protocol can be tracked, problems identified and overall systems improved. References are provided as more comprehensive resources on particular topics.

The science of safety within medicine has made dramatic strides over the past several years as the benefits of such elements as checklists, universal protocols and focused improvement on measurable metrics have become clear and increasingly utilized across the field. Accompanying this has been increasing interest and focus on the quality of evidence in the literature, with formal grading systems to assess this. Not coincidentally, governmental regulations and reimbursement (or the lack thereof) regarding "never events" – events that should presumably never occur – have pressed the medical field even further to systematize, measure and improve outcomes.

The process of systematizing critical processes was pioneered by the aviation industry, and it has been demonstrated that broadly and systematically employing processes that include standardized procedures to minimize variation, implement communication techniques and minimize distractions during critical steps lead to improved safety and reliability. In the initial phases of any system re-design, there is by its very nature a lack of statistically significant evidence upon which to base the initial changes. Additionally, some elements are impractical or even impossible to rigorously test in a prospective, randomized fashion. An example given for both its logical impact and humor value is the use of parachutes: there exists no prospective randomized study of parachutes versus no parachutes, nor will there ever be. Having stated this, however, no one would suggest abandoning the use of parachutes for lack of evidence that they are necessary. But in many areas, data are available and as systems are implemented, metrics are accumulated and followed, determinations of efficacy are made and future designs can be improved on the basis of stronger and stronger data.

This revision of the ICSI Perioperative protocol has a number of important changes and evolutions from previous versions in addition to incorporating the latest literature into the recommendations and protocol. It has combined two previously separate documents – the Preoperative guideline and the Perioperative protocol – into one comprehensive document, and the entire document has been extensively reorganized for easier reading and logical access to particular topics, elimination of redundancy and overall clarity. Evidence-based grading of the literature upon which the document is based has been utilized throughout the document. There are new recommendations on minimization of environmental hazards.

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## Scope and Target Population

The protocol describes appropriate evaluation for operative procedures for adult and pediatric patients. Pediatric patients for whom this protocol is intended are those between the ages of 2 and 15 years. Patients over age 15 are considered adults for the purposes of this protocol.

Emergent and urgent procedures are outside the scope of this protocol, but the topics of this protocol may still apply.

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## Aims

1. Increase the percentage of patients age two years and older with complete preoperative history and physical examination obtained prior to undergoing elective, non-high-risk surgery and no diagnostic tests performed without clinical indications. *(Annotation #1)*
2. Increase the percentage of patients age two years and older undergoing elective, non-high-risk surgery who receive appropriate management of stable comorbidities prior to procedure. *(Annotation #2)*
3. Decrease the percentage of patients age two years and older who have canceled or delayed elective, non-high-risk surgical procedures due to incomplete preoperative basic health assessment and ineffective communication between clinicians. *(Annotations #1, 4)*
4. Eliminate the wrong surgical procedure or surgery performed on the wrong body part, or on the wrong patient. *(Annotation #16)*
5. Eliminate unintentionally retained foreign objects during a surgical procedure. *(Annotation #16)*
6. Minimize the rate of wound infections in surgical patients. *(Annotations #3, 9, 17)*
7. Improve the adherence to the key components of the Perioperative protocol. *(Annotations #1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18)*

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## Clinical Highlights

- Provide a comprehensive preoperative basic health assessment for all patients undergoing a diagnostic or therapeutic procedure as defined in the protocol. *(Annotation #1)*
- Most laboratory and diagnostic tests including electrocardiograms are not necessary with routine procedures unless a specific indication is present. *(Annotation #1.21)*
- Patient education and instruction strongly influence perioperative outcomes (e.g., medication management, apnea screening, nicotine cessation and surgical site infection). *(Annotation #4; Aim #3)*
- Preoperative verification process includes patient identification, procedure(s), site(s), laterality and level. This process is confirmed by source documents, consent form, medical record and discussion with the patient. Additional verification must occur at designated points in the perioperative period. *(Annotation #5)*
- All procedure sites – including level, position, laterality, multiple sites/digits in the same anatomic location – and bilateral procedures will be marked with the surgeon's initials. The surgeon should follow the preoperative verification process prior to marking the sites. Surgeon initials must be visible at time of incision. Note: An anatomical diagram shall be used to identify surgical site(s) that are not visible through the surgical drape. *(Annotation #6)*

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- A Time-Out will be performed just prior to the start of the procedure (after the surgeon has scrubbed and gowned), with active verbal confirmation by all the professionals involved in the care of the patient. A repeat Time-Out will be performed for multiple procedures or position changes. An intraoperative pause shall be performed for all procedures that involve level, implants and/or laterality after an orifice or midline entry. *(Annotation #10)*
- A pre-procedure briefing will be conducted. The purpose of the briefing is to present the plan for the procedure and confirm with the team members what will be needed during the procedure and when it will be needed. *(Annotation #15)*
- When a hand-off is required, a structured process should be followed. *(Annotation #15)*
- A Hard Stop will occur when either the verification process is incomplete and/or a discrepancy is identified. The procedure will not proceed until the discrepancy is resolved. *(Annotations #12)*
- Baseline counts should be effectively and reliably performed for all countable items. *(Annotation #16.11)*
- Imaging is required if the final count is unable to be reconciled. *(Annotation #16.12)*

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# Implementation Recommendation Highlights

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.

- Develop a reliable, standardized system to obtain complete preoperative basic health assessments and appropriate preoperative testing to eliminate unwarranted variation. (See Appendix B, "Preoperative Questionnaire – Adult" and Appendix C, "Preoperative Questionnaire – Pediatric.")
- Establish a reliable mechanism to communicate completed preoperative basic health assessments, associated test results, and instructions to procedure location and patient prior to procedure. (See Appendix A, "Patient Preoperative Guide.")
- Develop a comprehensive patient-centered approach to education and appropriate procedure preparation.

**System implementation:**

- The facility is encouraged to customize the protocol with a key that identifies the individuals responsible for completing the algorithm tasks (e.g., green shapes for those individuals responsible for counts).
- Leadership support and a surgeon champion are absolutely essential for the successful implementation of this protocol.
- Develop a procedural checklist to document completion of each step, and ensure that all elements of the protocol are completed.
- Direct observations, along with coaching and immediate feedback, are effective strategies in gaining staff adherence to the protocol following implementation. Additionally, the use of crucial conversation tactics can be effective for staff.
- As it relates to this protocol, create and implement a process that allows for the detection and management of disruptive and inappropriate behavior. This process should include education of all physicians and non-physicians regarding appropriate professional behavior and the development of policies and procedures. Refer to The Joint Commission's leadership standards.

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- 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 to prevent/address the specific actions that pose the highest level of consequence and risk to safety of 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 the safest environment and delivery of the care process.
  - Suggested red rules:
    - Never operate on a patient without verifying the correct patient identity, correct procedure and correct site.
    - Baseline counts are consistently performed before the patient arrives in the operating/procedure room unless parallel processing is used.
    - Unreconciled counts require imaging verification, and wound closure stops until count reconciliation is achieved.

**Retained foreign object implementation:**

- The work group recommends that a preformatted whiteboard be used as the primary record of the count. Documenting counts on a whiteboard allows all surgical staff, and in particular the scrub technician, to independently view the count record. A public display of the count record in an area where the entire surgical team can view it is likely to reinforce the importance of the count process.
- The work group also recommends that a count worksheet be used as a memory aid when the whiteboard is not easily accessible in a timely manner. The count worksheet should be used only as a memory aid for the baseline count and, if needed, for subsequent counts. A piece of scratch paper should not be used. In contrast, if the whiteboard is located very close to the area when the count occurs, and if the circulating nurse can easily write the counts on the whiteboard without leaving the count area, there will be no need to use the count worksheet.
- Distractions and interruptions should be kept to a minimum during the count process. If a count is interrupted, then the category of items (e.g., laps) being counted will need to be recounted.

**Surgical infection implementation:**

- Use of order sets limits divergent practices and improves compliance with best practice protocols.
- Review patient education material to verify the message around no self-shaving before surgery. Distribute standardized patient education messages to surrounding outpatient clinics, as well.
- Remove all razors from the perioperative area.
- Use warming blankets, hats and booties routinely for patients to prevent hypothermia.
- Establish an effective surveillance process that includes post-discharge or outpatient surveillance. Use inpatient case-finding for post-discharge or outpatient. It is important to include the following:
  - Use standardized definitions for surveillance of infections. These definitions also need to take into account the setting in which the surgical procedure was performed (acute care, ambulatory surgical center, etc.).
  - Establish a risk stratification for estimating surgical infection that adjusts for risk factors associated with infection for different care settings and procedures.
  - Work with surrounding outpatient clinics to develop communication strategy for tracking surgical infections and reporting back to the hospital.

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## Choosing Wisely®

As part of a grant from the ABIM Foundation, ICSI is supporting the national *Choosing Wisely®* Campaign. The campaign's goal is to help physicians and patients talk about medical tests and procedures that are often used but may not be necessary and may in some cases cause harm.


The *Choosing Wisely* logo will appear in this document whenever a recommendation from a medical specialty society participating in the *Choosing Wisely* Campaign is in alignment with ICSI work group recommendations.

Permission to use the *Choosing Wisely* logo is granted by the ABIM Foundation.

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## Related ICSI Scientific Documents

**Guidelines**

- Antithrombotic Therapy Supplement
- Venous Thromboembolism Prophylaxis

**Protocols**

- Non-OR Procedural Safety
- Prevention of Unintentionally Retained Foreign Objects during Vaginal Delivery
- Pressure Ulcer Prevention and Treatment

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## Definitions

**Body cavity:** an anatomic cavity, orifice or a small cavity created as a result of the procedure being performed. This does not include the initial surgical incision.

**Clinician –** All health care professionals whose practice is based on interaction with and/or treatment of a patient.

**Colonization versus infection:** with colonization, a microorganism can inhabit a specific site on or in the body (e.g., the nares of the nasal passages) but not cause signs or symptoms of infection. However, the pathogen does have the capacity to cause an infection. Any colony can cause subsequent infection in the same patient or another person when it is transferred between sites or persons.

Colonization differs from infection in that an infection is caused by a pathogen that causes signs and/or symptoms of infection in a patient. Signs and symptoms may include redness, fever, pus, etc. *(Mangram, 1999b [Reference])*. In most cases, an infection is invasive, whereas with colonization, colonies of organisms may live on surface structures and not be actively fought by the body defense system.

**Count stages:**

**Baseline count:** conducted prior to the patient's arrival in the operating/procedure room (unless parallel process is used – see definition below) to establish the initial record of countable items that might be used during the procedure.

**Closing a cavity within a cavity count:** conducted before surgeon closes a cavity within a cavity. This count is performed to ensure that the count is reconciled prior to moving to the next level of wound closure.

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**Closing count:** performed before wound closure begins.

**Final count:** performed at skin closure.

**Count during hand-off that occurs with temporary relief of staff:** a count that occurs during the hand-off each time there is temporary relief of staff.

**Count during hand-off that occurs with permanent relief of staff (e.g., at shift change):** a count that occurs during the hand-off each time there is permanent relief of staff.

**Countable items:** any item that could be unintentionally left behind during a surgical procedure *(AORN, 2006 [Reference]; American College of Surgeons, 2005 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference]; Joint Commission International Center for Patient Safety, 2006 [Reference]; VHA Directive, 2006 [Reference])*. This includes the following:

- **Instruments:** tools or devices designed to perform a specific function such as cutting, dissecting, grasping, holding, retracting or suturing.
- **Miscellaneous items:** includes vessel clips, vessel loops, suture reels, peripheral intravenous catheters and introducers, vascular inserts, cautery scratch pads, trocar sealing caps, catheter sheaths, non-radiopaque items such as hernia tapes and other small items.
- **Sharps:** items with edges or points capable of cutting or puncturing through other items. In the context of surgery, sharps include, but are not limited to, suture needles, scalpel blades, hypodermic needles, electrosurgical needles and blades and safety pins.
- **Sponges:** includes any soft goods such as gauze pads, cottonoids, peanuts, dissectors, tonsil sponges, laparotomy sponges, and towels used to absorb fluids, protect tissues or apply pressure or traction.
- **Tucked sponge:** refers to any soft good used to stop bleeding or absorb liquid, or used in conjunction with an instrument or the surgeon's hand to obtain traction, and that is left in location for the duration of the procedure.

**Count documentation:** a standardized format to document the number of sponges/soft goods, sharps and instruments.

This may be in paper and/or electronic format. Organizations may or may not choose to store specific count information for future retrieval.

- **Whiteboard:** A preformatted dry erase board or computer screen, directly viewable by the entire surgical team, should be used to document sponges/soft goods, sharps, miscellaneous item counts, and when possible, instrument counts. The ability of the entire team to view 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 [Reference])*.
  - The whiteboard should have preformatted names of categories of countable items with standard columns and rows to record counts. In addition to the count, the whiteboard should include the patient's name and other pertinent or patient unique information.
  - It is the recommendation of the work group that, whenever possible, only one source of count information be used during the procedure.

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- **Paper:** a paper count sheet may be used in organizations where the use of a whiteboard is not possible due to space limitations.
  - A standardized, formatted paper count sheet may be used instead of the whiteboard or as a supplement for procedures where there is a large number and/or specificity of certain items (e.g., cardiac procedures).
  - The paper form should be a standardized, preformatted form and when possible, specific to the procedure specialty/service.

**Hard Stop:** Performed when either the safe site surgical verification process has not been followed completely and a discrepancy is identified or when a count discrepancy is identified. The procedure is halted and will not proceed until the appropriate verification/reconciliation steps have been performed and/or the discrepancy is resolved.

**High-risk procedure:** Any procedure that is known to expose a patient to the risk of permanent loss of function or injury *(Joint Commission on Accreditation of Health Care Organization, 2004 [Reference])*. Generally, this includes procedures requiring consent by the patient.

**Hospital-acquired surgical infection:** defined as an infection of the surgical site within 30 days after the operation. For procedures involving an implant, a hospital-acquired infection is defined as an infection occurring within six months (for bone grafts) and one year (for other implants) *(Mangram, 1999a [Reference])*.

- Excluded infections that are not reported as hospital-acquired surgical infections are stitch abscess infections; they are outside the scope of this protocol.
- Infection of an episiotomy or newborn circumcision site, or infected burn wounds are reported using other specific criteria and are outside the scope of this protocol.

**Criteria for defining surgical infection:** in addition to the definition above, surgical site infections are classified as either incisional or organ/space infections. Incisional infections are subdivided for those involving only the skin and subcutaneous tissue, and for those involving deeper soft tissue. Surveillance can include reviewing patients receiving antibiotic therapy for any reason within the defined period of time after a surgical procedure.

**Superficial incisional infections**: infection involving only the skin or subcutaneous tissue of the incision and one or more of the following:

- Purulent drainage from the superficial incision with or without laboratory confirmation
- Organisms confirmed by culture from either an aseptically obtained fluid or tissue from the superficial incision
- One or more signs of infection (pain/tenderness, localized swelling, redness or heat) AND the superficial incision is deliberately opened by the surgeon unless the incision is culture-negative
- A surgeon or attending physician diagnoses a superficial incision surgical site infection

**Deep incisional infections:** infection involving deep soft tissue of the incision such as facial and muscle layers and one or more of the following:

- Purulent drainage from the deep incision but not from the organ or space component of the surgical site
- The deep incision spontaneously separates or is deliberately opened by a surgeon when the patient has one or more of the signs of infection (fever over 38ºC, localized pain or tenderness) unless the site is culture-negative
- A surgeon or attending physician diagnoses a deep incision surgical site infection

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**Organ/space infections:** infection involving any part of the body, for example, organs or spaces, other than the incision, that was opened or manipulated during the procedure and one or more of the following:

- Purulent drainage from a drain that is placed through a stab wound into the organ/space
- Organisms confirmed by culture from either an aseptically obtained fluid or tissue from the organ/space
- Presence of an abscess or other evidence of infection involving the organ/space that is found on direct examination, during re-operation, or by histopathologic or radiologic examination
- A surgeon or attending physician diagnoses an organ/space surgical site infection

**Hypothermia:** defined as body temperature below 36ºC (96ºF) *(Mangram, 1999a [Reference])*.

**Intraoperative image:** a radiographic image obtained within the operating/procedure room, usually with portable radiographic equipment.

**Intra-procedure pause:** a pause during the procedure(s) when the clinician will indicate verbally:

- Level(s)
- Internal laterality after a midline or orifice entry
- Implant information

An intra-procedure pause should not to be confused with the Time-Out.

**Invasive procedure:** any procedure that exposes the patient to more than minimal risk. This includes, but is not limited to, any entry, puncture or insertion of an instrument or foreign material into tissues, cavities or organs. This applies to any procedure performed in settings such as special procedure units, rooms or clinics, or at the patient's bedside. These procedures may involve moderate or deep sedation. Generally, this includes procedures requiring consent by the patient. This excludes venipuncture, intravenous therapy, nasogastric tube insertion, Foley catheters, flexible sigmoidoscopy, and vaginal exams (Pap smears) *(Joint Commission on Accreditation of Health Care Organization, 2004 [Reference])*. See United States Department of Veterans Affairs for a detailed list.

**Laterality:** refers to any anatomical structure that occurs on both sides of the body, both internally and externally (i.e., right, left or bilateral). Reference to laterality is always with respect to the patient (i.e., the patient's right or left, not the clinician's) *(Joint Commission on Accreditation of Health Care Organization, 2004 [Reference])*.

**Level:** refers to any anatomical structures that include multiples occurring linearly (e.g., spinal vertebrae, ribs).

**Major surgical procedure:** a procedure performed in an operating/procedure room and involving general or regional anesthesia, monitored anesthesia care or conscious sedation.

**Micro needle:** a surgical needle that, for adults, is less than 13 mm in size. When using portable radiographic equipment, needles smaller than 13 mm in length are very difficult to detect in the adult torso *(Macilquham, 2003 [Reference])*; however, they may be visible in adult extremities or in children. Each organization will need to establish a policy for the use of intraoperative imaging when attempting to locate an unaccounted for micro needle. Unintentionally retained micro needles are not reportable as retained foreign objects.

**Normothermia:** defined as the core temperature 36º-38ºC (96.8º-100.4ºF) *(Mangram, 1999a [Reference])*.

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

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**Parallel process:** two separate activities performed simultaneously in the same area with two entirely separate groups of staff. Using a parallel processing is not multitasking. When parallel process is used in relation to this protocol, two circulators will be needed: one dedicated to patient care and one dedicated to the baseline count process, for example.

**Perioperative period:** the perioperative period is considered to be from the night before the surgical procedure until 48 hours postoperatively.

**Physician/clinician designee/dentist:** a member of the team performing the procedure who is a credentialed and privileged provider as defined by the institution's medical staff bylaws or who is a physician in residency training.

**Position:** refers to the placement or angle of the patient for the procedure (e.g., supine, prone). Reference to position is important when determining laterality *(Joint Commission on Accreditation of Health Care Organization, 2004 [Reference])*.

**Possibles:** refers to possible sites and/or procedures listed on the patient consent; the decision whether to perform the additional procedure is based on the findings of the initial procedure. These should follow the same process for site marking and verification listed for multiple sites.

**Radiology room image:** a radiographic image obtained in a radiographic room with a fixed tube and moving grid.

**Safety stop:** refers to taking a break from the procedure anytime a team member perceives a threat to patient safety. Examples include a perceived threat to patient safety stemming from how the Time-Out or a count was conducted.

**Selected surgical patient:** any adult or pediatric patient having had a surgical procedure, with an incision, performed in an operating/procedure room. Specific procedures include cardiac; orthopedic; abdominal; gynecologic; ear, nose, throat; and neurological surgeries, but the term applies to any surgical patient.

**Site:** the specific anatomic location of the procedure site (incision, insertion or injection) as indicated by a description of the body part(s), levels (e.g., spine level or ribs) and digits (for hands, use thumb, index, long, ring, small; for toes, use great toe, 2nd, 3rd, etc.) to be subjected to intervention. Midline not associated with laterality or level need not be marked; however, if the internal target site involves laterality, site marking is required to indicate the intended side and/or level. This mark is at or near the incision/instrumentation site to indicate correct side or level of proposed procedure. For spinal procedures, the incisional site, anterior or posterior, and general level (cervical, thoracic or lumbar) are marked *(Joint Commission on Accreditation of Health Care Organization, 2004 [Reference])*.

**Source document:** refers to an original radiology or pathology report that identifies laterality and/or specifies anticipated procedural location.

**Structured hand-off:** standardized method of communication to improve exchange of information during patient care transition.

**Surgeon:** a physician who treats disease, injury or deformity by operative methods. For the purposes of this document, surgeon refers to the individual(s) primarily responsible for the actual procedure; this may include individuals currently in a fellowship or residency program. Those individuals authorized to complete surgeon responsibilities should be determined by individual organizational policy.

**Surgical retained foreign object:** an object that is unintentionally retained after final closure of the wound, excluding micro needles.

**Surgical procedure:** a procedure performed in an operating/procedure room that involves an incision and general, regional, local or monitored anesthesia, or conscious sedation.

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**Surgical wound classification:** the following are the four definitions for types of surgical wounds.

**Class I/clean** – an uninfected surgical wound in which no inflammation is observed and the respiratory, alimentary, genital or uninfected urinary tract is not entered.

**Class II/clean-contaminated** – a surgical wound in which the respiratory, alimentary, genital or urinary tracts are entered as part of the planned surgical procedure and without unusual contamination.

**Class III/contaminated** – open, fresh accidental wounds or procedures with major breaks in sterile technique or gross gastrointestinal spillage. Also includes surgical wounds when acute, non-purulent inflammation is observed.

**Class IV/dirty-infected** – old wounds from trauma with retained devitalized tissue or surgical wounds with existing infection or perforated viscera.

**Teach Back:** simple mechanism to confirm patient's understanding of care instructions.

**Time-Out:** the full verification that is performed just prior to the start of the procedure, when the entire care team will actively and verbally confirm *(Joint Commission on Accreditation of Health Care Organization, 2004 [Reference])*:

- patient's identity (two identifiers);
- procedure to be performed;
- correct patient position;
- correct procedure side/site and/or level including visualization of surgeon's initials if applicable; and
- as appropriate, imaging, equipment, implants or special requirements (e.g., pre-procedure antibiotic administration).

**Vendor:** A non-hospital individual who provides support to the surgeon and surgical services personnel.

**Verification:** refers to checking for consistency between the:

- informed consent documentation,
- physician's order,
- diagnostic studies, and
- response of the patient/legal guardian.

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# Annotations

## 1. Preoperative Basic Health Assessment and Medication Review

**Recommendation:**

- A preoperative basic health assessment must be completed for all patients undergoing a diagnostic or therapeutic procedure (exceptions are addressed below) *(Strong Recommendation, Low Quality Evidence)*.

Preoperative assessment is expected before all surgical procedures. This assessment includes an appropriately directed comprehensive history and physical examination. In some cases this may include laboratory and additional testing to help direct management and assess surgical risk.

Choosing Wisely® An initiative of the ABIM Foundation From the Society of General Internal Medicine

http://www.choosingwisely.org/doctor-patient-lists/society-of-general-internal-medicine/

Don't perform routine preoperative testing before low-risk surgical procedures.

Preoperative assessment is expected before all surgical procedures. This assessment includes an appropriately directed and sufficiently comprehensive history and physical examination, and in some cases, properly includes laboratory and other testing to help direct management and assess surgical risk. However, preoperative testing for low-risk surgical procedures (such as cataract extraction) results in unnecessary delays and adds to significant avoidable costs and should be eliminated.

This protocol follows the basic premise that diagnostic tests (laboratory and x-ray) are not a part of the preoperative basic health assessment.

Roizen, et al. have said that "history-taking and the physical examination are still the best means of preoperative screening, and laboratory tests other than those indicated by the history and physical examination are not cost effective, do not provide medicolegal protection, and in fact may harm the patient" *(Roizen, 1987 [Low Quality Evidence])*.

Meneghini, et al. in reviewing charts of children classified as physical status 1 and 2 (using the American Society of Anesthesiologists Classification System) who underwent minor surgical procedures have said that "on the basis of our experience we believe that a thorough clinical assessment of the patient is more important than routine preoperative laboratory screening, which should be required only when justified by real clinical indications. Moreover, this practice eliminates unnecessary costs without compromising the safety and the quality of care" *(Meneghini, 1998 [Reference])*.

