Regions Hospital®

Subject Correct Site Verfication for Surgical Procedures, Invasive Procedural Areas, and Bedside Procedures	Attachments ☐ Yes ☒ No
Key words site marking, more than minimal rist, time out, pause for the cause	**Number** **RH-PC-PC-12-40**
Category Provision of Care (PC)	**Effective Date** **December 2006**
Manual Patient Care Manual	**Last Review Date** **December 2006**
Issued By Surgical Services	**Next Review Date** **2009 - 4th Quarter**
Applicable All Regions Hospital patient care areas	**Origination Date** **May 2003** **Retired Date**
Review Responsibility Operating Room Committee, Patient Care Committee, Medical Executive Committee	**Contact** Nursing Administration/Surgical Services

I. PURPOSE

The purpose of the surgical, invasive or more than minimal risk procedure site verification and marking protocol is to eliminate the risk of a surgery, invasive, or more than minimal risk procedure on the wrong patient, wrong side or site, or the wrong procedure. This protocol requires coordination between the staff surgeon or designee, the patient/legal guardian and staff from the operating room (OR), pre-operative holding room, anesthesia practitioner, nursing, radiology personnel, and other multidisciplinary teams. All personnel involved in the process must take an active role in this protocol. If at any time, a particular section of the protocol cannot/should not be performed (e.g. site marking), the other verification steps including time out (pause for the cause) still apply. This protocol applies to patients of all ages having any type of surgery, invasive or more than minimal risk procedure in any setting within Regions Hospital.

Surgical, invasive, or more than minimal risk procedures that are emergent are exempt from application of this policy. An emergency is defined as a condition that if not treated imminently could be life, limb or organ threatening to the patient.

II. POLICY

A. This protocol covers the procedures involving verification and marking of a surgical, invasive or more than minimal risk procedure. Any surgery, invasive or more than minimal risk procedure needs to have the full verification process, which includes:
   1. Correct Patient - assuring the correct patient is present.
   2. Correct Procedure - assuring the correct procedure to be performed.
   3. Time out: assuring everyone present actively and verbally affirms the five verifications:
      a. Patient identity; using two identifiers,
      b. Procedure(s) to be performed (including laterality, <u>multiples</u>, and/or level),
      c. Correct patient position,
      d. Correct procedure side or site; and
      e. Necessary imaging, equipment, implants, or special requirements (e.g. antibiotic

prophylaxis administration)

4. Site Marking -.Any procedure involving laterality or levels requires site marking. The surgery or procedure must have side or level documented in the patient's electronic health record and/or written consent form. When site marking does not apply "Not Applicable or N/A" should be indicated on the verification form. However, in all cases the other verification steps of the protocol still apply.
5. The surgery or procedure will not proceed without full completion of the above steps.

B. Definitions and Specifications

1. Emergency is defined as a condition that if not treated imminently could be life, limb or organ threatening to the patient.
2. High-risk procedure is any procedure that is known to expose a patient to the risk of permanent loss of function or death. Generally, this includes procedures requiring consent by the patient/legal guardian.
3. Invasive procedure is any procedure that exposes the patient to more than minimal risk. This includes, but is not limited to, any surgical entry, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. This applies to any procedure performed in the operating room or in other 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/legal guardian. This excludes venipuncture, intravenous therapy, NG or OG insertion, Foley catheter insertion, flexible sigmoidoscopy, and vaginal exams with or without a Pap smear.
4. Staff surgeon or designee is a member of the team performing the procedure who is a credentialed and privileged provider as defined by Regions' medical staff by-laws or who is a physician in residency training.
5. Laterality refers to any anatomical structures that occur on both sides of the body, both internally or externally (e.g., right, left, or bilateral).
6. Level refers to any anatomical structures that include multiples occurring linearly (e.g. spinal vertebrae, ribs).
7. Position refers to the placement or angle of the patient for the procedure (e.g. supine, prone).
8. Site is defined as the specific anatomic location of the procedure site (incision, or injection) as indicated by a description of the body part or parts (e.g. shoulder, knee, hip, back, abdomen, chest etc.), levels (e.g. spine level or ribs), or digits (for hands use thumb, index, long, ring, small; for toes, use great toe, 2nd, 3rd, 4th and 5th) to be subjected to the intervention.
9. Site marking is defined as mechanical labeling of a body part to indicate side. 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 spinal incisional site indicating anterior or posterior and general level (cervical, thoracic, or lumbar) is marked.
10. Possibles is defined as procedures that may or may not be performed in this setting. If there are "possibles" listed on the patient consent and laterality is indicated, then those "possibles" should follow the same process for site marking and verification as previously described.
11. Verification is defined as ensuring consistency between the consent form/informed consent documentation; diagnostic studies; and response from the patient/legal guardian.
12. Hard stop is defined as a complete halt in the procedure when any part of the verification process is not followed and/or a discrepancy is discovered. The procedure will not continue until all the steps of the verification process are completed and any discrepancies resolved.
13. Anatomical variation of the patient that may lead to difficulty in identifying site, side or

levels. When a patient is known to have anatomical variation involving the procedure site, this information will be shared with the care team prior to the start of the procedure and any additional steps taken to confirm the correct procedure site. These additional steps may include real time intra-operative or intra-procedure imaging or consultation with a second staff physician.

14. Outside events includes information used by the receiving organization to determine correct patient, side, site or level. Occasionally, events outside of the organization where the procedure is being performed can contribute to the occurrence of an error. Strict labeling of specimens including a verification of the electronic health record documentation or diagnostic study is strongly recommended.