A preoperative basic health assessment includes:

- **Medical history**

  Indication for surgical procedure

  Allergies and intolerances to medications, anesthesia or other agents (specify reaction type)

  Known medical problems

  Surgical history

  Trauma (major)

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Current medications (prescription, over-the-counter medications, herbal and dietary supplements)

Focused review of issues pertinent to the planned anesthesia and procedure:

- Current status of pertinent known medical problems
- Cardiac status
- Pulmonary status
- Functional status (the ability to perform at four or more METs) *(Eagle, 2002 [Reference])*
- Hemostasis status (personal or family history of abnormal bleeding)
- Possibility of severe (symptomatic) anemia
- Possibility of pregnancy
- Past personal or family history of anesthesia problems
- Smoking, alcohol history and illicit drugs
- Risk factors for development of surgical site infection (e.g., smoking, diabetes, obesity, malnutrition, chronic skin disease)
- A basic nutritional assessment should be considered on all patients undergoing surgery as malnutrition is a known risk factor for decreased wound healing and increased surgical site infections. Lab verification should be reserved for those patients at risk of malnutrition.

- **Physical examination**

  Weight, height and body mass index

  Vital signs – blood pressure, pulse (rate and regularity), respiratory rate

  Cardiac

  Pulmonary

  Other pertinent exam

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## 1.1 Basic Health Assessment

A preoperative basic health assessment as outlined in this protocol is required for all patients undergoing a diagnostic or therapeutic procedure, regardless of setting, except for:

- Otherwise healthy patients receiving peripheral nerve blocks, local or topical anesthesia, and/or no more than 50% nitrous oxide/oxygen and no other sedative or analgesic agents administered by any route – for example, most dental procedures or excision of simple skin lesions.
- Patients receiving "sedation/analgesia" (often referred to as "conscious sedation") defined as "a state that allows patients to tolerate unpleasant procedures while maintaining adequate cardiopulmonary function and the ability to respond purposefully to verbal command and/or tactile stimulation." This technique is commonly used for procedures such as endoscopy and bronchoscopy, and may be used for certain surgical procedures. Patient history must be available at the time they receive sedation/analgesia.

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Although the preoperative basic health assessment is not specifically required for sedation/analgesia and other minor procedures, a limited preoperative assessment and documentation is required and mandated by The Joint Commission and other organizations.

*(American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists, 2001 [Reference])*

The preoperative basic health assessment is usually done within 30 days of the planned procedure. However, a review of the current history and focused physical examination will occur at the surgical facility prior to the procedure.

The patient needs to be aware that the preoperative assessment is not a substitute for preventive services, but the preoperative evaluation may be used as an opportunity to address preventive services.

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## 1.2 Preoperative Testing

Abnormal findings (noted on the preoperative basic health assessment) are results that require further evaluation to assess and optimize any surgical/anesthesia risk or cares. Examples include patients on diuretics requiring a potassium level, patients with chest pains on exam or patients with markedly elevated blood pressure. Children's abnormal findings may include wheezing or significant upper respiratory infections noted on the preoperative assessment. Any of these findings may have a deleterious effect on surgery/anesthesia and would require further evaluation to assess the risk to the patient.

Further evaluation may be as simple as asking a few more questions, performing further physical examination, or ordering a laboratory or radiological exam. More in-depth evaluations may be needed, such as a consultation or cardiac stress testing.

The type and extent of evaluation required should be guided by standard medical practice, focusing on the patient's underlying medical condition and the planned procedure. For example, some clinicians will order a baseline preoperative hemoglobin if significant blood loss is anticipated.

Note that most laboratory and diagnostic tests (e.g., hemoglobin, potassium, coagulation studies, chest x-rays, electrocardiograms) are not routinely necessary unless a specific indication is present and may be beyond the scope of this protocol.

Other abnormal findings, though relevant to the patient's general health, may not have any impact on the planned procedure or the timing of the procedure. Evaluation and management of these incidental findings should follow standard medical practice and are beyond the scope of the protocol.

Preoperative questionnaires used to determine abnormal findings for adult and pediatric patients are attached in Appendix B, "Preoperative Questionnaire – Adult," and Appendix C, "Preoperative Questionnaire – Pediatric."

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### 1.21 Electrocardiogram

**Recommendations:**

- Perform electrocardiogram for all patients age 65 and over, within one year prior to procedure *(Weak Recommendation, Low Quality Evidence)*.
- Electrocardiograms are not indicated, regardless of age, for those patients having cataract surgery *(Strong Recommendation, High Quality Evidence)*.
- Preoperative electrocardiograms are not recommended for patients undergoing other minimal risk procedures, unless medical history/assessment indicate high-risk patient *(Strong Recommendation, High Quality Evidence)*.

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For high-risk patients:

- No electrocardiogram within last year in patients (regardless of age) with history of diabetes, hypertension, chest pain, congestive heart failure, smoking, peripheral vascular disease, inability to exercise or morbid obesity.
- At time of preoperative evaluation, patient has any intercurrent cardiovascular symptoms, or signs and symptoms of new or unstable cardiac disease.

Cardiac arrhythmias and conduction disturbances are common findings in the perioperative period, and the electrocardiogram may be useful as a baseline study, although no controlled or randomized trials have been done to justify this widespread practice.

A perioperative electrocardiogram may be obtained to screen for abnormalities that require further evaluation or that will influence care under anesthesia. In a study evaluating the efficacy of routine preoperative electrocardiograms in predicting perioperative cardiovascular complications in an essentially healthy population studied at a large academic medical center, Tait et al. concluded that the practice of routine electrocardiogram screening for patients with no cardiovascular risk factors was a poor predictor of perioperative complication in their patient population *(Tait, 1997 [Reference])*. There are no studies linking changes to patient outcomes, despite epidemiologic studies revealing a high incidence of electrocardiogram abnormalities that increase exponentially with age. The consensus of the protocol work group is to recommend an electrocardiogram for all patients age 65 and over, within one year prior to procedure *(Correll, 2009 [Low Quality Evidence])*. However, electrocardiograms are not indicated, regardless of age, for those patients having cataract surgery *(Schein, 2000 [High Quality Evidence])*. Evidence suggests that preoperative electrocardiograms are not recommended for patients undergoing other minimal risk procedures *(Schein, 2000 [High Quality Evidence])*.

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## 1.22 Hemoglobin

**Recommendation:**

- The reason to obtain a preoperative hemoglobin should be based on the patient's underlying medical condition and the planned procedure *(Strong Recommendation, Low Quality Evidence)*.

For example, patient has a history of anemia or history suggesting recent blood loss or anemia.

For example, bleeding and thrombotic complications in the perioperative period have been documented in patients with uncontrolled polycythemia; however, there is no evidence to quantitate the surgical and anesthetic risks of a patient with asymptomatic normovolemic anemia *(Wasserman, 1964 [Low Quality Evidence])*. The optimal hemoglobin level (that provides a reserve for unexpected blood loss or cardiorespiratory stress) varies by patient and by type of procedure.

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## 1.23 Potassium

- Patient is taking digoxin, diuretics, ACE inhibitors or angiotension receptor blockers.

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## 1.24 Chest X-Ray

- Patient has signs or symptoms suggesting new or unstable cardiopulmonary disease.

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### 1.25 Pregnancy Test

- Patient is of child-bearing age and
  a. is sexually active and history suggests possible pregnancy, e.g., delayed menstruation,
     or
  b. patient is concerned about possible pregnancy,
     or
  c. the possibility of pregnancy is uncertain.

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# 2. Medical Conditions

## 2.1 Cardiovascular Disease

### 2.11 Beta-Blockers

**Recommendations:**

- All surgical patients should be assessed for cardiac risk factors *(Strong Recommendation, High Quality Evidence)*.
- Beta-blocker therapy should be continued perioperatively in patients currently taking beta-blockers *(Strong Recommendation, High Quality Evidence)*.
- Initiation of beta-blocker therapy should be considered for patients undergoing vascular surgery with high cardiac risk (CAD, positive stress test or presence of more than one clinical risk factor) *(Strong Recommendation, Low Quality Evidence)*.
- Initiation of beta-blocker therapy should be considered in all patients undergoing intermediate-risk surgery with CAD or high cardiac risk (defined by the presence of more than one clinical risk factor) *(Strong Recommendation, Low Quality Evidence)*.
- Beta-blocker therapy should be initiated one to two weeks prior to surgery if possible, and titrated to goal heart rate 60-80 bpm *(Strong Recommendation, High Quality Evidence)*.
- Beta-blockers should be continued postoperatively for at least 30 days (longer if beta-blocker therapy was taken prior to surgical procedure) *(Strong Recommendation, High Quality Evidence)*.

Beta adrenoreceptor antagonists (beta-blockers) have been studied for their role in prevention of cardiac complications surrounding surgical procedures. These medications reduce heart rate and contractility, therefore increasing perfusion and decreasing oxygen demand. These effects may play a role in stabilizing vulnerable coronary plaques and reducing inflammation via decreased sympathetic tone *(Mason, 2006 [Reference])*.

Current literature suggests that perioperative ischemia, risk of myocardial infarction, and death may be reduced by beta-blocker use in high-risk patients. There is evidence to strongly suggest starting beta-blockers days to weeks before elective surgery, although this has not been proven true. Goal heart rate should be titrated to a resting heart rate of 60-80 beats per minute in the absence of hypotension *(Fleisher, 2007 [Low Quality Evidence])*.

For the remainder of patients undergoing non-cardiac surgery, the use of beta-blockers in the perioperative period remains controversial *(Fleischmann, 2009 [Low Quality Evidence]; Devereaux, 2005 [Reference]; Lindenauer, 2005 [Reference])*.

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The most recent ACC/AHA Guidelines on Perioperative Cardiovascular Evaluation and Care for Non-Cardiac Surgery (released 2007) were updated in 2009. These guidelines provide the evidence base for the recommendations listed above.

1) Each patient should be evaluated for his/her Revised Cardiac Risk Index *(Lee, 1999 [Reference])*.
   a) High-risk surgery (orthopedic, intraperitoneal, vascular, intrathoracic)? Yes____No___
   b) Ischemic heart disease? Yes____No___
   c) Cerebral vascular disease? Yes____No___
   d) Renal insufficiency (creatinine > 2.0)? Yes____No___
   e) Diabetes mellitus? Yes____No___
   f) Congestive heart failure? Yes____No___

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## 2.12 Statin Therapy

**Recommendations:**

- All surgical patients should undergo assessment of cardiac risk factors *(Strong Recommendation, Low Quality Evidence)*.
- Statin therapy for patients currently taking statins should be continued perioperatively *(Strong Recommendation, Low Quality Evidence)*.
- Initiation of perioperative statin therapy in patients undergoing vascular or intermediate risk procedures should be considered *(Strong Recommendation, Low Quality Evidence)*.

Current ACC/AHA guidelines provide recommendations regarding perioperative statin use. Observational studies have shown statins to be potentially cardio-protective surrounding non-cardiac surgery.

**Class I:**

For patients currently taking statins and scheduled for non-cardiac surgery, statins should be continued.

**Class IIa:**

For patients undergoing vascular surgery with or without clinical risk factors, statin use is reasonable.

**Class IIb:**

For patients with at least one clinical risk factor who are undergoing intermediate-risk procedures, statins may be considered *(Fleisher, 2007 [Low Quality Evidence])*.

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## 2.13 Anticoagulation and Blood Disorders

**Recommendation**:

- If clinical circumstances suggest a potential bleeding problem, clinician should perform coagulation studies *(Strong Recommendation, Low Quality Evidence)*.

Coagulation studies should be performed in patients with a known history of anticoagulation abnormalities, patients with recent history suggesting the potential for anticoagulation problems, patients who are currently taking anticoagulant therapy, and patients who may need postoperative anticoagulation (where a baseline may be needed).

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### 2.131 Coronary Stents

**Recommendations:**

- Surgery should be avoided for at least four weeks after bare-metal stent implantation *(Strong Recommendation, Low Quality Evidence)*.
- Surgery should be avoided for one year after drug-eluting stent implantation *(Strong Recommendation, Low Quality Evidence)*.
- If surgery cannot be avoided during the above time periods, dual anti-platelet therapy should be continued perioperatively unless strongly contraindicated (i.e., procedures associated with high-risk for clinically significant bleeding, such as intracranial surgery) *(Strong Recommendation, Low Quality Evidence)*.
- If deemed necessary to discontinue clopidogrel/prasugrel/ticlopidine preoperatively, aspirin should be continued, if at all possible, in the perioperative period in order to reduce cardiac risk *(Strong Recommendation, Low Quality Evidence)*.

There is clear evidence that premature discontinuation of dual anti-platelet therapy (aspirin combined with clopidogrel, prasugrel or ticlopidine for any reason after coronary stent placement results in a marked increased risk of myocardial infarction or death *(Schouten, 2007 [Reference])*. Therefore, a critical part of the preoperative evaluation of a patient who fits this description is a careful assessment of the benefits of the surgery itself and surgical bleeding risk versus the high risk of cardiac events if platelet therapy is reduced or stopped prematurely. Important stent considerations include how long the coronary stent has been in place and whether the stent is a bare-metal stent versus a drug-eluting stent.

The pre-surgical evaluation of risk in this group of patients may require discussion with cardiology and surgery.

General principles are as follows:

- For patients with bare-metal stents, surgery should be avoided for at least four weeks after stenting.
- For patients with drug-eluting stents, surgery should be avoided for one year after stenting.
- If surgery cannot be avoided during the above time periods, dual anti-platelet therapy should be continued perioperatively unless strongly contraindicated such as intracranial surgery. Alternatives such as stopping the clopidrogel/prasugrel/ticlopidine and continuing aspirin or stopping all anti-platelet therapy may be necessary to reduce bleeding risk but are associated with increased cardiac risk.
- If anti-platelet therapy is held prior to surgery, it should be restarted as soon as possible following surgery *(Grines, 2007 [Low Quality Evidence])*.

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### 2.132 Antithrombotic Therapy

General recommendations regarding antithrombotic therapy are beyond the scope of this document, given the different classes of medications and the variety of situations for which they are used. For patients on antithrombotic therapy, please refer to the ICSI Antithrombotic Therapy Supplement for more detailed information regarding management.

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### 2.133 Venous Thromboembolism Prophylaxis

Venous thromboembolism is a common and potentially fatal perioperative complication. All surgical patients should undergo risk assessment for the development of VTE and have appropriate measures taken to prevent both clotting and bleeding in the perioperative period.

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For more specific recommended prophylaxis based on surgery type, refer to the ICSI Venous Thromboembolism Prophylaxis guideline and the ICSI Antithrombotic Therapy Supplement.

Refer to Centers for Medicare and Medicaid Services (CMS) and the Joint Commission (JC) Surgical Care Improvement Project (SCIP) Care Measure VTE Prophylaxis guidelines at http://www.jointcommission.org.

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## 2.2 Sleep Apnea

**Recommendations:**

- Clinicians should screen patients for sleep apnea or sleep apnea symptoms and communicate to surgical team *(Strong Recommendation, Low Quality Evidence)*.
- Clinicians should remind patients who have been formally diagnosed with obstructive sleep apnea and have an oral appliance or continuous positive airway pressure equipment to bring their appliance or equipment with them on the operative day *(Strong Recommendation, Moderate Quality Evidence)*.

Obstructive sleep apnea increases the patient's risk for intra- and postoperative complications *(Gupta, 2001 [Low Quality Evidence])*. Patients with a diagnosis of obstructive sleep apnea often have oral appliances or continuous positive airway pressure equipment and should be reminded to bring those appliances or equipment on the operative day, for use during the recovery from anesthesia or sedation.

Some patients may not have a diagnosis of obstructive sleep apnea confirmed by polysomnography studies but are presumed to have obstructive sleep apnea based on the preoperative history and physical examination. Quick and inexpensive surrogates for polysomnography studies are not new and have several variants. Patients who score high on these indices may need to be treated in the perioperative period as though they have a formal diagnosis of obstructive sleep apnea. This information should be communicated to the surgeon and anesthesiologist before the patient undergoes any procedure involving general anesthesia, monitored anesthesia care, conscious sedation or the administration of narcotics *(Farney, 2011 [Moderate Quality Evidence]; Abrishami, 2010 [High Quality Evidence]; Vasu, 2010 [Low Quality Evidence]; Gupta, 2001 [Low Quality Evidence])*.

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## 2.3 Diabetes Mellitus

**Recommendations:**

- Individual patient evaluation and instruction should occur prior to surgery to avoid extremes in glucose levels *(Strong Recommendation, Low Quality Evidence)*.
- Doses of long-acting insulins (glargine, NPH, etc.) may be decreased by up to 50% preoperatively *(Strong Recommendation, Low Quality Evidence)*.
- Oral diabetic agents and short-acting insulins should not be taken preoperatively *(Strong Recommendation, Low Quality Evidence)*.
- Short-acting, sliding scale insulin should be used to treat high blood glucose values in patients holding their normal diabetic medications *(Strong Recommendation, Low Quality Evidence)*.

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- GLP-1 agonists (exenatide, liraglutide, pramlintide) should be held perioperatively *(Strong Recommendation, Low Quality Evidence)*.
- DPP-4 inhibitors (sitagliptin) can be continued perioperatively, if patient desires *(Strong Recommendation, Low Quality Evidence)*.

Given the complexities and wide variety of methodologies employed to achieve glycemic control, individual patient evaluation and instruction are required prior to surgery to avoid extremes in glucose levels.

Hypoglycemia can lead to harmful effects including cardiac rhythm problems and cognitive deficits. Hypoglycemia is difficult to detect in the sedated patient.

Hyperglycemia can lead to problems with electrolytes, acidosis and fluid balance and is associated with poor wound healing, increased risk of infection, as well as higher mortality in hospitalized patients.

The optimal glucose range needs further investigation.

General principles are as follows:

- Mild hyperglycemia is preferable to hypoglycemia.
- Patients should not take oral hypoglycemics on the day of the procedure.
- Patient should not take short-acting insulin bolus the morning of procedure.
- Long-acting or intermediate insulin may be used to cover basal insulin needs; 50-100% of usual dose is often reasonable.
- Insulin pumps should be continued but only to provide basal insulin coverage.
- The details of the insulin recommendations are influenced by the insulin sensitivity of the patient, the timing of the procedure, the length of the procedure, and how long the patient will need to take nothing by mouth following the procedure.

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## 2.31 Glycemic Control

**Recommendation:**

- Glycemic control should be directed at achieving blood glucose levels between 140-180 mg/dL and not be directed at more intensive goal targets (80-110 mg/dL) *(Strong Recommendation, High Quality Evidence)*.

Determination of a patient's glycemic control status is an important factor in preventing surgical site infection. In diabetics, outcomes are improved in patients with preoperative Hgb A1c less than 7; however, there are no data on interventions that establish tight control *(Dronge, 2006 [Reference])*.

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## 2.32 Oral Hypoglycemic Therapy

According to the American College of Endocrinology, oral hypoglycemic medications such as sulfonylureas and thiazolidinediones do not contribute to tight glycemic control and should be avoided in hospitalized patients unless they are eating a regular diet. Many of these medications do not directly affect serum glucose; instead, they increase insulin sensitivity. Metformin, specifically, is used with caution perioperatively due to the potential risk for development of postoperative lactic acidosis *(Martinez, 2007 [Reference])*.

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### 2.33 Newer Anti-Diabetic Medications

GLP-1 agonists, such as exenatide, slow gastric motility. This effect could potentially delay gastrointestinal recovery after surgery. For this reason, these medications should be held perioperatively.

The DPP-4 inhibitors, such as sitagliptin, require glucose in order to exert their effects *(Meneghini, 2009 [Reference])*. Hypoglycemia is unlikely if patients continue these medications around the time of surgery, however, if they are not taking anything by mouth, there is likely little reason to administer them.

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## 2.4 Chronic Medication Use

The work group acknowledges there is very little evidence surrounding the management of chronic medications perioperatively. Decisions about medications to be administered or held around the time of surgery are driven by case reports, expert opinion and pharmacokinetic principles. A table has been developed for health care clinicians to help guide decisions about preoperative medication management (see Appendix D, "Drugs to Stop/Drugs to Continue").

It is extremely important to obtain a complete and accurate list of all of the patient's medications, both prescription, non-prescription, herbal tinctures, naturopathic and homeopathic remedies. Optimally, this would occur at least two weeks before surgery.

Given that medication management is driven largely by expert opinion, communication with the consulting anesthesiologist may be warranted if there are specific questions or concerns related to continuing or discontinuing medications.

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### 2.41 Drugs to Continue

**Recommendations:**

- Clinicians should complete a thorough medication review (including all prescription, non-prescription and herbal or "natural" medicines) with the patient at least one week before surgery if at all possible *(Strong Recommendation, Low Quality Evidence)*.
- Medications contributing to the patient's current state of medical homeostasis should be continued (i.e., neuro/psych medications, anti-arrhythmic agents, HIV medications, statins, antihypertensives) with the exception of the medication groups listed below in Drugs to Stop *(Strong Recommendation, Low Quality Evidence)*.

In general, most prescription drugs can be continued up to the time of procedure and will not interfere with any anesthetic plan. The drugs to be continued should certainly include medications where discontinuation puts the patient at risk. Anti-Parkinson's drugs, anti-seizure medications, anti-hypertensives, statins, cardiac rhythm drugs, and all analgesics fall into this category. The possible exceptions to the above are the ACE inhibitors and the angiotensin receptor blockers, although cessation of these remains controversial *(Comfere, 2005 [Low Quality Evidence])*.

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**Factors for consideration**

Many of the drugs typically continued in order to sustain medical homeostasis in the patient are not continued without risk, especially considering potential drug interactions with anesthesia agents. Factors to consider are the following points if the patient is taking any of the medications listed below:

| Medication | Considerations |
|---|---|
| Angiotensin converting enzyme inhibitor (ACEI)/angiotensin receptor blocker (ARB) | Can decrease blood pressure at induction of anesthesia, and many drugs within this class have differing half-lives. |
| Monoamine-oxidase inhibitor (MAOI) including selegiline for Parkinson's disease | Avoid administration of meperidine/dextromethorphan/ephedrine and monitor closely while on narcotics (potential for reactions consisting of rigidity, hallucinating, fever, confusion, coma and death). |
| Tricyclic antidepressant (TCA) | Norepinephrine is a vasopressor of choice if needed. |
| Vitamin K antagonist (VKA) | Need to hold before surgery varies by surgery type – may not be necessary to hold for routine colonoscopy, cataract surgery or dermatological procedures. |
| Benzodiazepines | Continue these agents to avoid withdrawal; however, patient will likely have decreased anesthesia requirements. |
| Anti-epileptic agents | Continue these agents – Note: medications that depress the CNS may decrease anesthesia requirements. |
| Anti-psychotics | Can decrease seizure threshold and induce neuroleptic malignant syndrome – lithium can prolong the effect of neuromuscular blocking agents. |
| Venous thromboembolism (VTE) prophylaxis | See the ICSI VTE Prophylaxis guideline for specific recommendations regarding need for bridging.π |

*(Pass, 2004 [Low Quality Evidence]; Mercado, 2003 [Low Quality Evidence])*

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## 2.42 Drugs to Stop

**Recommendations:**

- Medications that do not contribute to the medical homeostasis of the patient should be discontinued in preparation for surgery (i.e., non-prescription medications, herbal or "natural" medicines and over-the-counter supplements) *(Weak Recommendation, Low Quality Evidence)*.
- Medications that may increase risk of adverse outcomes perioperatively should generally be discontinued according to pharmacokinetic principles (i.e., NSAIDS, angiotensin converting enzyme inhibitor [ACEI]/angiotensin receptor blocker [ARB], diabetes medications, anticoagulants, osteoporosis agents, hormone therapy) *(Weak Recommendation, Low Quality Evidence)*.
- Inadvertant administration of medications the night before or morning of surgery is not typically an indication for cancellation of surgical procedures *(Weak Recommendation, Low Quality Evidence)*.

Those drugs with a potential to cause harm to the patient in the perioperative period should be discontinued. For example, NSAIDS and other anticoagulants increase bleed risk perioperatively. Some herbal supplements can prolong bleeding time, as well as increase blood pressure. The effects of many herbal supplements are unknown, as the actual composition of each product varies widely (these products are not regulated by the U.S. Food and Drug Administration). Hormone replacement therapies and some osteoporosis agents may promote clot development perioperatively. Optimal time frame for discontinuation before surgery depends on the pharmacokinetic profile of the medication, as well as individual patient factors. In general, it takes a drug approximately five half-lives to be completely eliminated from the system.

There is currently controversy surrounding the potential risk of bleeding associated with the use of omega-3 fatty acids. The risk of bleeding is theoretical, and stems from the biochemical role of omega-3 fatty acids

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in eicosanoid metabolism. A summary by Harris reviewed research including patients undergoing major vascular surgery, currently taking omega-3 fatty acids, with or without additional anticoagulants. The results of this summary led the author to conclude that omega-3 fatty acids do not increase the risk of significant clinical bleeding episodes. Based on the information provided by this summary, inadvertent administration of omega-3 fatty acids the night before or the day of surgery does not warrant cancellation of the scheduled procedure *(Harris, 2007 [Reference])*.

Diabetic medications and antithrombotics are dealt with elsewhere in this document. Non-prescription drugs, supplements and vitamins can be held the morning of surgery *(Comfere, 2005 [Low Quality Evidence])*.

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## 2.5 Nicotine Cessation

**Recommendations:**

- Patients should be strongly encouraged always to quit nicotine use *(Strong Recommendation, Low Quality Evidence)*.

This work group recognizes the confusion and concern related with regards to nicotine cessation shortly before surgery: misinterpretation of initial studies had suggested that smoking increased postoperative pulmonary complications *(Shi, 2011 [Reference])*. However, the current literature, as well as this work group, consensus still agrees that patients should be strongly encouraged at all times to abstain from nicotine any time before surgery.

If patients are using nicotine replacement therapy, this should be continued perioperatively.

For certain procedures, e.g., vascular or orthopedic, the surgeon may require absolute nicotine cessation for at least three months prior to surgery, but that is beyond the scope of this document.

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# 3. Antibiotic Management

**Recommendations:**

- Clinicians should assess patients for known drug allergies *(Strong Recommendation, Low Quality Evidence)*.
- Clinicians should administer appropriate prophylactic antibiotic for procedure within one hour prior to surgical incision or two hours for vancomycin/fluoroquinolones when indicated *(Strong Recommendation, Low Quality Evidence)*.
- Prophylactic antibiotic should be discontinued within 24 hours after surgery end-time for all non-cardiac procedures *(Strong Recommendation, Low Quality Evidence)*.
- Prophylactic antibiotic should be discontinued within 48 hours after surgery end-time for all CABG/cardiac procedures *(Strong Recommendation, Low Quality Evidence)*.

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## 3.1 Antibiotic Selection

Antibiotic choice is based on the activity against the normal flora associated with the surgical site and addressing specific patient factors such as methicillin-resistant staphylococcus aureus status *(Medical Letter, Treatment Guidelines from the, 2009 [Reference]; Bratzler, 2005a [Low Quality Evidence] [Low Quality Evidence]; Prokuski, 2005 [Reference])*. See the Antibiotic Selection table in Appendix E for specific recommendations pertaining to antibiotic selection.

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New guidelines released by the American Society of Health-System Pharmacists in collaboration with the Infectious Diseases Society of America suggest weight-based dosing of cefazolin, the most frequently utilized preoperative antibiotic. Typical dosages of cefazolin are 1-2 grams given IV within 60 minutes of incision. The guidelines now recommend doses up to 3 grams, depending on patient weight. See the Antibiotic Dosing Table in Appendix F for specific dosing recommendations.

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### 3.11 Multi-Drug Resistant Organisms (MDRO)

In order to control or eradicate multidrug-resistant organisms (such as MRSA), a number of interventions need to be utilized *(Siegel, 2007 [Reference])*.

- Identify patients with known MDRO (active carrier or history).
- Enforce adherence to infection control practices (hand hygiene, standard/contact precautions, isolation rooms, dedication of non-critical medical equipment).
- Utilize antimicrobial agents judiciously.

Coverage for MRSA with vancomycin should be considered for patients with known MRSA colonization or at high risk for MRSA colonization in the absence of surveillance data. As vancomycin is less effective than cefazolin in preventing infection caused by MSSA, institutions should consider the use of both agents preoperatively when desiring coverage for both MRSA and MSSA.

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### 3.12 Penicillin Allergy Management

A number of articles by Pichichero have provided the following considerations regarding penicillin allergy management:

- Older data citing the cross-reactivity of penicillins with cephalosporins was 10% – this is an overestimate for a number of reasons. True risk is closer to 0.5%.
- IgE-mediated reactions (angioedema, laryngeal edema, urticaria, anaphylaxis) are the only true allergic reactions, and the only ones that should be considered when making choices about antibiotic alternatives.
- Due to differences in ring structures of penicillins and cephalosporins, there should be minimal immunologic cross-reactivity between the compounds.
- Most second- or third-generation cephalosporins are unlikely to be associated with any cross reactivity with penicillins.
- For patients with a true, documented IgE-mediated allergic reaction to penicillin avoid cephalosporins with similar side chains, or provide an alternate antibiotic (see the Antibiotic Table for a list of alternatives).
- Skin testing may be of benefit, as 90% of patients who possess IgE antibodies to penicillins do tolerate cephalosporins with similar side chains – and up to 94% of patients will test negative for IgE antibodies, eliminating the worry of potential adverse reaction *(Li, 2010)*.

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### 3.13 Skin Testing

The ability of penicillin skin testing to predict cephalosporin allergy is controversial. In order for penicillin skin testing to reliably predict corresponding cephalosporin allergy, the side chains must be similar. Skin testing does not necessarily predict a clinical reaction, as approximately 90% of patients who possess IgE antibodies to penicillin or amoxicillin do tolerate cephalosporins that contain similar or even identical side chains *(Pichichero, 2007 [Reference])*.

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### 3.14 Vancomycin Allergy Management

Vancomycin allergy is rare. Red-man syndrome, a pruritic, truncal redness, is caused by histamine release with rapid infusion rate. This reaction may be mislabeled as an allergy. Infusion times of 90-120 minutes at usual doses should prevent this reaction.

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### 3.15 "Clean" Procedures with Higher Infection Risk

The work group acknowledges the controversy surrounding antimicrobial prophylaxis in breast surgery, herniorrhaphy and other "clean" surgical procedures. While infection rates are low in these procedures, some studies have shown a reduced risk of infection when prophylactic antibiotics are administered. The decision whether or not to administer prophylactic antibiotics in these procedures should be left to the discretion of the physician, after weighing the risk of inducing microbial resistance and the benefit of potentially reducing surgical site infections *(Bunn, 2012 [Reference]; Medical Letter, Treatment Guidelines from the, 2009 [Reference])*.

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## 3.2 Prevention of Endocarditis

### 3.21 Patients with Cardiac Conditions

**Recommendation:**

- Patients diagnosed with certain cardiac conditions and undergoing specified procedures should receive appropriate antibiotic prophylaxis *(Strong Recommendation, Low Quality Evidence)*.

Cardiac conditions for which antibiotic prophylaxis is recommended:

- Prosthetic cardiac valve or prosthetic material used for cardiac valve repair
- Previous infective endocarditis
- Cardiac transplantation recipients who develop valvulopathy
- Congenital heart disease (CHD)
  - Unrepaired cyanotic CHD, including palliative shunts and conduits
  - Completely repaired congenital heart defect with prosthetic material or device, placed by surgery or by catheter intervention, during the first six months after the procedure
  - Repaired CHD with residual defects at site or adjacent to site of a prosthetic patch or prosthetic device

For patients with any of these conditions, prophylaxis is recommended **only** before:

- all dental procedures that involves manipulation of gingival tissue or of the periapical region of teeth, or perforation of oral mucosa,
- an invasive procedure of the respiratory tract that involves incision or biopsy of respiratory tract mucosa, including tonsillectomy and adenoidectomy, and
- any surgical procedures that involves infected skin or musculoskeletal structures.

Regimens for antibiotics are to be given as a single dose 30-60 minutes prior to procedure (pediatric dosing is in parentheses):

- Amoxicillin – 2 g oral (50 mg/kg) (dental procedures)
- Ampicillin – 2 g intramuscular or intravenous (50 mg/kg)

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- Cefazolin or Ceftriaxone – 1 g intramuscular or intravenous (50 mg/kg)
- Cephalexin – 2 g oral (50 mg/kg) (dental procedures)
- Clindamycin – 600 mg oral; intramuscular or intravenous (20 mg/kg)
- Azithromycin or Clarithromycin – 500 mg oral (15 mg/kg) (dental procedures)

*(Wilson, 2007 [Reference])*

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## 3.3 Procedures in Patients with Previous Total Joint Replacement

**Recommendation:**

- Patients with prosthetic joints should not receive prophylaxis to prevent infected joint prosthesis *(Strong Recommendation, Low Quality Evidence)*.

The latest guidelines released by the AAOS-ADA have altered their recommendations regarding antimicrobial prophylaxis in patients with artificial joints. This recommendation stems from dental procedures being unrelated to periprosthetic joint infections. No clear evidence exists showing that antibiotic prophylaxis reduces the risk for such infections *(American Academy of Orthopaedic Surgeons, 2012 [Reference])*.

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## 3.4 Colorectal Surgery

### 3.41 Bowel Preparation

#### 3.411 Mechanical

At least 10 randomized control trials have demonstrated no difference in surgical site infection rates for patients receiving mechanical bowel preparation *(Fa-Si-Oen, 2005 [Reference]; Wille-Jørgensen, 2005 [Reference])*. Mechanical bowel preparation for patients undergoing colorectal surgery is controversial and at the discretion of the surgeon. The classic dogma requiring a mechanical bowel preparation has been challenged recently, with a number of studies failing to identify a decrease in contamination of the wound after mechanical bowel preparation.

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#### 3.412 Antibiotic

In the era of availability of modern single- and double-agent prophylactic therapy at the time of surgery, an oral antibiotic for bowel preparation the day prior to surgery is controversial and at the discretion of the surgeon *(Nichols, 2005 [Reference]; Jimenez, 2003 [Reference]; Zmora, 2001 [Reference])*.

At the time of surgery, all patients should receive a dose of intravenous antibiotics with efficacy against colonic and skin flora.

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## 3.5 Antibiotic Administration

### 3.51 Preoperative

Antibiotics should be administered so that the bactericidal concentration is present in the tissues at the time of incision. For most antibiotics, that concentration is reached 30 minutes after infusion. Vancomycin and fluoroquinolone infusion should be initiated within 120 minutes prior to incision due to a longer infusion time.

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### 3.52 Intraoperative

Re-administration of antibiotics for surgical site infection prophylaxis is based on the antibiotic selected and the length of the surgical procedure. Newer guidelines are recommending only a single dose of intravenous antibiotics for procedures lasting less than four hours. In procedures lasting more than four hours or when major blood loss occurs, re-dosing should occur every one to two half-lives of the antibiotic (in patients with normal renal function) so that the bactericidal concentrations are maintained in the tissues while the incision remains open *(Bratzler, 2005a [Low Quality Evidence]; Zanetti, 2001 [Reference])*.

Institutions may consider adding a reminder system or note on anesthesiology flow sheets close to the four-hour point of a surgery to prompt the question of whether to re-dose the antibiotic. This system may help ensure that patients in longer surgeries receive sufficient concentration of antibiotic, while still decreasing the risk of antimicrobial resistance.

*(Medical Letter, Treatment Guidelines from the, 2009 [Reference])*

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### 3.53 Postoperative

Current SCIP recommendations regarding length of postoperative antibiotic now specify continuing antibiotics up to 48 hours post-procedure for all CABG/cardiac surgical procedures. An article by Mertz, et al. supports this recommendation. Prophylactic antibiotic therapy for all other surgical procedures should be discontinued at the discretion of the clinician.

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## 4. Patient Education and Communication

The goal of the preoperative assessment is to identify and manage medical conditions that may impact perioperative morbidity and mortality. During the communication process, preoperative clinicians should avoid specific anesthesia recommendations and "clearing" a patient for surgery. "Patient is medically optimized" is a more accurate reflection of the work done during the preoperative process.

Preop assessment results must be communicated to the location where the procedure will be conducted prior to the date of the scheduled procedure. The report should include a comprehensive assessment, any adjunctive evaluation or specific recommendations.

When providing patient education, adequate attention to patients' reading level, potential visual impairments (provide large print materials) and other potential learning barriers is a critical component for preparing them for surgery.

The use of Teach-Back is researched based literacy intervention that promotes adherence and patient safety to patient education. Teach-Back opportunities in preoperative preparation may include new medications and self-care techniques, as well as procedure preparations *(Minnesota Health Literacy Partnership, 2011)*.

- Patients and families should be educated on how to manage postoperative pain, when to resume activities of daily living and how to manage other risk factors such as diabetes, incontinence and impaired immune status/response.
- Patients will be educated on medications that are prescribed at discharge. Medication reconciliation will be completed and a current medication list sent home with the patient.
- All patients should be educated on the signs and symptoms of surgical site infection *(Mangram, 1999a [Reference])*.
- Patients and families should be provided emergency contact numbers and instructions on whom to call.

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- The nurse must confirm that discharge instructions have been explained, and patients and family should verbalize understanding. Because patients may forget verbal instructions, written instructions should be provided *(Schlossberg, 1992 [Reference])*.
- When necessary, the nurse should verify that the patient will have care assistance for at least 24 hours.
- Patient and families should be educated on the importance of good hand hygiene in the prevention of infection. Patients and families managing wound dressings should wash their hands (either soap and water or waterless hand gels) before and after every contact. Hand gels appear to be as effective as washing with soap *(Mangram, 1999a [Reference])*.
- Patients and families should be instructed on proper incision and wound care recommendations:
  - Protect the incision with a sterile dressing for 24-48 hours.
  - Minor surgical wounds can be allowed to get wet in the first 48 hours without increasing risk of infection *(Heal, 2006 [Reference])*.
  - Extremity wounds may be covered with a clear film dressing that reduces the rate of blistering and exudates *(Cosker, 2005 [Reference])*.
  - Surgical wounds in children may be left without dressings without risk of infection *(Merei, 2004 [Reference])*.

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## 4.1 Preoperative Showering/Shaving

For infection prevention purposes, patients should be advised to shower/bathe before arriving for their surgical procedure. They should be alerted not to shave or remove any hair at or near the surgical site. Each facility should establish specific guidelines for their patient population and the specific procedures being performed.

There is sufficient evidence to support that having patients cleanse the skin reduces the risk of infection *(AORN, 2012)*.

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## 4.2 Preoperative Fasting Recommendations (Nothing by Mouth)

Preoperative fasting guidelines have been revised and simplified over the last decade. The American Society of Anesthesiologists Task Force on Preoperative Fasting has issued practice guidelines that follow a "2, 4, 6, 8 hour" rule applying to all ages:

- The fasting period for clear liquids, including water, fruit juices without pulp, carbonated beverages, clear tea and coffee is recommended to be **two hours or longer** prior to surgery.
- The fasting period for breast milk is recommended to be **four hours or longer** prior to surgery.
- The fasting period for formula, non-human milk and light meals (such as toast) is recommended to be **six hours or longer** prior to surgery.
- The fasting period for fried and fatty foods or meat may be **eight hours** or longer, as these foods may prolong gastric emptying time. The amount and type of food should be taken into account to determine an appropriate fasting period.

Patients should be educated and informed of fasting requirements sufficiently in advance of the procedure.

*(American Society of Anesthesiologists Task Force on Preoperative Fasting, 1999 [Reference])*

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## 5. Patient, Procedure and Site Verification

The verification process will be carried throughout the organization's entire pre-procedure processes from scheduling through the verification of the patient/procedure/side/site at the time of presentation of the patient for surgery. Documentation of the verification process will be performed in the appropriate medical record.

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## 5.1 Pre-Procedure Planning and Preparation (Equipment, etc.)

Pre-procedure planning and preparation include those activities done at various times prior to the procedure to ensure preparedness for the patient and procedure. This includes the following:

- The circulating and scrub nurse review the surgeon orders, equipment requests, preference cards and any other information that will contribute to the specific preparation required for the patient and procedure. Share essential planning at preop brief.
- Preparation is carried out for special patient needs including positioning requirements, allergies, height, weight, etc.
- Prepare the room, ensuring all is in working order including such items as operating/procedure room table, lights, tourniquet and microscope.
- Limit the number of receptacles for discarded items, particularly for sponges.
- Confirm that all needed instruments and implants are available and ready.
- Confirm that all staff needed for the procedure are available and ready. This may include residents, hemodynamic staff or company representatives.

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## 5.2 Scheduling

A verification process must exist at the point of scheduling. To eliminate mistakes, such as left/right translation errors, made while documenting a clinic visit to evaluate and plan a surgical procedure, the work group recommends that the surgical scheduling process require corroboration between the surgical consent, the order to schedule a procedure and an independent source document dictation (such as a radiology report or pathology report). The clinical professional's attention must be directed specifically to the organ/joint in question and laterality, as appropriate, before proceeding to the scheduling process. Independently verified documentation should be provided on paper, facsimile or electronic format, not by telephone or verbal communication. The only exception to this is during emergency situations. Ideally, the patient should also be provided the same information in hard copy form.

Verification of consistency between the planned procedure, the consent and the radiology report or pathology report should occur when the patient arrives at the surgical facility, along with the rest of the preoperative verification process. A Hard Stop will occur during the verification process if a discrepancy is noted. The patient will not proceed through the perioperative process until the discrepancy has been resolved. The clinical professional will contact the attending surgeon for resolution of any discrepancies between the scheduled procedure, procedure order, consent, radiographic/pathology report or the final imaging review. The discrepancy must be reconciled at any point when such discrepancies are discovered.

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## 6. Surgical Site Marking with Initials

All personnel (e.g., preoperative nurse, circulating nurse, surgeon, and/or clinician designees, and anesthesia practitioner) involved in the surgical procedure must take an active role in this process. If at any time a particular section of the protocol is not required (e.g., site marking), the other verifications and consent steps still apply.

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## 6.1 Site Marking by Surgeon

- Before marking the surgical site with his/her initials, the surgeon will verify the patient's identity and the correct site of the surgical procedure:
  - Procedure and site identification information in the patient's informed consent
  - Information in the medical record
  - Diagnostic studies
  - Discussion with the patient/legal guardian

If there is a discrepancy regarding procedure and/or site in any of these information sources, the team will work together to resolve the discrepancy with relevant diagnostic sources before marking the site and proceeding with the case.

The initials indicating the surgical site will be written using an indelible surgical marker and will be **visible when the patient is positioned and draped**.

The work group recommends the use of an anatomical diagram when the surgeon's initials are not visible because of drapes or if it is not possible to mark the physical site.

**Sensitive site marking** – When there is a site sensitive area, mark the site on the correct operative side, directly above the site. Ensure that this marking is visible through drapes, or use an anatomical diagram if it will not be visible.

**For multiple sites/digits on the same anatomical site** – The procedures should be numbered on the informed consent documentation and the sites marked with the appropriate corresponding number, along with the surgeon's initials.

**For procedures involving laterality** – The informed consent documentation will indicate the laterality, and the site will be marked accordingly.

Laterality also applies to procedures that have a midline or orifice entry but the internal target location involves laterality. The laterality for procedures entered via midline or orifice entry will be indicated on the informed consent documentation and will be marked on an anatomical diagram. See the definition for Site for more information.

Both sites will be marked for bilateral procedures.

**For procedures involving level (spine or ribs)** – The informed consent documentation will indicate the laterality and level, and the site will be marked in a way to indicate anterior or posterior, and general level (cervical, thoracic, lumbar, or rib number). Following incision, a radiopaque marker will be placed at the planned surgical site, and an intraop radiographic image will be taken to confirm the exact surgical site.

Teeth – mark the operative tooth (teeth) on the dental radiographs or dental diagram.

Premature infants for whom the mark may cause a permanent tattoo – all infants under the corrected gestational age of 38 weeks should not be marked. It is recommended that the surgical site be marked on an anatomical diagram.

Situations where marking the site would cause the patient harm (e.g., emergency procedures and unstable back fractures) – the site should not be marked and the rationale documented in the patient record.

Patient refusals – the surgical/procedural site should be marked on an anatomical diagram in the event a patient refuses a site marking.

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**Exceptions to skin site marking**

**Midline structures**

- Single organ cases without laterality
- Endoscopies without intended laterality
- Procedures where the insertion site is not predetermined
- Caesarean sections, dilation and curettage/dilation and evacuation for miscarriage or pregnancy termination, hysterectomy for intrauterine fetal demise

**Site marking in multiple procedure cases involving multiple surgeons who cannot all mark their respective site(s) before patient is transported to operating/procedure room**

Surgeons will mark the surgical site on an anatomical diagram. (They will follow the site marking protocol before marking the diagram: The patient's chart and affirmation of informed consent will be checked, the relevant image[s] will be consulted where appropriate, and the patient and/or patient's representative[s] will be consulted, if available, before marking the anatomical diagram. A discrepancy between these information sources will be resolved before marking the site on the anatomical diagram.) Each diagram featuring the relevant site marking will be included in the patient's chart and will be referenced in the operating/procedure room during the Time-Out for that particular procedure. A Time-Out must be performed just prior to the onset of each procedure.

**Individual facilities are encouraged to consider and interpret the 2014 National Patient Safety Goal recommendations (effective January 2014).**

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## 7. Regional Anesthesia Techniques and Verification Process

Any regional anesthetic technique must start with a pre-procedure evaluation of the patient by the anesthesia care clinician. This includes obtaining informed consent from the patient, utilizing the same elements that compose informed consent for surgical anesthesia.

The elements of informed consent are *(American Medical Association, 2008 [Reference])*:

- The patient understands the diagnosis (if known), nature of the procedure and the indications for the proposed procedure.
- The patient understands potential short- and long-term risks and benefits of the proposed procedure.
- Reasonable alternatives have been discussed (regardless of their cost or the extent to which the treatment options are covered by health insurance).
- The risks and benefits of alternative treatment, including the option of no treatment, and consequences of refusing treatment are understood.

Before the patient receives sedation, the anesthesia care clinician will:

- verify it is the correct patient, using two identifiers;
- mark the site of the planned regional technique if needed for laterality or level; and
- confirm with the patient his/her understanding of the planned procedure.

Immediately before performing the regional technique, the anesthesia care clinician will perform an Anesthesia Time-Out to verify with the entire team that it is the correct patient, the correct procedure and the correct location.

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## 8. Patient Transported to Intraoperative Area Using Checklist (Reverify Patient Identification)

The transition of the patient from one location to another, whether or not the care clinicians change, creates the opportunity for errors to occur. Prior to moving the patient from the preoperative area to the operating/procedure room, the anesthesia care clinician or circulating nurse is responsible for final verification, including:

- verifying consent is complete;
- verifying preoperative checklist has been completed by all required staff. Refer to the Implementation Tools and Resources Table for additional information on pre-procedure verification checklist;
- verifying operative site is correctly marked (if applicable) by verifying the site marking against the patient's informed consent; and
- notifying preoperative staff, verbally and/or electronically, that the patient is being moved to the operating/procedure room.

Whenever possible, the patient should be an active participant in the verification process.

Immediately upon entry to the operating/procedure room:

1. The person who moved the patient to the room (anesthesia care clinician and/or circulating nurse) will introduce the patient to those present in the operating room (e.g., scrub) and state the procedure to be performed. (This is done to ensure that the patient is in the correct operation procedure room.)
2. To ensure that the correct patient documents arrived in the operating room with the patient, the patient's name and date of birth (or medical record number) on the patient's ID band should be checked against the same patient information documented on the patient's informed consent and anesthesia care record.
3. If an electronic medical record (EMR) is used, the patient information on the informed consent will be checked against the EMR to ensure the correct EMR is open. This should be done before moving the patient to the operation/procedure room table.
4. Persons doing final verification should be at least two members of the operating team. Ideally, this would be the circulating nurse and the anesthesia care clinician. If possible, the patient should participate in the verification process.

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## 9. Verify Site Marking/Position Patient/Skin Preparation/Clipping

## 9.1 Skin Preparation and Hair Removal

Most surgical site infections are from skin normal flora (coagulase-negative staphylococcus non-aureus).

- The surgical site should be assessed before skin preparation. Skin should be assessed for the presence of moles, warts, rashes or other skin conditions. Inadvertent removal of lesions may provide an opportunity for wound colonization.
- The surgical site and surrounding areas should be clean.
- Antiseptics are shown to reduce bacteria on the skin, but a corresponding decrease in surgical site infection rates has not been demonstrated. The Centers for Disease Control's 1999 guidelines do recommend the use of antiseptics *(Ellenhorn, 2005 [Reference]; Jacobson, 2005 [Reference]; Ostrander, 2005 [Reference]; Sowapat, 2005 [Reference]; Hibbard, 2002 [Reference])*. There

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is insufficient evidence from randomized trials to support the use of antiseptic preparation of the skin, or of one antiseptic over another *(Edwards, 2006 [Reference])*. Several antiseptic agents are available for preoperative preparation of skin at the incision site. Careful consideration should be given to the patient's condition. Some antiseptic agents may burn mucous membranes, and others are highly flammable. The prepared area must be large enough to extend the incisions or create drain sites. Some protocols recommend applying the antiseptic with sterile supplies, but again there is no literature to support this.

- Personnel should be knowledgeable in skin preparation techniques, including maintaining skin integrity and preventing injury to the skin *(Association of Operating Room Nurses, 2002 [Reference]; Mangram, 1999b [Reference])*. Special considerations should include:
  - preparing areas with high microbial counts last;
  - isolating colostomy sites, covering with an antiseptic-soaked sponge, and preparing them last;
  - using normal saline to prepare burned, denuded or traumatized skin;
  - avoiding the use of chorhexidine gluconate and/or alcohol based products on mucous membranes;
  - allowing sufficient contact time for antiseptics before applying sterile drapes;
  - allowing sufficient time for complete evaporation of flammable agents; and
  - preventing antiseptics from pooling beneath patients or equipment.
- Patient skin preparation should be documented in the patient record.
- Policies and procedures on skin prep should be reviewed regularly to assess new evidence.

See Appendix G, "Overview of Topical Antiseptics Used for Preoperative Skin Preparation."

**Hair removal**

- The patient and procedure room should be assessed for amount and degree of hair removal.
- Refrain from hair removal unless the hair at or around the incision may interfere with the procedure *(Winston, 1992 [Reference])*. Hair removal should be the exception, not the rule.
- Hair removal, when necessary, should occur as close as possible to the time of a surgical procedure and should be performed with clippers *(Mangram, 1999b [Reference])*. There is no evidence stating a specific time when to refrain from hair removal at or near the surgical site. Shaving more than 24 hours prior to the procedure is documented to increase infection risk *(Mangram, 1999a [Reference])*.

**Definitions for hair removal should be clarified**

- The shaving method uses a sharp blade over the patient's skin to cut hair close to its surface. The razor is typically disposable. Shaving with a razor may result in cuts and abrasions to the skin and therefore should not be used.
- The clipping method uses clippers with fine teeth to cut hair close to the patient's skin. It leaves a short stubble of hair typically one millimeter in length. A clipper typically has a disposable head or is disinfected between patients. Staff should follow manufacturer's instructions provided with the hair clippers. Clippers do not come in contact with the patient's skin, thus decreasing cuts and abrasions.
- The use of depilatory creams is a method in which chemicals dissolve the hair. This is a slower process lasting anywhere from 5 to 20 minutes. Chemical depilatories may irritate the skin or result in an allergic reaction. A patch test is recommended 24 hours prior to cream applications.

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- Consideration should be given to where hair removal occurs. Hair removal at the sterile field could potentially contaminate the surgical site and/or sterile fields due to loose hairs.
- For some surgical procedures, hair removal may not be necessary. Patients requiring emergent procedures may not have time for hair removal.
- Staff performing patient hair removal should be instructed to use the proper technique.
- Policies and procedures should indicate when and how to remove hair at the incision site. Hair removal should occur under physician orders and/or following protocol for particular surgical procedures.
- If hair removal occurs, it should be documented. Documentation should include condition of the skin at the surgical site, who has done the removal, the method of hair removal, area of hair removal and when it was done.

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## 10. Prior to Incision – Active Verbal Time-Out

The Time-Out is to be performed after the surgeon has scrubbed and gowned, and just prior to beginning the procedure. It is the final safety stop before the surgical procedure begins. The purpose of the Time-Out is to ensure that the correct patient, procedure to be performed, site of the procedure and patient positioning are all correctly verified.

All the elements to be included in The Joint Commission (2014 National Patient Safety Goals) – required Time-Out are consistent with the elements included in the briefing **and** Time-Out within this protocol.

The recommendation from this work group is to cover all those required elements, but to cover them in two distinct temporal steps. Also see Annotation #15.1, "Briefing," for the specific elements covered in the briefing.

During the Time-Out, each person in the operating/procedure room must cease his/her activity and actively participate in the process. The team includes the surgeon, resident(s), student(s), anesthesia care clinician, scrub and circulator. No individual (e.g., student[s], vendor[s]) is exempt from stopping his/her activity during the Time-Out. If a member of the team refuses to actively participate in the Time-Out, the scalpel or cutting/incising device is not handed to the surgeon until that individual is replaced and the Time-Out completed.

The Time-Out is to be initiated by the surgeon after he/she scrubs for the procedure. It should occur just prior to incision/procedure start. The scalpel or other cutting/incising device is not to be handed to the surgeon until the Time-Out has been completed.

It is recommended that a visual memory aid be used to remind the surgeon to initiate the Time-Out. For example, a Time-Out sign or towel can be used to cover the scalpel or cutting/incising device. When one of these aids is used, it is important to hand it off the surgical field at the conclusion of the Time-Out so it is not retained in the patient.

Each Time-Out must include the following standard elements:

- Patient name
- Procedure to be performed
- Site of procedure (and level, if applicable) including *visualization of the surgeon's initials* (either on the patient's body or on an anatomical diagram), if applicable
- Patient position

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The initiation of the Time-Out is the responsibility of the surgeon (e.g., "Let's do the Time-Out"). The team ceases activity. The circulator reads the patient's affirmation of informed consent for the Time-Out elements. Prior to its use, the consent must have been validated against other documents such as history and physical, radiology or pathology reports and progress notes in the preoperative area. After the circulator reads the patient, procedure and site from the patient's affirmation of informed consent and notes the patient position, the following team verification is recommended:

(a) Anesthesia clinician:

(i) reads patient's name, and states shorthand version of the procedure;

(ii) states antibiotic name, dose and minutes since administration (optional).

(b) Scrub:

(i) states procedure for which he/she has set up for, and

(ii) announces that he/she sees the site marking (if a site marking is required for the procedure). Note: in the event the site is marked on an anatomical diagram, the circulating nurse will use the anatomical diagram to confirm the site with the team.

(c) Surgeon – says patient's name, complete procedure and site from memory.

Environmental distractions are to be eliminated as much as possible during the Time-Out. For example, music is turned off, pagers are set on vibrate, talking other than participation in Time-Out ceases and no staff are permitted to enter or exit the room. If during the Time-Out an interruption or distraction occurs (pager goes off or an individual enters the room), the Time-Out must be restarted.

The attending surgeon may designate a surgical resident or fellow to initiate the Time-Out in the attending surgeon's absence. When the attending surgeon joins the case in the operating/procedure room, the surgical resident or fellow will communicate the patient's name and procedure to the attending surgeon.

A Time-Out is to be performed prior to the onset of each procedure when multiple procedures are performed on the same patient during the same surgical period, whether or not the procedures involve a new surgical team. The process and elements of the Time-Out as described above must occur prior to the start of each procedure.

If the patient is repositioned during the procedure and this repositioning affects the patient's presentation (e.g., the patient is turned from supine to prone), a Time-Out will be conducted. The Time-Out process will be conducted in the same manner as described above.

**Individual facilities are encouraged to consider and interpret the 2014 National Patient Safety Goal recommendations (effective January 2014).**

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## 11. Discrepancies

If during the Time-Out, discrepancies among the consent, team members, imaging and/or equipment are discovered, the scalpel or cutting/incising device will not be handed to the surgeon until the discrepancy is resolved.

Institutions must develop a culture of safety. It is important that the organization and surgical services leadership team set the expectation that staff may, at any time, raise concerns or objections related to elements of the Time-Out if they believe discrepancies do or may exist. Demeaning, derogatory or retaliatory statements and/or actions taken against one or more individuals as a result of a concern raised during the Time-Out or any other part of the procedure are not to be tolerated. Each organization must have a process for immediate management when such behavior exists (The Joint Commission 2014 requirement).

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## 12. Hard Stop

If any part of the verification process was not followed and/or a discrepancy is discovered, the procedure is halted and will not continue until the missing steps of the verification process are completed and the discrepancies resolved.

Resolution of discrepancies will include:

- reverification of patient identification,
- review of the information in informed consent documentation,
- review of the medical record,
- review of diagnostic studies, and
- discussion with the patient/legal guardian (if appropriate).

Conversations related to resolution of discrepancies will be held in a quiet location, away from activity/distractions. To consider a discrepancy resolved, confirmation of the correct procedure or surgical site and side must include all forms of documentation, as well as a discussion with the patient/legal guardian. After the discrepancy has been resolved, the procedure and site verification will be repeated.

**If the steps of the verification process cannot be completed or are not completed and/or any discrepancies cannot be resolved, the procedure is canceled and rescheduled.**

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## 13. Reverify/Pause If Internal Laterality/Implants/Spine Level

If the procedure performed involves internal laterality, spine levels or the insertion of one or more implants, an intraoperative pause will be conducted. The pause will include the following elements (as appropriate):

- Side or site involved (e.g., left ovary, right kidney)
- Level to be entered (e.g., T4 left side) using images to validate location. Procedures involving level (spine) will have preoperative and intraoperative imaging present in the operating/procedure room. During the intraoperative period, the level will be identified using high-quality imaging and marked with opaque markers with specific bony landmarks. The surgeon will stop after the initial incision and confirm the target level of the procedure by comparing the preoperative and intraoperative imaging.
- Implant to be inserted, specifically the:
  - implant specification/type/expiration date,
  - size, and
  - side or laterality.

The pause will include verbal confirmation by the surgeon, circulating nurse and scrub.

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## 14. Safe Site Implementation

- To facilitate implementation of the Hard Stop concept, have your chief executive officer communicate to all staff and physicians their support for the institution of the Hard Stop.
- The Time-Out is best followed when a particular person/role has responsibility to call the Time-Out. The surgeon should then be the one to take the lead on initiating the Time-Out and have the circulator begin the review of information.

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- Establish pre-procedure and post-procedure communication standards in the form of structured hand-offs.
- Develop a verification process at the point of scheduling. The work group recommends that this process include:
  - Corroboration between the surgical consent, the order to schedule a procedure and an independent source document dictation (such as a radiology report or pathology report).
  - Review of documents by a licensed independent practitioner or an RN, with attention directed specifically to the organ to be operated upon and laterality as appropriate before proceeding to the scheduling process.
  - The independently verified documentation provided on paper, fax or electronic format, not by telephone or verbal communication. The only exception to this is during emergency situations.

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# 15. Communication

## 15.1 Briefing

It is expected that the initial plan for the surgical procedure will have been disseminated prior to the day of surgery, preferably at the time of scheduling. The briefing is conducted to facilitate more effective and efficient case flow.

**An effective briefing:**

- confirms patient and/or case needs and the plan for a particular procedure, including what will be needed and when it will be needed,
- includes the operating/procedure room team (surgeon, circulating nurse, anesthesia care clinician, scrub) who will be present during the procedure so they can react to the same information at the same time,
- should be conducted in the operating room before anesthesia induction but no later than final patient positioning,
- helps to ensure that all team members are prepared for potential problems or issues that might arise, and
- helps cases to run more smoothly with less downtime.

Appropriate briefing elements include:

- team greeting or introduction of individual team members (if team members do not know each other) – recommended as mandatory,
- verification of implant(s), if the case will have implant(s) – recommended as mandatory,
- verification of image(s), if the case will have image(s) – recommended as mandatory,
- team is encouraged to comment or ask questions – recommended as mandatory, and
- fire risk assessment and mitigation strategy.

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Any special patient needs or potential issues including safety precautions based on patient history or medication use:

- Anticipated problems
- Patient positioning
- Status of the patient consent
- Patient allergies
- Medications
- Anticipated blood components
- Specimens, if applicable, and how they should be handled
- Details regarding special equipment
- Discussion of any special intraoperative requests (e.g., surgeon informs circulating nurse and scrub about times during the procedure when he or she would prefer that they avoid taking a break)

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## 15.2 Structured Hand-Off for Any Surgical Personnel Changes

During the perioperative period, care is serially assumed by various individuals. It remains extremely important to fully communicate patient-relevant information and pertinent problems each step of the way. A transfer of care occurs when one health care clinician transfers responsibility for the patient's care to another health care clinician. This occurs from pre-anesthesia to hospital discharge. Each care team is obligated to remain in close physical proximity to the patient as long as medically necessary until the receiving health care clinician has all the information needed to assume care. Dialogue between the health care clinicians must be verbal and face-to-face.

To increase efficiency and consistency in the exchange of information, it is recommended that a standard format be developed for giving "report" from one health care clinician to another. This includes, but is not limited to, patient name, procedure, medications given and to be given, pertinent problems, allergies, fluid status, cardiorespiratory status and laboratory values received or pending. The receiving health care clinician must be given the opportunity to ask questions and receive answers. It is STRONGLY recommended that this information be given verbally person to person, e.g., for transfer of the patient from the operating/procedure room or post-anesthesia care unit to the intensive care unit, physician-to-physician personal communication is optimal rather than information given through one or more intermediaries *(Guidelines for Patient Care in Anesthesiology, 2007 [Reference])*.

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## 15.3 Structured Hand-Off Process

A structured hand-off is a standardized method of communication to ensure a complete exchange of information occurs when the patient is transitioned from health care clinician to health care clinician whether or not that transition includes a geographic change. It is recommended that a safety checklist be used to note information needed to be handed off to the next caregiver.

The kind of information that should be provided during the transition includes the following:

- Patient name
- Type of procedure to be performed, being performed, or performed
- Critical test results

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- Patient status
- Recent/anticipated changes in patient condition
- Plan of care/goals
- What to watch for in next interval of care

Repeat verification process if the patient has been moved or the care team changes at any point during preoperative care, intraoperative care or postoperative care areas.

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# 16. Never Events

## 16.1 Retained Foreign Objects

For as long as the medical community has been performing surgery or invasive procedures, there has been the risk and misfortune of unintentionally leaving items behind. Many measures have been instituted to mitigate the likelihood of an unintentionally retained item, but unfortunately they continue to occur. Exactly how often it happens is unknown; however, it has been estimated that on a national basis, approximately 1,500 patients per year will have a foreign body unintentionally retained following surgery *(Gawande, 2003 [Reference])*.

Professional organizations such as the American College of Surgeons *(American College of Surgeons, 2005 [Reference])*, Surgical Clinics of North America *(Gibbs, 2005 [Reference])*, Association of PeriOperative Registered Nurses *(AORN, 2006 [Reference])*, Department of Veterans Affairs Veterans Health Administration *(Eldridge, 2006 [Reference]*; *VHA Directive, 2006 [Reference]*), Council on Surgical and Perioperative Safety *(Council on Surgical and Perioperative Safety, 2005 [Reference])*, American College of Obstetricians and Gynecologists *(ACOG Committee on Quality Improvement and Patient Safety, 2006 [Reference])* and The Joint Commission *(Joint Commission International Center for Patient Safety, 2006 [Reference])* have all developed guidelines for the prevention of retained items. In an article published in February 2006, the Association of PeriOperative Registered Nurses *(AORN, 2006 [Reference])* established a set of six practices that if implemented, are expected to significantly reduce the risk of an unintentionally retained item.

The Joint Commission categorizes the unintended retention of a foreign body after surgery or other procedure as a sentinel event. Health care organizations are required to conduct a root cause analysis and to develop a corrective action plan designed to reduce the probability of a repeat occurrence.

As part of the Minnesota Adverse Health Event law, these events are reported directly to the state and are publicly disclosed. In the Minnesota Department of Health's Fifth Annual Public Report, covering periods October 7, 2007-October 6, 2008, 312 total adverse events, were reported, with 37 reported as unintentionally retained objects *(Adverse Health Event in Minnesota, 2009 [Reference])*.

The operating/procedure room survey is a safety check done to ensure that all items associated with a previous patient and procedure are removed from the operating suite or room. This is done after the patient has left the operating/procedure room.

The circulating nurse will be the designated person in charge of the survey. Other surgical team members including scrub personnel, anesthesia personnel, surgical assistants and housekeeping will be expected to assist in this process. The circulating nurse will be the final designee expected to do the final survey of the room prior to preparation for the next patient and procedure including the first procedure of the day.

The room survey includes, but is not limited to, the following considerations:

- Remove all items related to the previous patient.
- Remove any paper or electronic medical records, labels or imaging films.

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- Verify that the whiteboard and other record-keeping documents are clean and do not contain information from the previous procedure.
- Observe for any personal items of the patient. Examples include hearing aids, eyeglasses, dentures, clothes or any medical devices such as braces or assistive devices. These items may have been left with family members or may have been brought to the operating/procedure room with the patient.
- Check all receptacles, particularly those used for sponges. Ensure they are empty and that depending on the method of disposal, all items or bags from the previous procedure are removed from the room.
- Remove any equipment or supplies from the previous procedure that will not be needed for the next procedure.

### Does Circulator Perform Room Survey Prior to Baseline Count?

If the circulator does not perform the room survey prior to the baseline count, then there is the potential for the baseline count to be compromised. In the event that the circulator does not perform the room survey prior to the baseline count, then all counts may be considered compromised and an image may be obtained at the close of the case.

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## 16.11 Baseline Count

**Perform baseline count before patient arrives in the operating/procedure room suite**

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 *(ACOG Committee on Quality Improvement and Patient Safety, 2006 [Reference]; AORN, 2006 [Reference]; CRICO/RMF, 2006 [Reference]; Eldridge, 2006 [Reference]; Harder, 2006 [Reference]; Joint Commission International Center for Patient Safety, 2006 [Reference]; American College of Surgeons, 2005 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference]; Gibbs, 2005 [Reference]; Brennan, 2004 [Reference]; Vincent, 2004 [Reference]; Thomas, 2000 [Reference]; Leape, 1991 [Reference])*.

In addition, articles on communication, teamwork, multitasking and interruptions and their relationship to unanticipated events were consulted *(Haig, 2006 [Reference]; ECRI, 2005 [Reference]; Leonard, 2004 [Reference]; Lingard, 2004 [Reference])*.

Accurately accounting for all items that could potentially become unintentionally retained is a priority of the entire surgical team, though the primary responsibility for performing the count process belongs to the circulator and scrub. There must be no distractions (e.g., extraneous conversation, music, unnecessary interruptions). The circulator must be a registered nurse *(AORN, 2006 [Reference]; American College of Surgeons, 2005 [Reference])*.

Radiographic imaging is not a substitute for performing accurate count procedures. Count procedures may be omitted or modified in an extreme patient emergency. This exception will be documented in the patient's medical record and when the patient's condition allows, radiographic imaging should be obtained to rule out the possibility of an unintentionally retained foreign object.

**What items will be included in the count process**

Best practice is the use of only radiopaque items in the surgical wound *(AORN, 2006 [Reference]; VHA Directive, 2006 [Reference]; American College of Surgeons, 2005 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference])*. The work group recognizes that not every item that may be used during a surgical procedure is radiopaque.

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It is the recommendation of the work group that radiopaque items should be used if that product is manufactured in a radiopaque form and all non-radiopaque items should be counted, regardless of whether that item is a required, countable item.

**Sponges/soft goods** – Sponges/soft goods will be counted for all procedures when they are used. Only radiopaque sponges/soft goods will be present within the surgical field *(AORN, 2006 [Reference]; VHA Directive, 2006 [Reference]; American College of Surgeons, 2005 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference])*.

Laparotomy sponges or 4x8 sponges will not be cut into pieces or otherwise used for dressing *(AORN, 2006 [Reference]; VHA Directive, 2006 [Reference]; Council on Surgical and Perioperative Safety, The, 2005 [Reference])*.

Non-radiopaque gauze used for dressing will be held in a separate area until the wound is closed *(AORN, 2006 [Reference]; American College of Surgeons, 2005 [Reference])*.

**Sharps** – Sharps will be counted for all procedures when they are used *(AORN, 2006 [Reference]; American College of Surgeons, 2005 [Reference])*.

An unintentionally retained micro needle is not reportable as a retained foreign object. Organizations will need to define a micro needle depending on their patient population (e.g., infants).

**Miscellaneous items** – Miscellaneous items will be counted for all procedures (*AORN, 2006 [Reference]; American College of Surgeons, 2005 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference])*.

Examples of a miscellaneous item include vessel clips, vessel loops, vascular inserts, cautery scratch pads, trocar sealing caps, catheter sheaths, non-radiopaque items such as hernia tapes and other small items.

**Instruments** – Instruments will be counted for all procedures when the possibility exists that an instrument could be unintentionally left behind *(AORN, 2006 [Reference])*.

Organizations will need to define instruments that are at risk for being unintentionally retained. The work group has listed the following guiding principles to assist organizations in defining instruments to be counted:

- Size of the wound relative to the instruments being used
- Instruments that leave the hand of the operator after being placed in the operative field
- Instruments that are obscured within the wound and not clearly visible throughout the procedure (clips, guide wires, small clamps, etc.)

Instruments that are to be counted should be identified by specialty/service and specific to the procedure and surgical technique employed.

Examples of surgical procedures where instruments may be identified as a required countable item include chest, open abdominal, and pelvic procedures.

When the Count Process Will Be Performed *(AORN, 2006 [Reference]; VHA Directive, 2006 [Reference])*

- The baseline count will be performed before the patient is brought to the operating/procedure room unless parallel processing is used. When parallel a process is used, two different circulators will be needed: one dedicated to a focused count process and one dedicated to focused patient care.
- At the time of closure of a cavity within a cavity
- Before wound closure (e.g., fascia)

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- At the end of the procedure/final closure (e.g., skin) – Sponges/soft goods used for wound debridement procedures for burn patients are exempt from the final count process. A final count, as outlined in the protocol, must be performed for all other items (sharps, miscellaneous items, instruments) used in wound debridement procedures for burn patients.
- Any time a member of the surgical team has concerns about the accuracy of the counts, even when the counts appear correct
- Whenever there is a permanent staff change of the circulator and/or scrub:
  - All visible items will be counted and all items in use in the surgical field will be accounted for.
  - When the circulator and/or scrub is changed for a short duration (e.g., lunch break), a structured hand-off is required but a count is not. The structured hand-off is performed for two purposes:
    (1) To maintain the scrub's safety with sharps on the field
    (2) To account for items in use in the field
- At final closure of a wound that was intentionally delayed (damage control), temporary implants are used, or a wound is temporarily closed with a non-radiopaque item (e.g., wound vacuum sponge)

**How the count process will be performed**

- The circulator and scrub (the circulator must be a registered nurse) will directly view the items being counted and will count out loud and concurrently *(AORN, 2006 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference])*.
- There is evidence that distractions, multitasking and conflicting priorities, especially during critical cognitive steps, will, with high predictability, lead to an error. It is recommended by the work group that the surgeon declare critical times, if known, during the briefing so the team can appropriately plan for breaks/reliefs. The surgical team is otherwise advised to use critical thinking skills to determine safe case interruption times *(ACOG Committee on Quality Improvement and Patient Safety, 2006 [Reference])*. Therefore, distractions and interruptions should be minimized during the count process *(ACOG Committee on Quality Improvement and Patient Safety, 2006 [Reference]; American College of Surgeons, 2005 [Reference])*. If the count process is interrupted, the circulator and scrub will restart the count of the count category that was interrupted.
- The circulator will document the number and type of sponges/soft goods, sharps, miscellaneous items, and instruments on a preformatted whiteboard or other standardized, preformatted documentation record. The scrub verbally confirms the number.
  - It is best practice for the circulator to document the number of each item immediately after counting them. This diminishes the likelihood that the number will be recalled incorrectly or the circulator will forget to document the number on the whiteboard.
  - Best practice is to use a preformatted whiteboard, directly viewable by the entire surgical team *(France, 2005 [Reference])*.
  - For procedures where there is a large number and/or specificity of certain items (e.g., cardiac procedures), a standardized, preformatted paper record may be used.
  - It is the recommendation of the work group that, whenever possible, only one source of count information be used during the procedure.

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- All sponges/soft goods, sharps, miscellaneous items, and instruments will be counted in the same order each time *(AORN, 2006 [Reference])*.
    - It is the recommendation of the work group that items be counted in the order they are listed on the preformatted whiteboard.
- Sponges/soft goods will be separated and counted individually *(AORN, 2006 [Reference])*.
    - Some organizations allow 4x8 sponges to be held by the bottom third and counted by individually separating the top two-thirds of each sponge. It is the work group's recommendation that best practice is to separate all sponges and count them individually.
- Every sponge/soft good will be visually inspected to ensure that the radiographic-detectible indicator is present *(AORN, 2006 [Reference]; American College of Surgeons, 2005 [Reference]; Council of Surgical and Perioperative Safety, 2005 [Reference])*.
    - If the indicator is not present, the entire package of sponges/soft goods will be removed from the suite and given to the designated person for follow-up with the manufacturer *(AORN, 2006 [Reference])*.
- Instruments should be counted in sets.
    - It is the work group's recommendation that best practice is for all instruments, regardless of whether they are required countable items or not, be added to the surgical field in pairs and retrieved in pairs.
- Packages where the labeling on the package does not match the number of items in the package will be removed from the suite and given to the designated person for follow-up with the manufacturer *(AORN, 2006 [Reference])*.
- Counts will begin at the surgical field and move away from the patient.
- Gauze and other soft goods used by anesthesia will not enter the surgical field or be mixed in with sponges/soft goods used and counted for the surgical procedure.
- Sponges/soft goods, sharps, miscellaneous items, and instruments added during a procedure will be counted prior to entering the surgical field *(AORN, 2006 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference])* and documented as soon as possible.
- Used sponges/soft goods will be unballed, separated and pulled apart for counting.
- All sharps, miscellaneous items, and instruments will be inspected for broken or missing pieces when counted *(AORN, 2006 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference])*.
- Any sponge/soft good, sharp, miscellaneous item, or instrument dropped during the procedure will be retrieved, shown to the person responsible for counting, and isolated from the surgical field to be included in the final count.
- Gauze and other soft goods used for wound dressing will not be present in the surgical field until the wound is closed.
- Any item intentionally left behind in a patient because it would do more harm to retrieve will be documented in the patient's medical record.
- New technology may be used to supplement or support the manual counting process but does not take the place of a manual two-person count.

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**Recommendations for waiving baseline count with life-threatening cases**

If the baseline count cannot be performed prior to the patient being brought to the operating/procedure room (unless a parallel process is used – see below), the counts should be considered compromised and inaccurate. Continue to follow the Perioperative protocol and obtain portable, intraoperative radiographic imaging for a potentially retained foreign object.

Some organizations are utilizing a parallel process to improve operating/procedure room turnover times. A parallel process is when two separate activities with two entirely separate groups of staff are performed simultaneously. A parallel process is **not** multitasking. For the count process, two different circulators will be needed: one dedicated to the count process and one dedicated to patient care.

If separate staff is not available, the baseline count must occur before the patient arrives in the operating/procedure room.

**Communication of unresolved counts in operating/procedure room:** In the event that a countable item is lost and cannot be accounted for, surgical teams that may be performing subsequent procedures in the same room prior to its terminal cleaning should be alerted. The circulator should record the date, time, type and number of the missing item on the room's whiteboard, if present, or other salient documentation devices so that the next surgical team is aware of the unresolved discrepancy. Word of mouth is an insufficient means for communicating this information.

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## 16.12 For Appropriate Cases, Do Wound or Body Cavity Exploration and Imaging If Counts Not Reconciled: Postoperative Follow-Up If Counts Remain Unreconciled

Radiographic imaging, whether a portable radiographic image obtained in the operating/procedure room or a postoperative image obtained in a radiographic room, is not a substitute for performing an accurate count process and methodical wound exploration.

An intraoperative radiographic image can be used to exclude the possibility of a retained foreign object. Portable radiographic imaging has limitations that should be considered, especially for visualizing micro needles. In addition, the type of imaging equipment (e.g., C-arm) used and cassette orientation relative to the surgical site should be considered.

The highest quality radiographic imaging is obtained in a radiographic room with fixed radiographic equipment and moving grid. If there are still unreconciled counts, it is recommended that the surgeon have a discussion with the patient and make a follow-up plan. The plan could include additional imaging (x-ray, computed tomography, magnetic resonance imaging).

**Portable imaging considerations and limitations:**

- Patient condition
- Size and type of retained item (non-radiopaque items, micro needles)
- Limited placement options of the radiographic film cassettes under operating/procedure room tables limiting anatomy included on the images
- Lower tube power
- Instruments obscuring the image area
- Availability of portable radiographic equipment and staff

**Portable intraoperative imaging should be obtained when:**

- counts are off and cannot be reconciled,

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- the patient's condition did not allow for the count process to be followed (rushed counts, incomplete counts),
- any individual has a concern about the accuracy of the counts, or
- before final closure when the wound was previously intentionally left open/packed.

Imaging requests to rule out a possible retained foreign object need to include the following information:

- Callback number and surgeon's name
- Location and status of patient (e.g., in operating/procedure room with wound closure suspended, in post-anesthesia care unit)
- Type of surgery
- Type of item missing
- Details of the surgery as appropriate

The radiology technologist will review the radiographic images for quality and repeat the imaging as necessary.

Prior to the radiographic images being interpreted by radiology, the surgeon will review the radiographic images for adequate anatomic coverage related to the procedure and operative site. If the surgeon is unable to verify adequate anatomic coverage on the portable intraoperative images, postoperative radiographic imaging with fixed radiographic equipment should be obtained.

The work group recommends that the radiologist and surgeon simultaneously review the radiographic images both verbally and visually to correlate the anatomical coverage of the images with the surgical procedure, as well as a description of the potentially retained foreign object.

If a radiologist is not immediately available, the preliminary interpretation of the radiographic images to exclude a potentially retained foreign object is the responsibility of the surgeon.

**Postoperative radiographic imaging in a radiographic room with fixed radiographic equipment and moving grid should be obtained as soon as possible when there is a discrepancy in the counts and:**

- the patient's condition did not allow for intraoperative imaging to be obtained,
- the entire anatomic area was not included in the portable intraoperative imaging, or
- the intraoperative imaging failed to locate the retained foreign object and the counts could not be reconciled.

Prior to the radiographic images being interpreted by radiology, the surgeon will review the radiographic images for adequate anatomic coverage related to the procedure and operative site. The radiology technologist will review the radiographic images for quality and repeat the imaging as necessary *(AORN, 2006 [Reference]; VHA Directive, 2006 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference])*.

**Body cavity entered/created**

Entering an existing body cavity or creating an artificial cavity during a surgical procedure, whether it is an open surgical wound or through a laparoscopic or hand-assisted procedure, increases the risk for an unintentionally retained foreign object. For the purposes of this protocol, an existing or artificially created body cavity are treated the same.

A methodical wound exploration will be performed prior to the closure of the wound and/or any body cavity. It is possible that the surgeon may perform multiple wound/body cavity explorations during the procedure

(e.g., the stomach and abdominal cavities *(AORN, 2006 [Reference]; Eldridge, 2006 [Reference]; VHA Directive, 2006 [Reference]; American College of Surgeons, 2005 [Reference])*.

Whenever possible, the surgeon will use both visualization and touch during the cavity exploration. Generally, the type of surgical procedure performed guides the wound exploration technique employed. It is recommended that the wound exploration be methodical and performed by each physician the same way each time (e.g., top to bottom, quadrant to quadrant) *(Eldridge, 2006 [Reference]; American College of Surgeons, 2005 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference]; Gibbs, 2005 [Reference])*.

A methodical wound exploration may be omitted or abbreviated in an extreme patient emergency or if the patient becomes clinically unstable. Ideally, the method used to perform the wound exploration will be documented by the surgeon as part of the operative note.

The cavity exploration may be performed simultaneously with the counting by the scrub and circulator. The cavity will not be closed until counts have been reconciled. If the counts cannot be reconciled even after a thorough exploration of the cavity and the cavity is expected to be closed at the end of the procedure, an intraoperative film must be obtained prior to the cavity closure.

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## 16.13 Perform Delayed Wound Closure/Open Packing, Final Count and Retained Foreign Object Prevention Process

Certain circumstances require that a wound be left open following a surgical procedure with the intent that the patient will return to the operating/procedure room at a later time for final wound closure. Examples of these cases include grossly contaminated wounds (Class III and IV wounds) or when the patient is unstable or has the potential to develop instability (e.g., damage control procedure).

When the closure of a wound is intentionally delayed (damage control) or when implants are used as part of the treatment (e.g., antibiotic beads, wound-vacuum sponges), the following will be performed:

- Radiopaque items will be used if that product is manufactured in a radiopaque form *(AORN, 2006 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference])*.
- Count the items and document the item categories and numbers in the procedure record.
- Any sponges/soft goods packed in the operating/procedure room and removed must be counted and documented in the patient's medical record.
- Any sponge/soft goods packed into or left on the wound must be counted and documented in the patient's medical record.

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## 16.14 Patient Returns to the Operating/Procedure Room for Final Wound Closure

- Establish a baseline count of sponges/soft goods, sharps and instruments that will be used in the final wound closure and document them on a preformatted whiteboard (or on a preformatted count worksheet if a preformatted whiteboard is not available).
- When the patient returns to the operating/procedure room for final wound closure, sponges/soft goods removed from the open wound should be isolated from sponges/soft goods used during the final wound closure.
- Count packed items as they are removed from the wound, and reconcile the items and number of items with what was previously documented in the patient's medical record.
- When there is a discrepancy between what was removed and what was documented as left in the wound, an attempt to reconcile the discrepancy will be performed as described in Annotation #16.15, "Hard Stop – Perform Reconciliation Process."

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- A thorough wound exploration will be performed prior to closing the wound and documented in the patient's record.
- Count the sponges/soft goods, sharps and instruments that were used in the final wound closure procedure, and reconcile the count with what is documented on the preformatted whiteboard (or on a preformatted count worksheet if a preformatted whiteboard is not available).
- When there is a discrepancy between the baseline count and the final count record, an attempt to reconcile the discrepancy is performed as described in Annotation #16.15, "Hard Stop – Perform Reconciliation Process."
- An intraoperative radiographic image should be obtained prior to final wound closure to ensure all items have been removed.

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## 16.15 Hard Stop – Perform Reconciliation Process

**Process for managing count discrepancies**

When a discrepancy in countable items is identified, the missing item and number are reported to the surgical team by the circulator. A discussion (involving the surgeon, circulator nurse and scrub) will occur during which the circulator will communicate to the surgeon the type(s) and number(s) of missing foreign objects. If the patient's condition permits, wound closure should be suspended during the discussion regarding the missing foreign object. If wound closure has begun it will not continue until the discussion occurs. This is a Hard Stop.

The work group recommends that the circulating nurse organize used countable items in such a way that counts (e.g., closing a cavity within a cavity, initial closing count, final count) performed after the baseline count can be performed effectively and efficiently. Sponge count bags and numbered needle boards are tools that will help to organize items for counting.

If a closing count is incorrect, the following steps will be taken to reconcile the count if the patient's condition permits *(AORN, 2006 [Reference]; VHA Directive, 2006 [Reference])*:

(1) The surgeon must be notified immediately. A discussion will occur, during which the circulator will communicate to the surgeon the type(s) and number(s) of missing items. This is a Hard Stop.

(2) The circulating nurse will summon additional personnel to the operating/procedure room to assist with resolving the count.

(3) The surgeon will re-explore the wound, paying special attention to the location where that particular item may be retained (e.g., sponges tucked behind organs).

(4) The count is repeated and verified. A discrepancy with the count will never be resolved by using the number listed on opened packages.

(5) Surgical closure may continue at the surgeon's discretion, but final skin closure cannot occur until all x-ray results are reviewed and communicated back to the surgeon by the radiologist.

(6) If the item is still missing after the recount and wound exploration, the scrub team must search the drapes, field, Mayo stand and back table. At the same time, the circulating nurse must search the sponge count bag, trash, linen, floor, kick bucket(s) and all items that have been counted off the field. Sponges/soft goods will be unballed and separated for counting.

(7) If the item is located in this search, a complete recount must be conducted and the correct count documented.

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(8) If counts cannot be reconciled by team members, and the missing item is radiopaque, notify the attending surgeon and obtain an x-ray order to "rule out retained foreign object."

(i) These images will be marked "STAT" and will be prioritized before other radiology requests.

(ii) Portable intraoperative imaging should be obtained and reviewed by the surgeon and radiologist before wound closure. See Annotation #16.16, "Imaging If Counts Not Reconciled: Postoperative Follow-Up If Counts Remain Unreconciled."

(iii) The intraoperative film order will indicate a phone number for the appropriate operating/procedure room for proper follow-up to occur.

(iv) In response to a film ordered to "rule out retained foreign object," the interpreting radiologist will discuss the findings with the surgeon. The two individuals will view the images simultaneously to identify all findings. The name of the surgeon and time the call was made will be recorded in the radiology report. Additional films with various angles may also be requested in order to view the possible retained foreign object.

If the counts cannot be reconciled, all the measures taken and the outcomes of those steps should be documented per the organization's policy. A radiographic image obtained in a radiology room with fixed equipment and moving grid should be obtained.

**Note:** The Minnesota Adverse Event Reporting law requires the reporting of a retained foreign object. The above reconciliation steps give consideration to the current definition of a reportable event and are intended to avoid such an adverse event. The work group will continue to review for evidence supporting best practice.

**Policy exception:**

An exception may occur when the attending surgeon decides that any delay required for an intraoperative x-ray or removal of the foreign object(s) will cause harm to the patient due to his or her emergent medical condition.

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## 16.16 Imaging If Counts Not Reconciled: Postoperative Follow-Up If Counts Remain Unreconciled

Radiographic imaging, whether a portable radiographic image obtained in the operating/procedure room or a postoperative image obtained in a radiographic room, is not a substitute for performing an accurate count process and methodical wound exploration.

An intraoperative radiographic image can be used to exclude the possibility of a retained foreign object. Portable radiographic imaging has limitations that should be considered, especially for visualizing micro needles. In addition, the type of imaging equipment (e.g., C-arm) used and cassette orientation relative to the surgical site should be considered.

The highest quality radiographic imaging is obtained in a radiographic room with fixed radiographic equipment and moving grid. If there are still unreconciled counts, it is recommended that the surgeon have a discussion with the patient and make a follow-up plan. The plan could include additional imaging (x-ray, computed tomography, magnetic resonance imaging).

**Portable imaging considerations and limitations:**

- Patient condition
- Size and type of retained item (non-radiopaque items, micro needles)
- Limited placement options of the radiographic film cassettes under operating/procedure room tables limiting anatomy included on the images

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- Lower tube power
- Instruments obscuring the image area
- Availability of portable radiographic equipment and staff

**Portable intraoperative imaging should be obtained when:**

- counts are off and cannot be reconciled,
- the patient's condition did not allow for the count process to be followed (rushed counts, incomplete counts),
- any individual has a concern about the accuracy of the counts, or
- before final closure when the wound was previously intentionally left open/packed.

**Imaging requests to rule out a possible retained foreign object need to include the following information:**

- Callback number and surgeon's name
- Location and status of patient (e.g., in operating/procedure room with wound closure suspended, in post-anesthesia care unit)
- Type of surgery
- Type of item missing
- Details of the surgery as appropriate

The radiology technologist will review the radiographic images for quality and repeat the imaging as necessary.

Prior to the radiographic images being interpreted by radiology, the surgeon will review the radiographic images for adequate anatomic coverage related to the procedure and operative site. If the surgeon is unable to verify adequate anatomic coverage on the portable intraoperative images, postoperative radiographic imaging with fixed radiographic equipment should be obtained.

The work group recommends that the radiologist and surgeon simultaneously review the radiographic images both verbally and visually to correlate the anatomical coverage of the images with the surgical procedure, as well as a description of the potentially retained foreign object.

If a radiologist is not immediately available, the preliminary interpretation of the radiographic images to exclude a potentially retained foreign object is the responsibility of the surgeon.

**Postoperative radiographic imaging in a radiographic room with fixed radiographic equipment and moving grid should be obtained as soon as possible when there is a discrepancy in the counts and:**

- the patient's condition did not allow for intraoperative imaging to be obtained,
- the entire anatomic area was not included in the portable intraoperative imaging, or
- the intraoperative imaging failed to locate the retained foreign object and the counts could not be reconciled.

Prior to the radiographic images being interpreted by radiology, the surgeon will review the radiographic images for adequate anatomic coverage related to the procedure and operative site. The radiology technologist will review the radiographic images for quality and repeat the imaging as necessary *(AORN, 2006 [Reference]; VHA Directive, 2006 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference])*.

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### 16.17 Close Wound

**Close wound and finish procedure**

A radiographic image prior to closure of the wound does not need to be obtained when count processes are rigorously followed and all counts can be reconciled.

**Post-procedure tasks**

- Any countable item that accompanies the patient out of the operating/procedure room will be communicated to the circulator and documented *(AORN, 2006 [Reference]; Council on Surgical and Perioperative Safety, 2005 [Reference])*.
- After the counts have been reconciled, all items will be removed from the operating/procedure room. No items will be removed from the operating/procedure room until all counts have been reconciled and inspections completed.
- The whiteboard will be cleaned at the end of the procedure and before setup begins for the next procedure.
    - Note: The date, time, type and number of any unaccounted for item will be recorded on the whiteboard and communicated to each subsequent surgical team until the operating/procedure room is terminally cleaned.

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## 17. Environmental

## 17.1 Normothermia Planning and Management

**Temperature control**

Development of hypothermia in the patient has been shown to be associated with increased risk of infection. Prevention of hypothermia begins prior to patient arrival in the room. The room temperature should be such that a minimally clothed patient is comfortable. It is appropriate to adjust room temperature to a level comfortable for the operating/procedure room personnel once the patient has received active or passive measures to prevent heat loss.

The American Society of Anesthesiologists' Practice Management Guidelines for perioperative normothermia document consequences of "even mild hypothermia (one to two degrees C below normal)" as:

- prolonged drug action and delayed recovery and hospital discharge *(Lenhardt, 1997 [Reference]; Leslie, 1995 [Reference]; Heier, 1991 [Reference])*,
- post-anesthetic shivering and thermal discomfort *(Kurz, 1995 [Reference]; Sessler, 1991 [Reference])*,
- increased susceptibility to infection *(Melling, 2001 [Reference]; Kurz, 1996 [Reference]; Bremmelgaard, 1989 [Reference])*,
- impaired coagulation and increased transfusion requirements *(Winkler, 2000 [Reference]; Schmied, 1996 [Reference])*, and
- cardiovascular stress and cardiac complications *(Persson, 2001 [Reference]; Frank, 1997 [Reference]; Frank, 1995a [Reference]; Frank, 1995b [Reference])*.

The causes of perioperative hypothermia include:

- anesthetic-induced impairment of thermo-regulatory control,

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- body cavities and organs exposed to cool operating/procedure room environment *(Roe, 1971 [Reference])*, and
- core-to-peripheral redistribution of body heat *(Matsukawa, 1995 [Reference])*.

**Recommendations:**

Temperature should be monitored in all patients receiving anesthesia when significant changes in body temperature are intended, anticipated or suspected *(American Society of Anesthesiologists Standards, Guidelines and Statements, 2007 [Reference])*. Many means to monitor temperature exist, with varying levels of accuracy and ease of use. These include oral, tympanic membrane, esophageal, axillary, skin, bladder, rectal, trachea, nasopharynx, and pulmonary artery catheters. The choice of the site depends on access, type of surgery and accuracy.

**Considerations:**

- There is evidence that suggests alternative active warning measures to maintain body temperature, including control of ambient temperature, administration of warmed intravenous fluids, and surface warming with forced hot air, warmed gel pads, radiant heat, warmed blankets or circulating water mattresses. The choice of modalities is a medical judgment made by the anesthesiologist considering the patient and procedural issues in an individual case.
- An effective means of maintaining perioperative normothermia is prevention through prewarming.
- Achievement of an immediate postoperative temperature greater than 36ºC is an important and beneficial goal for patients undergoing general anesthesia.
- Core temp is the best measurement tool. Oral temperature measurement is recommended as best practice method when core thermometry is not possible.
- Intraop, all patients should receive limited skin exposure, passive warming measures, ambient room temp maintained from 20º-25ºC.
- If the procedure is anticipated to be more than 30 minutes and/or patient is at risk for hypothermia or its complications, active forced air warming should be implemented.

*(Hooper, 2009 [Reference])*

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## 17.2 Preventing Fires in the OR/Procedure Room

**Recommendations:**

- Each organization should have an OR fire prevention policy structured to fit the physical environment of the OR suites *(Strong Recommendation, Low Quality Evidence)*.
- The policy should be reviewed each year after the fire drill practice and updated with any needed changes *(Strong Recommendation, Low Quality Evidence)*.
- Each organization should have a comprehensive fire drill at least once a year. This should include different fire scenarios each year *(Strong Recommendation, Low Quality Evidence)*.
- All members of the perioperative team and support services in the surgical environments should participate in the drill *(Strong Recommendation, Low Quality Evidence)*.

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- Local fire department members and organizational life safety representation should participate in the fire drill *(Strong Recommendation, Low Quality Evidence)*.

Fire prevention is the responsibility of every member of the perioperative team. The promotion of a culture of fire safety relies on department leadership (directors, managers, educators and clinical nurse specialists) to maintain safety standards, identify safety protocols, and implement staff education and instruction on fire prevention methodology and strategies. Clinical staff (perioperative nurses, technicians, support personnel, surgeons, residents, anesthesia clinicians and visiting health care vendors, and students) are accountable for participation in department fire safety training and mock evacuations.

All department staff and clinicians are accountable for participation in department fire safety training.

OR fire drills will be performed periodically.

A permanently mounted air-oxygen blender or alternative device or equipment will be available to titrate the oxygen concentration.

All ORs and interventional areas will have CO2 fire extinguishers for fires near or on the patient.

The fire alarm will be activated for any fire in order to notify the fire department.

A fire risk assessment will occur for all surgical procedures and communicated during briefings and/or time-outs. The fire risk assessment will be documented on the whiteboard and in the EHR.

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## 17.3 General Environmental Concerns

Each facility should establish an effective method of infection event surveillance that includes data collection, review and considerations for process improvement.

**Preoperative preparation for colon surgery**

As a result of pivotal trials performed in the 1970s by Condon, Gorbach and Nichols, surgeons of the last generation incorporated routine mechanical and oral antibiotic bowel preparations into the practice of surgery on the colon. However, a number of recent trials in the modern era suggest that these two mainstays of preparation may not be necessary.

**Recommendations for surgical staff**

**Hand hygiene**

- Current hand hygiene recommendations should be met.

**Management of surgical personnel**

- Educate and encourage staff to report promptly to their supervisor if they have signs and symptoms of a transmissible infectious illness.
- Develop policies on reporting illness, work restrictions and work clearance following an illness.
- Culture and exclude from direct patient care surgical personnel who have exudative skin lesions or weeping dermatitis until infection has been ruled out or therapy resolves it.
- All staff members working in the surgical services environment at risk of exposure to blood-borne pathogens should receive the hepatitis B vaccine unless medically contraindicated *(Centers for Disease Control, 2012 [Reference]; U.S. Department of Labor, 2006 [Reference]; Centers for Disease Control, 1991 [Reference])*.

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**Recommendations for operating/procedure room environmental controls**

Operating/procedure room environmental controls are mandated and regulated by each state's department of health. For specific recommendations from the Minnesota Department of Health, see:

http://www.health.state.mn.us

**Management of operating/procedure room surfaces**

Health care workers should assume that any patient could be potentially infectious with blood-borne or other pathogens. Infection control practices should be followed at all times. Environmental cleaning and disinfection is a team effort involving surgical and environmental services personnel. Recommended practices from these specialty areas should be implemented *(AORN, 2012; Centers for Disease Control, 2011)*.

**Sterilization of operating/procedure room devices**

- Inadequate sterilization of surgical instruments has resulted in surgical infections, and routine monitoring of the quality of the sterilization process is recommended. Surgical instruments should be sterilized according to the manufacturer's recommendations.

Immediate-use steam sterilization can be a safe and effective process if used correctly. However, it should not be used as a matter of convenience. Communication and planning is key to managing equipment and sterilization needs. Immediate-use steam sterilization should be used only in selected clinical situations. Those situations include the following:

- When a one-of-a-kind instrument has been contaminated and needs to be replaced to the sterile field immediately
- When an item has dropped on the floor and is needed to continue a surgical procedure
- When specific instruments are needed for an emergency procedure
- When there is no other sterilization alternative

Immediate-use sterilization should not be performed on the following devices:

- Implants, except in a documented emergency situation when no other option is available
- Post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease (CJD) or similar disorders
- Devices or loads that have not been validated with the specific cycle employed
- Devices that are sold sterile and intended for single-use only.

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## 17.4 Environmental Controls: Operating/Procedure Room Survey

**Recommendations for operating/procedure room environmental controls**

There must be no distractions (e.g., extraneous conversation, music, unnecessary interruptions) and when the circulator and/or scrub is changed for a short duration (e.g., lunch break), a structured hand-off is required but a count is not. Operating/procedure room environmental controls are mandated and regulated by each state's department of health. For specific recommendations from the Minnesota Department of Health, see http://www.health.state.mn.us.

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**Noise control to minimize distraction and patient stimuli**

There must be no distractions (e.g., extraneous conversation, music, unnecessary interruptions). Adjust music volume to level that is appropriate to work being performed. The music should not interfere with communication among members of the operating/procedure room team.

**Recommendations for operating/procedure room vendor access**

The surgical environment can be enhanced by establishing guidelines for effective control of operating/procedure room access to external constituencies. Vendors can be granted access to the operating/procedure room when services are pertinent to patient care. It is recommended that a specific policy be established for the purposes of defining vendor access. Examples of vendor procedure statements may include the following:

- All vendors must initially contact hospital administration through the proper institutionally designated process.
- **Vendors will be admitted to the operating/procedure room only after the patient has been draped for the purpose of providing a resource to the surgeon or staff in the use of instrumentation, equipment or patient care items.**
- One vendor per operating/procedure room per surgeon unless there are clinical reasons.
- Appointments will be pre-arranged and scheduled by one of the following: surgeon, nurse manager/supervisor or charge nurse.
- The nurse manager/supervisor and/or surgeon's secretary will contact the surgical administration office to confirm prior vendor approval.
- Vendors who have received access to the operating/procedure room will register at the surgical administration office and be provided an identification tag to be worn during their operating/procedure room visit.
- Vendors will not set up displays in or around the operating/procedure room unless a surgical services educator or designee has requested an educational display be provided for staff.
- The vendor is accountable to the surgeon and surgical personnel while in the operating/procedure room.
- Surgery administration reserves the right to govern and restrict vendor access visits to the operating/procedure room.
- **Vendors do not provide patient care. Vendors must not open any surgical supplies, implantables or surgical instrumentation. The purpose of a site visit to the operating/procedure room is to answer questions about the operation of their equipment or to troubleshoot any problems occurring with the use of the equipment.**
- Demonstration of new equipment to be used for new procedures will be done in an appropriate setting outside of the operating/procedure room.
- Vendors will restrict their visit to the designated area. Expanded visits require pre-arrangement with the nurse manager/supervisor or designee of other specialty areas.
- No cell phones or personal digital assistants are allowed in the operating/procedure room.
- Vendors must have closed-toe, non-fabric shoes that are clean and professional in appearance.
- Pagers will be set on silent.

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**Example of vendors check-in process**

- Fill out visitor card yearly (kept for one calendar year), filed by vendor name.
- Provide business card (dated by office staff and filed in card file).
- Visitor name badge is required.
- Receive locker assignment.
- Change into surgical scrubs.
- Return to the surgical administration office.
- Lock all cell phones, cameras, personal digital assistants and other personal items in the locker.
- Escort to appropriate operating/procedure room.

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## 18. Follow-Up Appointments

Patients should be encouraged to schedule and keep all follow-up appointments with their surgeon and primary clinician. Follow-up appointments provide the opportunity for the surgeon and primary clinician to assess the patient for signs and symptoms of infection related to the surgical procedure and intervene or modify the care plan as appropriate *(Mangram, 1999b [Reference])*.

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The Aims and Measures section is intended to provide protocol users with a menu of measures for multiple purposes, which may include the following:

- Population health improvement measures
- Quality improvement measures for delivery systems
- Measures from regulatory organizations such as The Joint Commission
- Measures that are currently required for public reporting
- Measures that are part of Center for Medicare Services Physician Quality Reporting initiative
- Other measures from local and national organizations aimed at measuring population health and improvement of care delivery

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
- Implementation Recommendations
- Implementation Tools and Resources
- Implementation Tools and Resources Table

# Aims and Measures

### Outcome Measures

1. Increase the percentage of patients age two years and older with complete preoperative basic health assessment obtained prior to undergoing elective, non-high-risk surgery and no diagnostic tests performed without clinical indications. *(Annotation #1)*

   Measures for accomplishing this aim:

   a. Percentage of patients with a preoperative basic health assessment completed prior to the day of the scheduled procedure.

   b. Percentage of patients undergoing elective non-high-risk surgery having laboratory tests/imaging unrelated to positive findings on preoperative basic health assessment.

   c. Percentage of patients undergoing cataract surgery who have electrocardiograms performed as part of the preoperative assessment prior to cataract surgery.

2. Increase the percentage of patients age two years and older undergoing elective, non-high-risk surgery who receive appropriate management of stable comorbidities prior to procedure. *(Annotation #2)*

   Measures for accomplishing this aim:

   a. Percentage of patients with comorbidities undergoing elective non-high-risk surgery who have appropriate management of comorbidities, prior to surgery, including:

      - Antithrombotic therapy
      - Recent coronary stent/antiplatelet therapy
      - Beta-blocker therapy
      - Diabetic mellitus
      - Sleep apnea
      - Nicotine cessation

   b. Percentage of patients with comorbidities undergoing elective non-high-risk surgery who have preoperative recommendations documented/communicated to the patient and/or surgical facility for all of the following applicable comorbidities:

      - Antithrombotic therapy
      - Recent coronary stent/antiplatelet therapy
      - Beta-blocker therapy
      - Diabetic mellitus
      - Sleep apnea
      - Nicotine cessation

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c. Percentage of patients with comorbidities who have preoperative education documented for all of the following applicable comorbidities:

- Antithrombotic therapy
- Recent coronary stent/antiplatelet therapy
- Beta-blocker therapy
- Diabetic mellitus
- Sleep apnea
- Nicotine cessation

3. Decrease the percentage of patients age two years and older who have canceled or delayed elective, non-high-risk surgical procedures due to incomplete preoperative basic health assessment and ineffective communication between clinicians. *(Annotations #1, 4)*

   Measures for accomplishing this aim:

   a. Percentage of patients who have canceled or delayed non-high-risk surgical procedures due to incomplete preoperative history and physical examination documentation.

   b. Percentage of patients who have canceled or delayed surgical procedures due to ineffective communication regarding patient information as defined by organizational procedures.

4. Eliminate the wrong surgical procedure or surgery performed on the wrong body part, or on the wrong patient. *(Annotation #16)*

   Measures for accomplishing this aim:

   a. Wrong surgery events per month.

   b. Rate of wrong surgery events per month.

   c. Near misses reported per month.

5. Eliminate unintentionally retained foreign objects during a surgical procedure. *(Annotation #16)*

   Measures for accomplishing this aim:

   a. Number of unintentionally retained foreign objects in surgery.

   b. Rate of unintentionally retained foreign objects in surgery.

6. Minimize the rate of wound infections in surgical patients. *(Annotations #3, 9, 17)*

   Measure for accomplishing this aim:

   a. Rates of postoperative wound infections by wound classifications:

      1. Class I: clean
      2. Class II: clean contaminated
      3. Class III: contaminated

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## Process Aim and Measures

7. Improve the adherence of the key components of the Perioperative protocol. *(Annotations #1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18)*

   Measures for accomplishing this aim:

   **Process Measures:**

   a. Percentage of surgical patients with documentation of preoperative verification of correct patient, procedure and site/side/level.

   b. Percentage of appropriate surgical patients who had their site marked by the surgeon in preoperative with his/her initials.

   c. Percentage of surgical cases in which a verbal, active Time-Out has been conducted by all appropriate members of the surgical team prior to incision.

   d. Percentage of surgical cases where the baseline count was conducted prior to the patient arriving in the operating/procedure room.

   e. Percentage of surgical cases where counts were not reconciled and imaging was performed.

   f. Percentage of surgical patients with prophylactic antibiotic received within one hour prior to surgical incision. (SCIP-Inf-1*)

   g. Percentage of surgical patients receiving prophylactic antibiotic selection consistent with protocols for specific surgical type. (SCIP-Inf-2*)

   h. Percentage of surgical patients whose prophylactic antibiotic is discontinued within 24 hours after surgery end time (Applies to hip and knee arthroplasty, colon surgery, hysterectomy and vascular surgery); within 48 hours after surgery end time (Applies to CABG and other cardiac surgery). (SCIP-Inf-3*)

   i. Percentage of cardiac surgery patients with controlled 6 a.m. blood glucose (greater than or equal to 200 mg/dL) on postoperative day one (POD1) and postoperative day two (POD2) with anesthesia end date being postoperative day zero (POD0). (SCIP-Inf-4*)

   j. Percentage of selected surgical patients with appropriate surgical site hair removal. No hair removal, hair removal with clippers or depilatory is considered appropriate. Shaving is considered inappropriate. (SCIP-Inf-6*)

   k. Percentage of patients with urinary catheter removed on postoperative day one (POD1) or postoperative day two (POD2) with day of surgery being day zero. (SCIP-Inf-9*)

   l. Percentage of surgery patients for whom either active warming was used intraoperatively for the purpose of maintaining normothermia or who had at least one body temperature equal to or greater than 96.8ºF/36ºC recorded within the 30 minutes immediately prior to or the 15 minutes immediately after anesthesia end time. (SCIP-Inf-10*)

   m. Percentage of surgical patients on beta-blocker therapy prior to arrival who received a beta-blocker during the perioperative period. (SCIP-Card-2*)

   n. Percentage of surgery patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission. (SCIP-VTE-1*)

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o. Percentage of surgery patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the intensive care unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer). (SCIP-VTE-2*)

p. Percentage of surgical patients who have had all required components of the perioperative protocol applied.

* For current and comprehensive information on SCIP measures, refer to the Specifications Manual for National Hospital Inpatient Quality Measures at http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx

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# Measurement Specifications

## Measurements #1a

Percentage of patients undergoing elective non-high-risk surgery with a preoperative basic health assessment completed prior to the day of the scheduled procedure.

## Population Definition

All patients age two years and older undergoing elective non-high-risk surgical procedures.

## Data of Interest

$$\frac{\text{\# of patients with documentation of preoperative basic health assessment prior to the day of the scheduled procedure}}{\text{\# of patients age two years and older undergoing elective non-high-risk surgical procedures}}$$

## Numerator and Denominator Definitions

Numerator: Number of patients with documentation of preoperative basic health assessment prior to the day of the scheduled procedure.

Denominator: Number of patients age two years and older undergoing elective non-high-risk surgery.

- Elective non-high-risk surgery including planned, scheduled and non-emergent surgical procedures that allow time for a scheduled preoperative health assessment.

Denominator exclusions:

- Patients younger than two years of age.
- High-risk procedures, such as cardiac or procedures, anticipated to be prolonged (usually longer than four hours) are not included.

## Method/Source of Data Collection

Query EMR for records for patients age two years and older who had a non-high-risk elective surgery within the measurement period. Determine whether patients had documentation of preoperative basic health assessment prior to the day of the scheduled procedure.

## Time Frame Pertaining to Data Collection

For more frequent tracking of process improvement purposes, data should be collected monthly. Once the goals have been reached, data can be tracked on a less frequent basis, e.g., quarterly or semi-anually.

## Notes

This is a process measure, and improvement is noted as an increase in the percentage of patients medically optimized for surgery.

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## Measurements #1b

Percentage of patients undergoing elective non-high-risk surgery having laboratory tests/imaging unrelated to positive findings on preoperative basic health assessment.

## Population Definition

All patients age two years and older undergoing elective non-high-risk surgical procedures.

## Data of Interest

$$\frac{\text{\# of patients having laboratory tests/imaging unrelated to positive findings on preoperative basic health assessment}}{\text{\# of patients age two years and older undergoing elective non-high-risk surgery}}$$

## Numerator and Denominator Definitions

Numerator: Number of patients having laboratory tests/imaging unrelated to positive findings on a preoperative basic health assessment.

Denominator: Number of patients age two years and older undergoing elective non-high-risk surgery.

- Elective non-high-risk surgery including planned, scheduled and non-emergent surgical procedures that allow time for a scheduled preoperative health assessment.

Denominator exclusions:

- Patients younger than two years of age.
- High-risk procedures, such as cardiac or procedures, anticipated to be prolonged (usually longer than four hours) are not included.

## Method/Source of Data Collection

Query EMR records for patients age two years and older who had a non-high-risk elective surgery within the measurement period. Determine whether patients had documentation of having laboratory tests/imaging unrelated to positive findings on preoperative basic health assessment.

## Time Frame Pertaining to Data Collection

For more frequent tracking of process improvement purposes, data should be collected monthly. Once the goals have been reached, data can be tracked on a less frequent basis, e.g., quarterly or semi-anually.

## Notes

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

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## Measurements #1c

Percentage of patients undergoing cataract surgery who have electrocardiograms performed as part of the preoperative assessment prior to cataract surgery.

## Population Definition

All patients age two years and older undergoing cataract surgical procedures.

## Data of Interest

$$\frac{\text{\# of patients having who have electrocardiograms performed as part of the preoperative assessment}}{\text{\# of patients age two years and older undergoing cataract surgery}}$$

## Numerator and Denominator Definitions

Numerator: Number of patients having electrocardiograms performed as part of the preoperative assessment for his/her cataract surgery.

Denominator: Number of patients age two years and older undergoing cataract surgery.

Denominator exclusions:

- Patients younger than two years of age.
- Non-cataract surgical procedures.

## Method/Source of Data Collection

Query EMR records for patients age two years and older who had cataract surgery within the measurement period. Determine whether patients had documentation of having an electrocardiogram performed as part of the preoperative assessment.

## Time Frame Pertaining to Data Collection

For more frequent tracking of process improvement purposes, data should be collected monthly. Once the goals have been reached, data can be tracked on a less frequent basis, e.g., quarterly or semi-anually.

## Notes

This is a process measure, and zero rate is the goal.

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## Measurement #2a

Percentage of patients with comorbidities undergoing elective non-high-risk surgery who have appropriate management of comorbidities prior to surgery, including:

- Antithrombotic therapy
- Recent coronary stent/antiplatelet therapy
- Beta-blocker therapy
- Diabetic mellitus
- Sleep apnea
- Nicotine cessation

## Population Definition

All patients age two years and older undergoing elective non-high-risk surgical procedures.

## Data of Interest

$$\frac{\text{\# of patients having appropriate management of comorbidities prior to surgery}}{\text{\# of patients age two years and older with comorbidities undergoing elective non-high-risk surgery}}$$

## Numerator and Denominator Definitions

Numerator: Number of patients having appropriate management of comorbidities prior to surgery, including:

- Antithrombotic therapy
- Recent coronary stent/antiplatelet therapy
- Beta-blocker therapy
- Diabetic mellitus
- Sleep apnea
- Nicotine cessation

Denominator: Number of patients age two years and older with comorbidities undergoing elective non-high-risk surgery.

- Elective non-high-risk surgery including planned, scheduled and non-emergent surgical procedures that allow time for a scheduled preoperative health assessment.

Denominator exclusions:

- Patients younger than two years of age.
- High-risk procedures, such as cardiac or procedures, anticipated to be prolonged (usually longer than four hours) are not included.

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## Method/Source of Data Collection

Query EMR for records for patients age two years and older with comorbidities who have had a non-high-risk elective surgery within the measurement period. Determine whether patients had documentation of having appropriate management of comorbidities prior to surgery, including:

- Antithrombotic therapy
- Recent coronary stent/antiplatelet therapy
- Beta-blocker therapy
- Diabetic mellitus
- Sleep apnea
- Nicotine cessation

## Time Frame Pertaining to Data Collection

For more frequent tracking of process improvement purposes, data should be collected monthly. Once the goals have been reached, data can be tracked on a less frequent basis, e.g., quarterly or semi-anually.

## Notes

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

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## Measurement #2b

Percentage of patients with comorbidities undergoing elective non-high-risk surgery who have preoperative recommendations documented/communicated to the patient and/or surgical facility for all of the following applicable comorbidities:

- Antithrombotic therapy
- Recent coronary stent/antiplatelet therapy
- Beta-blocker therapy
- Diabetic mellitus
- Sleep apnea
- Nicotine cessation

## Population Definition

All patients age two years and older undergoing elective non-high-risk surgical procedures.

## Data of Interest

$$\frac{\text{\# of patients having preoperative recommendations documented/communicated to the patient and/or surgical facility for all applicable comorbidities}}{\text{\# of patients age two years and older with comorbidities undergoing elective non-high-risk surgery}}$$

## Numerator and Denominator Definitions

Numerator: Number of patients having preoperative recommendations documented/communicated to the patient and/or surgical facility for all of the following applicable comorbodities:

- Antithrombotic therapy
- Recent coronary stent/antiplatelet therapy
- Beta-blocker therapy
- Diabetic mellitus
- Sleep apnea
- Nicotine cessation

Denominator: Number of patients age two years and older with comorbidities undergoing elective non-high-risk surgery.

- Elective non-high-risk surgery including planned, scheduled and non-emergent surgical procedures that allow time for a scheduled preoperative health assessment.

Denominator exclusions:

- Patients younger than two years of age.
- High-risk procedures, such as cardiac or procedures, anticipated to be prolonged (usually greater than four hours), are not included.

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## Method/Source of Data Collection

Query EMR for records for patients age two years and older with comorbidities who have had a non-high-risk elective surgery within the measurement period. Determine whether patients had documentation of having appropriate management of comorbidities prior to surgery, including:

- Antithrombotic therapy
- Recent coronary stent/antiplatelet therapy
- Beta-blocker therapy
- Diabetic mellitus
- Sleep apnea
- Nicotine cessation

## Time Frame Pertaining to Data Collection

For more frequent tracking of process improvement purposes, data should be collected monthly. Once the goals have been reached, data can be tracked on a less frequent basis, e.g., quarterly or semi-anually.

## Notes

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

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## Measurement #2c

Percentage of patients with comorbidities who have preoperative education documented for all of the following comorbidities:

- Antithrombotic therapy
- Recent coronary stent/antiplatelet therapy
- Beta-blocker therapy
- Diabetic mellitus
- Sleep apnea
- Nicotine cessation

## Population Definition

All patients age two years and older undergoing elective non-high-risk surgical procedures.

## Data of Interest

$$\frac{\text{\# of patients who have preoperative education documented for all of the applicable comorbidities}}{\text{\# of patients age two years and older with comorbidities undergoing elective non-high-risk surgery}}$$

## Numerator and Denominator Definitions

Numerator: Number of patients who have preoperative education documented for all of the following comorbidities, including:

- Antithrombotic therapy
- Recent coronary stent/antiplatelet therapy
- Beta-blocker therapy
- Diabetic mellitus
- Sleep apnea
- Nicotine cessation

Denominator: Number of patients age two years and older with comorbidities undergoing elective non-high-risk surgery.

- Elective non-high-risk surgery including planned, scheduled and non-emergent surgical procedures that allow time for a scheduled preoperative health assessment.

Denominator exclusions:

- Patients younger than two years of age.
- High-risk procedures, such as cardiac or procedures, anticipated to be prolonged (usually longer than four hours) are not included.

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## Method/Source of Data Collection

Query EMR for records for patients age two years and older with comorbidities who have a non-high-risk elective surgery within the measurement period. Determine whether patients who have preoperative education documented for all of the following comorbidities, including:

- Antithrombotic therapy
- Recent coronary stent/antiplatelet therapy
- Beta-blocker therapy
- Diabetic mellitus
- Sleep apnea
- Nicotine cessation

## Time Frame Pertaining to Data Collection

For more frequent tracking of process improvement purposes, data should be collected monthly. Once the goals have been reached, data can be tracked on a less frequent basis, e.g., quarterly or semi-anually.

## Notes

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

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## Measurement #3a

Percentage of patients who have canceled or delayed non-high-risk surgical procedures due to incomplete preoperative basic health assessment documentation.

## Population Definition

All patients age two years and older undergoing elective non-high-risk surgical procedures.

## Data of Interest

$$\frac{\text{\# of surgeries canceled or delayed due to incomplete documentation of preoperative basic health assessment}}{\text{\# of elective non-high-risk surgeries for patients age two years and older}}$$

## Numerator and Denominator Definitions

Numerator: Number of surgeries canceled or delayed due to incomplete documentation of preoperative basic health assessment.

Denominator: Number of elective non-high-risk surgeries for patients age two years and older.

- Elective non-high-risk surgery including planned, scheduled and non-emergent surgical procedures that allow time for a scheduled preoperative health assessment.

Denominator exclusions:

- Patients younger than two years of age.
- High-risk procedures, such as cardiac or procedures, anticipated to be prolonged (usually greater than four hours), are not included.

## Method/Source of Data Collection

Query EMR for records for patients age two years and older who have had a non-high-risk elective surgery within the measurement period. Determine whether patients had documentation of having surgeries canceled or delayed due to incomplete documentation of preoperative basic health assessment.

## Time Frame Pertaining to Data Collection

For more frequent tracking of process improvement purposes, data should be collected monthly. Once the goals have been reached, data can be tracked on a less frequent basis, e.g., quarterly or semi-anually.

## Notes

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

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## Measurement #3b

Percentage of patients who have canceled or delayed surgical procedures due to ineffective communication regarding patient information as defined by organizational procedures.

## Population Definition

All patients age two years and older undergoing elective non-high-risk surgical procedures.

## Data of Interest

$$\frac{\text{\# of surgeries canceled or delayed due to ineffective communication regarding patient information as defined by organizational procedures}}{\text{\# of elective non-high-risk surgeries for patients age two years and older}}$$

## Numerator and Denominator Definitions

Numerator: Number of surgeries canceled or delayed due to ineffective communication regarding patient information as defined by organizational procedures.

Denominator: Number of elective non-high-risk surgeries for patients age two years and older.

- Elective non-high-risk surgery including planned, scheduled and non-emergent surgical procedures that allow time for a scheduled preoperative health assessment.

Denominator exclusions:

- Patients younger than two years of age.
- High-risk procedures, such as cardiac or procedures, anticipated to be prolonged (usually greater than four hours), are not included.

## Method/Source of Data Collection

Query EMR for records for patients age two years and older who have had a non-high-risk elective surgery within the measurement period. Determine whether patients had documentation of having surgeries canceled or delayed due to ineffective communication regarding patient information as defined by organizational procedures.

## Time Frame Pertaining to Data Collection

For more frequent tracking of process improvement purposes, data should be collected monthly. Once the goals have been reached, data can be tracked on a less frequent basis, e.g., quarterly or semi-anually.

## Notes

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

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## Measurements #4a and 4b

1a. Number of wrong surgery events per month

or

1b. Rate of wrong surgery events per N surgical procedures.

## Population Definition

Patient of all ages who have a surgical procedure performed.

## Data of Interest

1a. # of wrong surgery events per month, see definition below

1b. Rate of wrong surgery events per N surgical procedures

$$\frac{\text{\# of wrong surgery events}}{\text{Total \# of surgical cases per month}} \times N$$

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 and less than 1,000, use rate of per 1,000

If denominator is greater than 1,000 and less than 10,000, use a rate of per 100,000

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

## Numerator and Denominator Definitions

Numerator: Wrong surgery event is defined as a wrong surgical procedure, a surgical procedure performed on the wrong patient, or a surgical procedure performed on the wrong side, site or level.

Denominator: Surgery is defined as an invasive procedure that takes place in an operating/procedure room by surgeon.

## Method/Source of Data Collection

Event data should be reported through an incident or sentinel event report or follow the hospital's policy for reporting.

Total surgical cases can be collected through the surgical schedule, log or hospital billing.

## Data Collection Time Frame

The suggested time period is a calendar month, but three months could be consolidated into quarterly data points, as well, if case load and/or event numbers are small.

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## Measurements #5a and 5b

5a. Number of unintentionally retained foreign objects in surgery.

or

5b. Rate of unintentionally retained foreign objects in surgery.

## Population Definition

Patient of all ages who have a surgical procedure performed.

## Data of Interest

5a. # of unintentionally retained foreign objects (reported as a raw number)

5b. Rate of unintentionally retained foreign objects

$$\frac{\text{\# of unintentionally retained foreign objects}}{\text{Total \# of surgical cases per month}}$$

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 and less than 1,000, use rate of per 1,000

If denominator is greater than 1,000 and less than 10,000, use a rate of per 100,000

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

## Numerator and Denominator Definitions

Numerator: Unintentionally retained foreign object is any object unintentionally retained after a surgical procedure.

Denominator: Surgery is defined as an invasive procedure that takes place in an operating/procedure room by a surgeon.

## Method/Source of Data Collection

Event data should be reported through an incident report or sentinel event report.

Total surgical cases can be collected through the surgical schedule, log or hospital billing.

## Data Collection Time Frame

The suggested time period is a calendar month, but three months could be consolidated into quarterly data points, as well, if case load and/or event numbers are small.

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## Measurement #6a

Rates of postoperative wound infections by wound classifications:

1. Class I: clean
2. Class II: clean contaminated
3. Class III: contaminated

## Numerator and Denominator Definitions

Numerator: Number of postoperative wound infections by wound classifications:

1. Class I: clean
2. Class II: clean contaminated
3. Class III: contaminated

Denominator: Number of surgery patients

- If reporting as a rate, take the numerator divided by the denominator and multiple by 1,000

Denominator exclusions:

- Patients who had a principal or admission diagnosis suggestive of preoperative infectious diseases
- Patients with documentation by physician of infection prior to surgical procedure

## Method/Source of Data Collection

Sample size: It is suggested to begin by looking for total surgical site infections. If less than or equal to 25 cases occur per month, analyze the total number. If greater than 25, choose to review all or take a random sample of 25.

## Time Frame Pertaining to Data Collection

Monthly.

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## Measurements #7a-e

a. Percentage of surgical patients with documentation of preoperative verification of correct patient, procedure and site/side/level.

b. Percentage of appropriate surgical patients who had their site marked by the surgeon in preoperative with his/her initials.

c. Percentage of surgical cases in which a verbal, active Time-Out has been conducted by all appropriate members of the surgical team prior to incision.

d. Percentage of surgical cases where the baseline count was conducted prior to the patient arriving in the operating/procedure room.

e. Percentage of surgical cases where counts were not reconciled and imaging was performed.

## Population Definition

Patients of all ages who have a surgical procedure performed.

## Data of Interest

7a. # of charts/flowsheets/electronic medical record with documentation of verification of correct patient, correct site/side and correct procedure

---

Total # of surgical patients reviewed

7b. # of surgical patients with sites marked with surgeon's initials

---

Total # of patients appropriate for site marking

7c. # of surgical cases observed to have active, verbal participation in the Time-Out prior to incision/ insertion by all appropriate surgical team members

---

Total # of surgical cases observed

7d. # of patients having a baseline count conducted and documented on the whiteboard prior to the patient arriving in the operating/procedure room

---

Total # of surgical cases

7e. # of surgical cases where counts were not reconciled and imaging was performed

---

Total # of surgical cases

## Method/Source of Data Collection

Retrospective collection of any measures associated with documentation can be done by randomly sampling charts of patient cases.

Concurrently, collection will need to be done through direct observation either by a quality/safety advocate or "secret shopper," someone who has a dual function on the team but whose observation and measurement function is not known.

## Data Collection Time Frame

Suggested sample size and time frame for any of these measures would be minimum of 10 per month. A larger hospital with a large caseload for surgery and adequate resources could have a larger sample size.

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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
- Develop a reliable, standardized system to obtain complete preoperative basic health assessments and appropriate preoperative testing to eliminate unwarranted variation. (See Appendix B, "Preoperative Questionnaire – Adult" and Appendix C, "Preoperative Questionnaire – Pediatric.")
- Establish a reliable mechanism to communicate completed preoperative basic health assessments, associated test results, and instructions to procedure location and patient prior to procedure. (See Appendix A, "Patient Preoperative Guide.")
- Develop a comprehensive patient-centered approach to education and appropriate procedure preparation.

**System implementation:**

- The facility is encouraged to customize the protocol with a key that identifies the individuals responsible for completing the algorithm tasks (e.g., green shapes for those individuals responsible for counts).
- Leadership support and a surgeon champion are absolutely essential for the successful implementation of this protocol.
- Develop a procedural checklist to document completion of each step, and ensure that all elements of the protocol are completed.
- Direct observations, along with coaching and immediate feedback, are effective strategies in gaining staff adherence to the protocol following implementation. Additionally, the use of crucial conversation tactics can be effective for staff.
- As it relates to this protocol, create and implement a process that allows for the detection and management of disruptive and inappropriate behavior. This process should include education of all physicians and non-physicians regarding appropriate professional behavior and the development of policies and procedures. Refer to The Joint Commission's leadership standards.
- 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 to prevent/address the specific actions that pose the highest level of consequence and risk to safety of 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 the safest environment and delivery of the care process.
    - Suggested red rules:
        - Never operate on a patient without verifying the correct patient identity, correct procedure and correct site.

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- Baseline counts are consistently performed before the patient arrives in the operating/procedure room unless parallel processing is used.
- Unreconciled counts require imaging verification, and wound closure stops until count reconciliation is achieved.

**Retained foreign object implementation:**

- The work group recommends that a preformatted whiteboard be used as the primary record of the count. Documenting counts on a whiteboard allows all surgical staff, and in particular the scrub technician, to independently view the count record. A public display of the count record in an area where the entire surgical team can view it is likely to reinforce the importance of the count process.
- The work group also recommends that a count worksheet be used as a memory aid when the whiteboard is not easily accessible in a timely manner. The count worksheet should be used only as a memory aid for the baseline count and, if needed, for subsequent counts. A piece of scratch paper should not be used. In contrast, if the whiteboard is located very close to the area when the count occurs, and if the circulating nurse can easily write the counts on the whiteboard without leaving the count area, there will be no need to use the count worksheet.
- Distractions and interruptions should be kept to a minimum during the count process. If a count is interrupted, then the category of items (e.g., laps) being counted will need to be recounted.

**Surgical infection implementation:**

- Use of order sets limits divergent practices and improves compliance with best practice protocols.
- Review patient education material to verify the message around no self-shaving before surgery. Distribute standardized patient education messages to surrounding outpatient clincs, as well.
- Remove all razors from the perioperative area.
- Use warming blankets, hats and booties routinely for patients to prevent hypothermia.
- Establish an effective surveillance process that includes post-discharge or outpatient surveillance. Use inpatient case-finding for post-discharge or outpatient. It is important to include the following:
  - Use standardized definitions for surveillance of infections. These definitions also need to take into account the setting in which the surgical procedure was performed (acute care, ambulatory surgical center, etc.).
  - Establish a risk stratification for estimating surgical infection that adjusts for risk factors associated with infection for different care settings and procedures.
  - Work with surrounding outpatient clinics to develop communication strategy for tracking surgical infections and reporting back to the hospital.

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# Implementation Tools and Resources

### Criteria for Selecting Resources

The following tools and resources specific to the topic of the protocol were selected by the work group. Each item was reviewed thoroughly by at least one work group member. It is expected that users of these tools will establish the proper copyright prior to their use. The types of criteria the work group used are:

- The content supports the clinical and the implementation recommendations.
- Where possible, the content is supported by evidence-based research.
- The author, source and revision dates for the content are included where possible.
- The content is clear about potential biases and when appropriate conflicts of interests and/or disclaimers are noted where appropriate.

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# Implementation Tools and Resources Table

| Author/Organization | Title/Description | Audience | Web Sites/Order Information |
|---|---|---|---|
| American Academy of Pediatrics | Comprehensive Web site – includes clinical practice guidelines health topics and patient and family surgical resources. | Health Care Professionals; Patients and Families | http://www.aap.org |
| American College of Physicians | Contains guidelines and clinical information. | Health Care Clinicians | http://www.acponline.org |
| American College of Surgeons | The American College of Surgeons is a scientific and educational association of surgeons that work to improve the quality of care for the surgical patient. The Web site provides information for patients, the public, and surgeons. | Health Care Professionals; Patients and Families | http://www.facs.org |
| American Heart Association | Comprehensive Web site – includes clinical information, guidelines, health topics and patient educations resources. | Health Care Professionals; Patients and Families | http://www.heart.org |
| American Hospital Association | Tips for Safer Surgery – A tip sheet for patients and their families with questions to ask before surgery. | Patients and Families | http://www.aha.org |
| American Society of Anesthesiologists | Comprehensive Web site – includes clinical information, patient education brochures (some in Spanish) and patient safety resources. | Health Care Professionals; Patients and Families | http://www.asahq.org |
| American Society of Anesthesiology | The American Society of Anesthesiology is an educational, research and scientific association of physicians organized to raise and maintain the standards of the medical practice of anesthesiology and improve the care of the patient. | Health Care Professionals | http://www.asahq.org |
| American Society of PeriAnesthesia Nurses (ASPAN) | The American Society of PeriAnesthesia Nurses is the professional specialty nursing organization representing the interests of nurses practicing in all phases of preanesthesia and postanesthesia care, ambulatory surgery, and pain management. | Health Care Professionals | http://www.aspan.org |
| Association of Peri-Operative Registered Nurses (AORN) | The Association of periOperative Registered Nurses (AORN) is a professional association that "empowers the operating/procedure room nurse with education, standards of practice, and peer networking." | Health Care Professionals | http://www.aorn.org |

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| Author/Organization | Title/Description | Audience | Web Sites/Order Information |
|---|---|---|---|
| Department of Veterans Affairs Veterans Health Administration, Washington, DC 20420 | VA National Center for Patient Safety (NCPS)<br>The Web site provides information for health care professionals and health care administrators. However, veterans and the general public are encouraged to explore the site. The Patient Safety section provides information, tips and tools, and resources for patients and families. | Health Care Professionals; Patients and Families | http://www.patientsafety.gov |
| Institute for Healthcare Improvement | Independent not-for-profit organization helping to lead the improvement of health care throughout the world. Web site provides various tools supporting patient safety. | Health Care Professionals | http://www.ihi.org |
| The Joint Commission | Joint Commission Web site for regulatory standards and patient safety goals. | Health Care Professionals | http://www.jointcommission.org |
| Minnesota Department of Health | Minnesota Department of Health<br>The site provides patient safety information that includes adverse event reporting and information for consumers and patients. | Health Care Professionals; Patients and Families | http://www.health.state.mn.us/patientsafety/index.html |
| Minnesota Hospital Association | The Minnesota Hospital Association Safe Site Call to Action<br>Web site includes tools that address procedures outside the operating room. | Health Care Professionals | http://www.mnhospitals.org |
| National Initiative for Children's Healthcare Quality Pediatric Affinity Group | Reducing Surgical Complications/ Surgical Site Infections: Pediatric Supplement<br>A how-to guide for surgical site infection in the pediatric population. | Health Care Professionals | http://www.nichq.org/areas_of_focus/patient_safety_infections.html |

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The subdivisions of this section are:

- References
- Appendices

 

# References

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

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# Appendix A – Patient Preoperative Guide

This guide is designed to assist as you prepare for your surgical procedure.

Your surgery _____ is scheduled for _____ at _____
Date/Time Location

| | |
|---|---|
| **Information you should have after your visit to the surgeon:** | |
| | Reasons for surgery, including alternative treatments, risks of planned surgery, expected outcome, and the expected duration of the surgical procedure. |
| | If you are having an outpatient procedure or if hospitalization is required, you should know how long you will be at the surgical facility and how it will be decided when you will go home. |
| | Need for anesthesia, techniques considering the planned operative procedure, how anesthesia will be performed, who will be performing it and when you will meet the individual performing the anesthesia. |
| | Whether a preoperative evaluation will be required and whether your surgeon or primary care physician will complete it. (If a preoperative clinic is used, you should know where it is and whom to contact at the clinic.) |
| | If your surgeon requests a preoperative evaluation, you should schedule an appointment no earlier than 30 days before your procedure and no later than 72 hours before your procedure. |
| | When you will feel better after the procedure and when you will be able to resume regular activities such as return to work. |
| | Where your family can wait, and when and where the surgeon will communicate with your family and friends after your surgery. |
| | Who will you contact if you should develop symptoms that increase your risk of infection prior to surgery, a respiratory infection, fever, etc. |
| | Answers to any other concerns you have regarding the surgery. |
| | Check with your insurance plan or the business office of the surgical facility regarding insurance coverage and personal cost. |
| **Preoperative evaluation:** | |
| | Bring bottles of your prescription (including all inhalers and eye drops) and non-prescription medications, vitamins and herbal supplements that you are currently taking. |
| | You will receive specific instructions regarding what you are to do in the 24 hours preceding your surgery. |
| **No later than one week before your surgical procedure, complete the following list:** | |
| | Read facility specific information on what to expect before, during and after surgery. If you have not received a copy of the information from the surgical facility, please contact your surgeon's office or the surgical facility directly. |

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| | |
|---|---|
| **Last 24 hours before surgery:** | |
| | Take prescription and non-prescription medications according to physician's instructions. |
| | Arrange for a responsible person to drive you home and care for you after your surgery. |
| **Night before surgery:** | |
| | Eat a regular meal unless otherwise directed by your surgeon. |
| | Pack the items you will bring to the surgical facility. |
| | Do not bring jewelry, money, credit cards and other valuables. |
| | Pack storage containers for dentures, removable bridges, contacts and glasses. |
| | Bring your insurance cards. |
| | Shower with a special soap, if asked. |
| | Do not shave or remove any hair at or near the surgical site. |
| | If you have a continuous positive airway pressure (CPAP) device that you use when you sleep, bring that device with you the morning of surgery. |
| **After midnight:** | |
| | Follow specific instructions for what you may eat and drink. |
| | Take any medications as directed by your physician. |
| **Especially for children:** | |
| | Call your surgeon's office if your child has an upper respiratory infection or fever 24 hours before the procedure. |
| | Talk to your child about what is expected. |
| | Follow any special feeding instructions. |
| | Bring the child's favorite toy or blanket. |
| | You may want to arrange for a tour of the facility where available. |

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# Appendix B – Preoperative Questionnaire – Adult

Patient Name _____
Age _____

| Yes | No | |
|---|---|---|
| ❑ | ❑ | Do you ever have any **pain or discomfort in your chest**? |
| ❑ | ❑ | Have you ever had a **severe pain or pressure** across the front of your **chest** lasting for **half an hour or more**? |
| ❑ | ❑ | Do you have **swelling** in your feet or ankles at times? |
| ❑ | ❑ | Are you **troubled by shortness of breath** when:<br>Walking on the level?<br>Walking up a slight hill?<br>Sleeping at night? |
| ❑ | ❑ | Do you sometimes get **pains in the calves of your legs** when you walk? |
| ❑ | ❑ | Does your chest ever sound **wheezy or whistling**? |
| ❑ | ❑ | Have you been told that you **snore, choke or gasp** most nights while sleeping? |
| ❑ | ❑ | Do you currently have a **cold, bronchitis or other respiratory infection**? |
| ❑ | ❑ | Have you had a cold, bronchitis or other **respiratory infection within the last two weeks**? |
| ❑ | ❑ | Do you usually have a **cough**? |
| ❑ | ❑ | Do you or does anyone in your family have **serious bleeding problems** such as prolonged bleeding following surgeries or cuts? |
| ❑ | ❑ | Have you taken any **aspirin, other blood thinners or arthritis medicine** in the last two weeks? |
| ❑ | ❑ | Have you ever had problems with anemia or been told to take **iron pills**? |
| ❑ | ❑ | Have you had any **abnormal blood loss** such as black, tarry or bloody stools, or (for women) abnormal vaginal bleeding? |
| ❑ | ❑ | Have you or any of your relatives ever had **problems with anesthesia**? |
| | | **(For women)** |
| ❑ | ❑ | Is there any chance that you may be pregnant? |
| | | Last period when?_____ |

**-- Please complete and bring with you to your preoperative visit --**

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# Appendix C – Preoperative Questionnaire – Pediatric

Patient Name_____

Age _____

| Yes | No | |
|---|---|---|
| ❑ | ❑ | Has your child had **good growth, development and good exercise tolerance**? |
| ❑ | ❑ | Was your child ever intubated (used a **tube** to help him/her breathe)? How long did your child use it? |
| ❑ | ❑ | Has your child ever been **short of breath** while exercising or been **blue around the lips**? |
| ❑ | ❑ | Does your child's chest ever sound **wheezy or whistling**? |
| ❑ | ❑ | Does your child **snore**? |
| ❑ | ❑ | Has your child had a **cold or other respiratory infection within the last four weeks**? |
| ❑ | ❑ | Does your child have or does anyone in the family have **nerve or muscle problems**? |
| ❑ | ❑ | Does your child have or does anyone in the family have **serious bleeding or bruising problems?** |
| ❑ | ❑ | Has your child been given **ibuprofen aspirin** or similar medications in the past **two weeks**? |
| ❑ | ❑ | Has your child ever had problems with **anemia** or been told to take iron pills? |
| ❑ | ❑ | Has your child or other family member ever had **problems with anesthesia**? |
| | | For female children: |
| | | Has your child started her periods? Yes ❑ No ❑<br>If yes, complete the following:<br>Last period when? _____ |
| ❑ | ❑ | Is there a chance of pregnancy? |

**- - Please complete and bring with you to your child's preoperative visit --**

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# Appendix D – Drugs to Stop/Drugs to Continue

**Drugs to Stop**

| Drug Type | Drug/Drug Class | Considerations |
|---|---|---|
| Cardiovascular | ACEI/ARB | Hold morning of surgery/suspend for 1 dosage interval before surgery<br>If drug already taken, watch blood pressure closely at induction |
| NSAID | Non-COX selective | Short-acting (ibuprofen, indomethacin, etc.) – stop one day before surgery<br>Long-acting (naproxen, sulindac, etc.) – stop three days before surgery |
| | Cox-2 inhibitors | Stop at least two days before surgery due to renal effects |
| Anticoagulant/ Antiplatelet | VKA (warfarin) | Stop at least five days before surgery (see factors for consideration for possible exceptions/need for bridging) |
| | Dabigatran | Stop two days before surgery (CrCl >/= 50 mL/min.)<br>Stop five days before surgery (CrCl < 50 mL/min.) |
| | Aspirin | Stop at least five days before surgery |
| | Plavix | Stop at least five days before surgery – may need to hold elective procedures off for at least six months after stent |
| | Ticlopidine | Stop at least five days before surgery |
| | Aggrenox | Stop at least seven days before surgery |
| | Cilostazol | Stop three days before surgery |
| Endocrine | Hormone therapy (estrogen) | Stop four weeks before surgery if able<br>If unable to stop, ensure adequate venous thromboembolism prophylaxis perioperatively<br>Weigh risk of symptoms/unwanted pregnancy vs. risk for developing clot |
| Osteoporosis | Raloxifene | Stop at least one week before high-risk venous thromboembolism procedures |
| | Alendronate | Stop perioperatively due to difficult administration during hospitalization |
| Herbals | All types | Stop at least one week before surgery<br>Many prolong bleeding time/increase blood pressure<br>Inadvertent omega-3 administration day of surgery is not a contraindication to surgery |
| Diabetes | Oral agents | Hold morning of surgery/while nothing by mouth |
| | Metformin | Hold at least 24 hours before surgery to prevent lactic acidosis |

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**Drugs to Continue**

| Drug Type | Drug/Drug Class | Considerations |
|---|---|---|
| Cardiovascular | Beta-blockers | Continue if patient has been taking<br>Consider initiating if patient has high CV risk (ACC/AHA guideline) |
| | Clonidine | Continue – utilize patch formulation if anticipate extended NPO status |
| | Calcium channel blockers | Continue (consider holding if left ventricular dysfunction) |
| | Statins | Continue if patient taking chronically<br>Consider initiating if patient has high CV risk (ACC/AHA guideline) |
| | Anti-arrythmics | Continue perioperatively |
| Neuro/Psych | All types | Continue – see factors for consideration |
| HIV | All types | Continue – if necessary to discontinue, re-initiate all medications at the same time |
| Endocrine | Thyroid replacement | Continue |
| | Corticosteroid therapy | Continue – add stress dosing if > 5 mg prednisone per day (or equivalent) in six months prior to surgery, or on chronic therapy |
| Rheumatology | All types | Continue – anecdotal evidence of increased wound infections/delayed healing |
| Osteoporosis | Tamoxifen | May increase risk of deep vein thrombosis – discuss with oncologist before decided to stop medication preoperatively |
| Diabetes | Insulin | Decrease basal/long acting insulin by up to 50%<br>Cover with sliding-scale, short-acting insulin |

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# Appendix E – Antibiotic Selection Table

| Procedure Type/Surgical Site | Common Pathogens | Antibiotic Choice[1] | Alternative to First Choice When IgE Allergy Present |
|---|---|---|---|
| Cardiovascular | S.epidermidis<br>S.aureus | cefazolin or cefuroxime (intranasal mupirocin the night before, day of surgery and BID x 5 days if nares positive for MRSA) | vancomycin or clindamycin |
| Gastroduodenal<br>High risk only[2] | Enteric gram-negative bacilli, gram positive cocci | cefazolin or cefotetan or cefoxitin or ceftizoxime or cefuroxime | clindamycin + (ciprofloxacin, levofloxacin, gentamicin or aztreonam) |
| Biliary tract<br>High risk only[3] | Enteric gram-negative bacilli, enterococci, clostridia | cefazolin or ceftizoxime | clindamycin + (ciprofloxacin, levofloxacin, gentamicin or aztreonam) |
| Endoscopic retrograde chlangiopancreatography (ERCP) (no antibiotic needed without obstruction) | Enteric gram-negative bacilli, enterococci, clostridia | If obstruction or possible incomplete drainage:<br>ciprofloxacin or ceftizoxime or piperacillin/tazobactam | clindamycin + (ciprofloxacin, levofloxacin, gentamicin or aztreonam) |
| Colorectal, includes appendectomy[4] | Enteric gram-negative bacilli, anaerobes, enterococci | cefazolin + metronidazole cefoxitin or cefotetan or ampicillin-sulbactam or ertapenem[5] | clindamycin + (ciprofloxacin, levofloxacin, gentamicin or aztreonam) or metronidazole + aztreonam + (ciprofloxacin, levofloxacin or gentamicin) |
| Head and neck (Antibiotics appear efficacious only for procedures involving oral/pharyngeal mucosa. Uncontaminated head and neck surgery does not require prophylaxis.) | Anaerobes, enteric gram-negative bacilli, S.aureus | clindamycin or cefazolin + metronidazole | gentamicin + clindamycin |
| Neurosurgical | S.aureus,<br>S.epidermidis | cefazolin | vancomycin or clindamycin |
| Orthopedic[6] | S.aureus,<br>S.epidermidis | cefazolin or cefuroxime or ceftriaxone | clindamycin or vancomycin |
| Urologic (anibiotics needed only if preoperative bacteriuria [positive culture or unavailable] or preop catheter) | Enteric gram-negative bacilli, enterococci | Preoperative bacteriuria:<br>cefazolin every 8 hours for 1 to 3 doses perioperatively followed by oral antibiotic (nitrofurantoin or TMP-SMX until catheter removed or for 10 days)<br>Trans-rectal prostate biopsy:<br>ciprofloxacin 500 mg by mouth 2 hours before biopsy and repeated 12 hours after | |
| Obstetric/gynecologic | Enteric gram-negative bacilli, anaerobes, Gp B strep, enterococci | laproscopic, vaginal or abdominal hysterectomy:<br>cefazolin or cefoxitin or cefotetan or cefuroxime or ampicillin-sulbactam<br>Caesarean: cefazolin | Clindamycin + (ciprofloxacin, levofloxacin, gentamicin, or aztreonam) |
| Ophthalmic | S.epidermidis, S.aureus, streptococci, enteric gram-negative bacilli, Pseudomonas spp. | Multiple drops topically over 2-24 hrs:<br>gentamicin, tobramycin, ciprofloxacin, gatifloxacin, levofloxacin, moxifloxacin, ofloxacin, or neomomycin-gramicidin-polymyxin B, cefazolin, providone-iodine | |
| Thoracic (non-cardiac) | S.aureus, S.epidermidis, streptococci, enteric gram-negative bacilli | Cefazolin or cefuroxime | Vancomycin |
| Vascular | S.aureus, S.epidermidis, enteric gram-negative bacilli, clostridia | Cefazolin | Vancomycin |

*The information in this table was compiled from The Sanford Guide to Antimicrobial Therapy 2009, and Treatment Guidelines from the Medical Letter, Antimicrobial Prophylaxis for Surgery 2009 and is current as of August 31, 2010. For the most up-to-date medication and prescribing information, consult with your pharmacist or consider the following sources: www.micromedex.com, www.uptodate.com and The Sanford Guide to Antimicrobial Therapy.*

1. New guidelines are recommending only a **single dose** of antibiotics for procedures lasting **less than four hours**. In procedures lasting more than four hours or those with major blood loss, intra-operative re-dosing should occur every one to two half-lives of the antibiotic in patients with normal renal function *(Medical Letter Treatment Guidelines, 2009 [Reference]; Fonseca, 2006 [Reference])*.
2. High-risk patients for infection include esophageal obstruction, morbid obesity, reductions in gastric acidity or gastric motility (due to obstruction, hemorrhage, gastric ulcer, malignancy, or proton pump inhibitor therapy). Not indicated for routine gastroesophageal endoscopy.
3. High-risk patients include greater than 70 years, acute cholecystitis, a non-functioning gallbladder, obstructive jaundice, common bile duct stones with cholangitis, treat as infection, not prophylaxis.
4. In the era of availability of modern single- and double-agent prophylactic therapy at the time of surgery, an oral antibiotic for bowel preparation the day prior to surgery is at the discretion of the surgeon *(Nichols, 2005 [Reference]; Jimenez, 2003 [Reference]; Zmora, 2001 [Reference])*.
5. The 2009 Medical Letter guidelines advise against the routine administration of carbapenems for surgical prophylaxis because widespread use of these drugs may result in increased rates of resistance.
6. If a tourniquet is used in procedure, the entire dose of antibiotic must be infused prior to its inflation.
7. Single-dose antibiotic prophylaxis with amoxicillin/clavulonic acid reduced wound related infections and problems after groin incision varicose vein surgery, thus should be considered for this procedure *(Mekako, 2010)*.

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# Appendix F – Antibiotic Dosing Table

| Antibiotic (all IV formulations) | Adult Dosing | Pediatric Dosing |
|---|---|---|
| Ampicillin-sulbactam | 3 g | 50 mg/kg ampicillin component |
| Cefazolin | Wt < 120 kg: 2 g<br>Wt >/ = 120 kg: 3 g | 30 mg/kg |
| Cefoxitin | 2 g | 40 mg/kg |
| Ciprofloxacin | 400 mg | 10 mg/kg |
| Clindamycin | 900 mg | 10 mg/kg |
| Metronidazole | 500 mg | 15 mg/kg |
| Vancomycin | 15 mg/kg | 15 mg/kg |

*(Bratzler, 2013 [Low Quality Evidence])*

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# Appendix G – Overview of Topical Antiseptics Used for Preoperative Skin Preparation

The properties listed in the left-hand column are those that are desirable in a skin preparation product. No one product has all desirable traits and is also without potential risk. No studies have adequately assessed the comparative effects of these preoperative skin antiseptics on surgical site infection risk in well-controlled, operation-specific studies. However, the presence of an alcohol-based solution is preferred.

| Properties | Chlorhexadine (CHG) | Povodine-iodine (PVP-I) | Alcohol | CHG + Alcohol | PVP-I + Alcohol | PCMX |
|---|---|---|---|---|---|---|
| ***Examples of trade names*** | Hibiclens | Betadine | Alcohol | Chloraprep | Duraprep | Technicare* |
| **Killing gram pos. bacteria** | Excellent | Excellent | Excellent | Excellent | Excellent | Good |
| **Killing gram neg. bacteria** | Good | Good | Excellent | Excellent | Excellent | Fair (*Good against Pseudomonas*) |
| **Rapidity of action** | Intermediate | Intermediate | Most Rapid | Rapid | Rapid | Intermediate |
| **Persistence** | Excellent | Minimal but will maintain as long as present on skin | None | Excellent | Minimal but will maintain as long as present on skin | Good |
| **Maintains activity in presence of organic material** | Yes | No | No | Yes | No | Yes |
| **Minimal systemic absorption** | Yes | No | Yes | Yes | No | Yes |
| **Toxicity** | Ototoxicity<br>Corneal injury<br>Avoid contact with meninges<br>Keep away from eyes, ears and mouth | Absorption from skin with possible thyroid toxicity – especially in low-birth-weight infants | Drying to skin<br>Should not be used near eyes | Ototoxicity<br>Corneal injury<br>Avoid contact with meninges<br>Keep away from eyes, ears and mouth | Drying to the skin<br>Absorption from skin with possible thyroid toxicity – especially in very-low-birth-weight infants | Non-toxic in the Technicare formulation |
| **Comments** | Incidence of skin irritation minimal. When used for cleansing superficial wounds, will not cause additional tissue injury or delay healing. May be more effective and safer than iodophors | Significant transcutaneous absorption may occur after the topical application in infants and can cause alterations in thyroid function – especially in very-low-birth-weight infants. | Flammable – care must be taken to remove excess liquid and allow to completely dry prior to using cautery | See comments on CHG and alcohol | See comments on PVP-I and alcohol. Duraprep adds benefit of "shellac" type activity that adheres to the skin and *may* inhibit organisms from releasing into the wound. | Can be used for treatment of chronic wounds. Is not harmful to eyes or ears |

**References:**
**MicroMedex Online**
**CDC Guidelines for Prevention of Surgical Site Infection – 1999**
**CareTech Laboratories information on Technicare online:** http://www.caretechlabs.com/DesktopDefault.aspx?tabid=18
*** Reflects published data – however, formulation enhances the performance of PCMX. See Caretechlab.com.**
Prepared by Sue Gustafson, Infection Control Department, Fairview Health Services, 2/16/2005

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# Appendix H – Veterans Administration Methodical Wound Exploration Process

A methodical wound exploration will be performed prior to the closure of that cavity. Surgeons will use both touch and sight during the exploration whenever possible and should not rely on just one sensory perception.

A methodical wound exploration may be omitted or abbreviated in an extreme patient emergency or if the patient becomes critically unstable. This exception will be documented in the surgical record and if appropriate, a radiograph should be performed as soon as is reasonable, based on the patient's condition.

### Abdominal and Pelvic Process

Unless contraindicated for a specific patient, these steps should be performed prior to the removal of stationary or table-mounted retractors. The methodical wound exploration process includes the exploration of all four quadrants of the abdomen.

- Lift and examine around the transverse colon.
- Examine above and around the liver.
- Examine around the spleen.
- Examine within and between the loops of bowel.
- For the pelvis:
  - Examine behind the bladder.
  - Examine behind the uterus (if present).
  - Examine around the upper rectum.
- Examine the area inside of the vagina if it was entered as part of the procedure.
- Examine in and around anyplace a retractor or retractor blades were placed.

### Mediastinum or Thorax Process

Unless contraindicated for a specific patient, these steps should be performed for all procedures involving the mediastinum or thorax.

- For cardiac procedures:
  - Examine the heart by elevating the apex of the heart, and examine the retrocardiac space.
  - Examine the transverse sinus to the right and left of the aorta and pulmonary vein.
  - For procedures involving the mediastinum, if the mediastinal pleura was opened, examine the ipsilateral pleural cavity.
  - For thoracic procedures:
    - Examine the thoracic cavity, paying particular attention to the thoracic apex and base of the lungs, paravertebral sulcus and inferior recesses. Examination includes placing a hand or finger behind the lung and palpating from apex to base.

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# Appendix I – ICSI Shared Decision-Making Model

ICSI Institute for Clinical Systems Improvement

The technical aspects of Shared Decision-Making are widely discussed and understood.

- **Decisional conflict** occurs when a patient is presented with options where no single option satisfies all the patient's objectives, where there is an inherent difficulty in making a decision, or where external influencers act to make the choice more difficult.
- **Decision support** clarifies the decision that needs to be made, clarifies the patient's values and preferences, provides facts and probabilities, guides the deliberation and communication and monitors the progress.
- **Decision aids** are evidence-based tools that outline the benefits, harms, probabilities and scientific uncertainties of specific health care options available to the patient.

However, before decision support and decision aids can be most advantageously utilized, a Collaborative Conversation™ should be undertaken between the provider and the patient to provide a supportive framework for Shared Decision-Making.

## Collaborative Conversation™

A collaborative approach toward decision-making is a fundamental tenet of Shared Decision-Making (SDM). The Collaborative Conversation™ is an inter-professional approach that nurtures relationships, enhances patients' knowledge, skills and confidence as vital participants in their health, and encourages them to manage their health care.

Within a Collaborative Conversation™ , the perspective is that both the patient and the provider play key roles in the decision-making process. The patient knows which course of action is most consistent with his/her values and preferences, and the provider contributes knowledge of medical evidence and best practices. Use of Collaborative Conversation™ elements and tools is even more necessary to support patient, care provider and team relationships when patients and families are dealing with high stakes or highly charged issues, such as diagnosis of a life-limiting illness.

The overall framework for the Collaborative Conversation™ approach is to create an environment in which the patient, family and care team work collaboratively to reach and carry out a decision that is consistent with the patient's values and preferences. A rote script or a completed form or checklist does not constitute this approach. Rather it is a set of skills employed appropriately for the specific situation. These skills need to be used artfully to address all aspects involved in making a decision: cognitive, affective, social and spiritual.

**Key communication skills** help build the Collaborative Conversation™ approach. These skills include many elements, but in this appendix only the questioning skills will be described. (For complete instruction, see O'Connor, Jacobsen "Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting Their Health" [2007], and Bunn H, O'Connor AM, Jacobsen MJ "Analyzing decision support and related communication" [1998, 2003].)

1. **Listening skills:**

   **Encourage** patient to talk by providing prompts to continue such as "*go on, and then?, uh huh,*" or by repeating the last thing a person said, "*It's confusing*."

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**Paraphrase content of messages shared by patient** to promote exploration, clarify content and to communicate that the person's unique perspective has been heard. The provider should use his/her own words rather than just parroting what he/she heard.

**Reflection of feelings** usually can be done effectively once trust has been established. Until the provider feels that trust has been established, short reflections at the same level of intensity expressed by the patient without omitting any of the message's meaning are appropriate. Reflection in this manner communicates that the provider understands the patient's feelings and may work as a catalyst for further problem solving. For example, the provider identifies what the person is feeling and responds back in his/her own words like this: "*So, you're unsure which choice is the best for you*."

**Summarize the person's key comments** and reflect them back to the patient. The provider should condense several key comments made by the patient and provide a summary of the situation. This assists the patient in gaining a broader understanding of the situations rather than getting mired down in the details. The most effective times to do this are midway through and at the end of the conversation. An example of this is, "*You and your family have read the information together, discussed the pros and cons, but are having a hard time making a decision because of the risks*."

**Perception checks** ensure that the provider accurately understands a patient or family member, and may be used as a summary or reflection. They are used to verify that the provider is interpreting the message correctly. The provider can say "*So you are saying that you're not ready to make a decision at this time. Am I understanding you correctly?*"

2. **Questioning Skills**

**Open and closed questions** are both used, with the emphasis on open questions. Open questions ask for clarification or elaboration and cannot have a yes or no answer. An example would be "*What else would influence you to choose this?*" Closed questions are appropriate if specific information is required such as "*Does your daughter support your decision?*"

Other skills such as summarizing, paraphrasing and reflection of feeling can be used in the questioning process so that the patient doesn't feel pressured by questions.

Verbal tracking, referring back to a topic the patient mentioned earlier, is an important foundational skill (Ivey & Bradford-Ivey). An example of this is the provider saying, "*You mentioned earlier…*"

3. **Information-Giving Skills**

**Providing information** and **providing feedback** are two methods of information giving. The distinction between providing information and giving advice is important. Information giving allows a provider to supplement the patient's knowledge and helps to keep the conversation patient centered. Giving advice, on the other hand, takes the attention away from the patient's unique goals and values, and places it on those of the provider.

Providing information can be sharing facts or responding to questions. An example is "*If we look at the evidence, the risk is…*" Providing feedback gives the patient the provider's view of the patient's reaction. For instance, the provider can say, "*You seem to understand the facts and value your daughter's advice*."

## Additional Communication Components

Other elements that can impact the effectiveness of a Collaborative Conversation™ include:

- Eye contact
- Body language consistent with message
- Respect

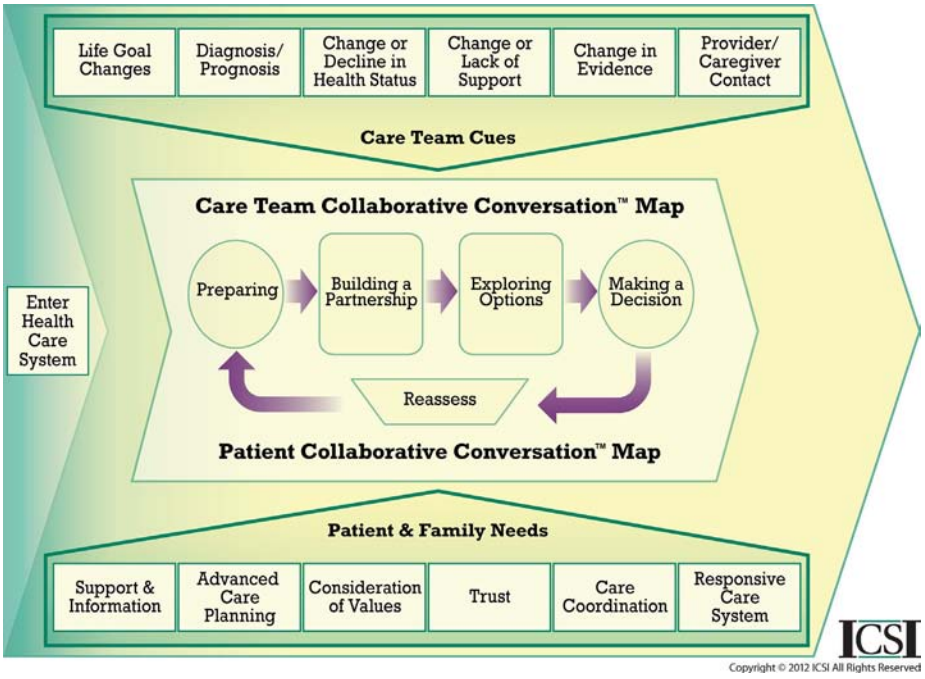
- Empathy
- Partnerships

Self-examination by the provider involved in the Collaborative Conversation™ can be instructive. Some questions to ask oneself include:

- Do I have a clear understanding of the likely outcomes?
- Do I fully understand the patient's values?
- Have I framed the options in comprehensible ways?
- Have I helped the decision-makers recognize that preferences may change over time?
- Am I willing and able to assist the patient in reaching a decision based on his/her values, even when his/her values and ultimate decision may differ from my values and decisions in similar circumstances?

## When to Initiate a Collaborative Conversation™

A Collaborative Conversation™ can support decisions that vary widely in complexity. It can range from a straightforward discussion concerning routine immunizations to the morass of navigating care for a life-limiting illness. Table 1 represents one health care event. This event can be simple like a 12 year-old coming to the clinic for routine immunizations, or something much more complex like an individual receiving a diagnosis of congestive heart failure. In either case, the event is the catalyst that starts the process represented in this table. There are cues for providers and patient needs that exert influence on this process. They are described below. The heart of the process is the Collaborative Conversation™. The time the patient spends within this health care event will vary according to the decision complexity and the patient's readiness to make a decision.




Regardless of the decision complexity there are cues applicable to all situations that indicate an opportune time for a Collaborative Conversation™. These cues can occur singularly or in conjunction with other cues.

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## Cues for the Care Team to Initiate a Collaborative Conversation™

- **Life goal changes:** Patient's priorities change related to things the patient values such as activities, relationships, possessions, goals and hopes, or things that contribute to the patient's emotional and spiritual well-being.
- **Diagnosis/prognosis changes:** Additional diagnoses, improved or worsening prognosis.
- **Change or decline in health status:** Improving or worsening symptoms, change in performance status or psychological distress.
- **Change or lack of support:** Increase or decrease in caregiver support, change in caregiver, or caregiver status, change in financial standing, difference between patient and family wishes.
- **Change in medical evidence or interpretation of medical evidence:** Providers can clarify the change and help the patient understand its impact.
- **Provider/caregiver contact:** Each contact between the provider/caregiver and the patient presents an opportunity to reaffirm with the patient that his/her care plan and the care the patient is receiving are consistent with his/her values.

Patients and families have a role to play as decision-making partners, as well. The needs and influencers brought to the process by patients and families impact the decision-making process. These are described below.

## Patient and Family Needs within a Collaborative Conversation™

- **Request for support and information:** Decisional conflict is indicated by, among other things, the patient verbalizing uncertainty or concern about undesired outcomes, expressing concern about choice consistency with personal values and/or exhibiting behavior such as wavering, delay, preoccupation, distress or tension. Generational and cultural influencers may act to inhibit the patient from actively participating in care discussions, often patients need to be given "permission" to participate as partners in making decisions about his/her care.

  Support resources may include health care professionals, family, friends, support groups, clergy and social workers. When the patient expresses a need for information regarding options and his/her potential outcomes, the patient should understand the key facts about options, risks and benefits, and have realistic expectations. The method and pace with which this information is provided to the patient should be appropriate for the patient's capacity at that moment.
- **Advance Care Planning:** With the diagnosis of a life-limiting illness, conversations around advance care planning open up. This is an opportune time to expand the scope of the conversation to other types of decisions that will need to be made as a consequence of the diagnosis.
- **Consideration of Values:** The personal importance a patient assigns potential outcomes must be respected. If the patient is unclear how to prioritize the preferences, value clarification can be achieved through a Collaborative Conversation™ and by the use of decision aids that detail the benefits and harms of potential outcomes in terms the patient can understand.
- **Trust:** The patient must feel confident that his/her preferences will be communicated and respected by all caregivers.
- **Care Coordination:** Should the patient require care coordination, this is an opportune time to discuss the other types of care-related decisions that need to be made. These decisions will most likely need to be revisited often. Furthermore, the care delivery system must be able to provide coordinated care throughout the continuum of care.

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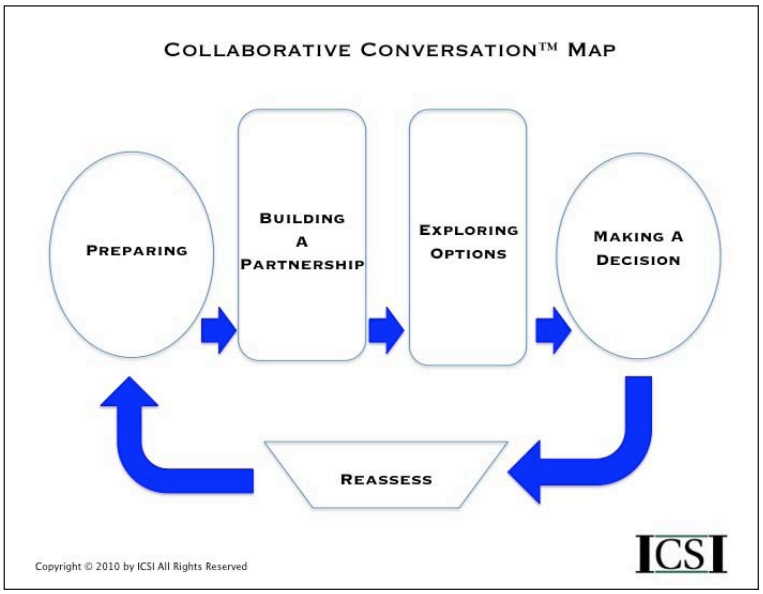
- **Responsive Care System:** The care system needs to support the components of patient- and family-centered care so the patient's values and preferences are incorporated into the care he/she receives throughout the care continuum.

The Collaborative Conversation™ Map is the heart of this process. The Collaborative Conversation™ Map can be used as a stand-alone tool that is equally applicable to providers and patients as shown in Table 2. Providers use the map as a clinical workflow. It helps get the Shared Decision-Making process initiated and provides navigation for the process. Care teams can used the Collaborative Conversation™ to document team best practices and to formalize a common lexicon. Organizations can build fields from the Collaborative Conversation™ Map in electronic medical records to encourage process normalization. Patients use the map to prepare for decision-making, to help guide them through the process and to share critical information with their loved ones.




## Evaluating the Decision Quality

Adapted from O'Connor, Jacobsen "Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting Their Health" [2007].

When the patient and family understand the key facts about the condition and his/her options, a good decision can be made. Additionally, the patient should have realistic expectations about the probable benefits and harms. A good indicator of the decision quality is whether or not the patient follows through with his/her chosen option. There may be implications of the decision on patient's emotional state such as regret or blame, and there may be utilization consequences.

Decision quality can be determined by the extent to which the patient's chosen option best matches his/her values and preferences as revealed through the Collaborative Conversation™ process.

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# Appendix J – *Choosing Wisely*®

For references, please click on the links below each society's name. Where applicable, links for patient materials are also included.

**From the American College of Cardiology**

http://www.choosingwisely.org/doctor-patient-lists/american-college-of-cardiology/

**Don't perform stress cardiac imaging or advanced non-invasive imaging in the initial evaluation of patients without cardiac symptoms unless high-risk markers are present.**

Asymptomatic, low-risk patients account for up to 45% of unnecessary "screening." Testing should be performed only when the following findings are present: diabetes in patients older than 40 years; peripheral arterial disease; or greater than 2% yearly risk for coronary heart disease events.

For patient-friendly materials regarding this recommendation:

http://www.choosingwisely.org/doctor-patient-lists/heart-imaging-tests-before-surgery/

Heart imaging tests before surgery

When you need them – and when you don't

**From the American College of Radiology**

http://www.choosingwisely.org/doctor-patient-lists/american-college-of-radiology/

**Avoid admission or preoperative chest x-rays for ambulatory patients with unremarkable history and physical exam.**

Performing routine admission or preoperative chest x-rays is not recommended for ambulatory patients without specific reasons suggested by the history and/or physical examination findings. Only 2% of such images lead to a change in management. Obtaining a chest radiograph is reasonable if acute cardiopulmonary disease is suspected or there is a history of chronic stable cardiopulmonary disease in a patient older than age 70 who has not had chest radiography within six months.

**From the American Society for Clinical Pathology**

http://www.choosingwisely.org/doctor-patient-lists/american-society-for-clinical-pathology/

**Avoid routine preoperative testing for low risk surgeries without a clinical indication.**

Most preoperative tests (typically a complete blood count, Prothrombin Time and Partial Prothomboplastin Time, basic metabolic panel and urinalysis) performed on elective surgical patients are normal. Findings influence management in under 3% of patients tested. In almost all cases, no adverse outcomes are observed when clinically stable patients undergo elective surgery, irrespective of whether an abnormal test is identified. Preoperative testing is appropriate in symptomatic patients and those with risks factors for which diagnostic testing can provide clarification of patient surgical risk.

**From the American Society of Nuclear Cardiology**

http://www.choosingwisely.org/doctor-patient-lists/american-society-of-nuclear-cardiology/

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**Don't perform cardiac imaging as a preoperative assessment in patients scheduled to undergo low- or intermediate-risk non-cardiac surgery.**

Non-invasive testing is not useful for patients undergoing low-risk non-cardiac surgery or with no cardiac symptoms or clinical risk factors undergoing intermediate-risk non-cardiac surgery. These types of testing do not change the patient's clinical management or outcomes and will result in increased costs. Therefore, it is not appropriate to perform cardiac imaging procedures for non-cardiac surgery risk assessment in patients with no cardiac symptoms, clinical risk factors or who have moderate to good functional capacity.

For patient-friendly materials regarding this recommendation:

http://www.choosingwisely.org/doctor-patient-lists/imaging-stress-tests/

Imaging stress tests

When you need them for your heart – and when you don't

**From the Society of Cardiovascular Computed Tomography**

http://www.choosingwisely.org/doctor-patient-lists/society-of-cardiovascular-computed-tomography/

**Don't order coronary artery calcium scoring for preoperative evaluation for any surgery, irrespective of patient risk.**

No evidence exists to support the diagnostic or prognostic potential of coronary artery calcium scoring in individuals in the preoperative setting. This practice may add costs and confound professional guideline-based evaluations.

**From the Society of Thoracic Surgeons**

http://www.choosingwisely.org/doctor-patient-lists/the-society-of-thoracic-surgeons/

**Patients who have no cardiac history and good functional status do not require preoperative stress testing prior to non-cardiac thoracic surgery.**

Functional status has been shown to be reliable for prediction of perioperative and long-term cardiac events. In highly functional asymptomatic patients, management is rarely changed by preoperative stress testing. It is therefore appropriate to proceed with the planned surgery without it.

Unnecessary stress testing can be harmful because it increases the cost of care and delays treatment without altering surgical or perioperative management in a meaningful way. Furthermore, low-risk patients who undergo preoperative stress testing are more likely to obtain additional invasive testing with risks of complications.

Cardiac complications are significant contributors to morbidity and mortality after non-cardiac thoracic surgery, and it is important to identify patients preoperatively who are at risk for these complications. The most valuable tools in this endeavor include a thorough history, physical exam and resting EKG. Cardiac stress testing can be an important adjunct in this evaluation, but it should only be used when clinically indicated.

**From the Society for Vascular Medicine**

http://www.choosingwisely.org/doctor-patient-lists/society-for-vascular-medicine/

**Avoid cardiovascular testing for patients undergoing low-risk surgery.**

Preoperative stress testing does not alter therapy or decision-making in patients facing low-risk surgery.

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**From the American College of Surgeons**

http://www.choosingwisely.org/doctor-patient-lists/american-college-of-surgeons/

**Avoid admission or preoperative chest x-rays for ambulatory patients with unremarkable history and physical exam.**

Performing routine admission or preoperative chest x-rays is not recommended for ambulatory patients without specific reasons suggested by the history and/or physical examination findings. Only 2% of such images lead to a change in management. Obtaining a chest radiograph is reasonable if acute cardiopulmonary disease is suspected or there is a history of chronic stable cardiopulmonary diseases in patients older than age 70 who has not had chest radiography within six months.

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ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at http://bit.ly/ICSICOI.

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ICSI facilitates and coordinates the protocol development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

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## Acknowledgements:

# Perioperative

All ICSI documents are available for review during the revision process by member medical groups and sponsors. In addition, all members commit to reviewing specific documents each year. This comprehensive review provides information to the work group for such issues as content update, improving clarity of recommendations, implementation suggestions and more. The specific reviewer comments and the work group responses are available to ICSI members at Periop.

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# Acknowledgements

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ICSI
Institute for Clinical Systems Improvement

# Document History and Development:
# Perioperative

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| **First Edition Feb 2009** |
| **Second Edition Oct 2009** |
| **Third Edition Nov 2010** |
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## Document History

In 2005-2007, ICSI hospital members championed patient safety activities aimed at advancing efficient surgical process flow and creating safe and reliable practices that reduced the number of adverse events in surgery. In collaboration with its members, ICSI developed standardized surgical protocols for safe site marking, the reduction of surgical site infection and retained foreign objects. This work resulted in the creation of three specific safety protocols:

*Safe Site Protocol for All Invasive, High-Risk or Surgical Procedures; Prevention of Unintentionally Retained Foreign Objects in Surgery;* and *Prevention of Surgical Site Infection*.

In 2007-2008, ICSI facilitated a Reliability Centered Surgical Care Redesign Collaborative, which provided a collaborative learning environment for participants to become knowledgeable in reliability theory and principles. This collaborative provided an opportunity for participants to share their learnings as they worked to implement these and other surgical related protocols.

Recognizing that these surgical processes are part of the comprehensive perioperative experience, these three distinct protocols were merged in 2008 to create one comprehensive Perioperative consistent with the requirements established by The Joint Commission National Patient Safety Goals.

In 2013-2014, the Preoperative guideline and Perioperative protocol were merged into one document.

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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.

## Audience and Intended Use

The information contained in this ICSI Health Care Protocol is intended primarily for health professionals and other expert audiences.

This ICSI Health Care Protocol should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Protocol and applying it in their individual case.

This ICSI Health Care Protocol is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

## Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other protocols, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the protocol. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each protocol as part of the revision process. They provide comment on the scientific content, recommendations, implementation strategies and barriers to implementation. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the protocol is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

## Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the protocols. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

## Document Revision Cycle

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. 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 midcycle 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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