C. Site Marking

1. When applicable, the surgical or procedural site must be verified, marked with the initials of the staff physician or designee performing the procedure, and documented in the patient record. "Not Applicable or "NA" should be written when site marking does not apply.
2. Exceptions to site marking include:
    a. Single organ cases (e.g., Cesarean section, cardiac procedures)
    b. Teeth – however the operative tooth name(s) is to be indicated on the consent or in the electronic health record and/or the operative tooth (teeth) is marked by the staff physician or designee on the dental radiographs or dental diagram.
    c. 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.
    d. Interventional procedures where the insertion site is not predetermined and/or essential to the patient outcome (e.g., cardiac catheterization, PICC line, central line, or arteriogram).
    e. Situations when the process of marking or the time it would take to mark the site would cause the patient harm (e.g., emergency procedure or unstable back fracture). The rationale for not marking will be documented in the patient's electronic health record.
    f. Procedures that enter through an orifice where the internal target organ is not associated with pre-determined laterality (e.g., endoscopy, cystoscopy, or bronchoscopy).
    g. Sensitive areas may be marked above or lateral to the procedure site (e.g. scrotal procedure sites will be marked on the groin area on the appropriate side of the body and breast/nipple procedure sites will be marked on the breast or above the breast on the upper chest area).
    h. When the staff physician or designee performing the procedure is in continuous physical attendance with the patient from the time it is determined to do the procedure to the conclusion of the procedure.
3. If a patient refuses to have their surgical/procedure site marked, the staff physician or designee will document the patient's refusal in the patient's electronic health record. Nursing personnel will document the patient's refusal in the site-marking box on the verification form.
4. The other steps of the verification process, which includes validating the correct patient and procedure and conducting the time out, apply even if site marking is exempted.

D. Stop the Line

1. If there are any discrepancies or differences in understanding related to patient identification, procedure, procedural approach, or site, by ANY member of the care team, including the patient/legal guardian, the procedure does not move forward until the discrepancy has been resolved.
2. The following reconciliation steps are to be taken:
    a. The staff physician or designee and the OR/procedural area charge nurse are notified

immediately

b. A re-verification process will be implemented through a group review of the consent, electronic health record, and discussion with the patient/legal guardian
c. Resolution of the discrepancy will be documented in the patient's electronic health record by the staff physician or designee.

3. If the discrepancy cannot be resolved the procedure must be rescheduled.

III. PROCEDURE(S)

A. Surgery

1. Pre-operative Verification Process:

All surgical patients will be identified and all surgical procedures verified via the procedure outlined below. All members of the perioperative team (pre-operative nurse or nurse in attendance, certified registered nurse anesthetist (CRNA), staff surgeon, and circulating operating room (OR) nurse are responsible for verifying the patient and consented procedure(s). All personnel involved in the process must take an active role. If at any time, a particular section of the protocol cannot/should not be performed (e.g., site marking), the other verification steps still apply.

a. If possible, verification of the correct person, procedure and site will occur in collaboration with the patient/legal guardian.
b. The pre-operative verification process will be completed:
   i. At the time the surgery is scheduled in the clinic
   ii. Any time the responsibility for care of the patient is transferred to another care giver (ex.-Pre-op to Surgery, etc.)
   iii. Before the patient leaves the pre-operative area or enters the operating room.
c. The pre-operative verification process for surgery is as follows:
   i. In the pre-op holding area prior to sedation, the pre-operative nurse or nurse in attendance, CRNA, and the circulating nurse will:
      - Identify the patient comparing the patient's name, electronic health record number and date of birth indicated on the consent and in the surgery schedule against their identification (ID) band.
      - Verify the surgical procedure with the consent and surgery schedule.
      - Verify the consent with the patient including:
        1) The consent is signed by the patient/legal guardian
        2) The consent is signed by the staff surgeon
        3) The consent is dated, and
        4) The staff surgeon performing the surgery is documented on the consent.
      - Verify the surgical site marking, if applicable, and that it is consistent with the consent, schedule, patient/legal guardian's understanding of the site of surgery, if able, and the electronic health record.
   ii. After staff has verified this information, they will document their initials and signature on the verification form in the appropriate box and line. If surgical site marking is "Not Applicable" documentation of "N/A" on the verification form is necessary.
d. The staff surgeon or designee (resident, certified physician assistant, or credentialed surgical assistant) will confirm the site through review of:
   i. Pertinent diagnostic studies for the patient;
   ii. Discussion with the patient/legal guardian; and
   iii. Consent form/informed consent documentation
e. If a discrepancy is discovered, the staff surgeon or designee and the OR charge nurse will be notified immediately and a re-verification process will be implemented as described in the Stop the Line process.
f. Imaging Data verification (if applicable): If imaging data is used to confirm the

surgical site, the staff surgeon or designee and the OR circulating nurse will confirm the images are correct and properly labeled. The circulating nurse will document on the verification form which member(s) of the team confirmed the imaging data. Imaging data verification must be documented on the form. “Not Applicable” or “N/A” should be written if imaging data is not used.

g. Patients bypassing the pre-op holding area and going directly to the operating room, (i.e. stat c-sections, trauma cases or vented patients), will have the pre-operative verification completed in the OR by the CRNA and the circulating nurse.

2. Site Marking for Operative Areas:
   a. Areas that must be marked are:
      i. Laterality (right, left, or bilateral),
      ii. Multiple digits – for hands use thumb, index, long, ring, and small and for toes use great toe, 2nd, 3rd, 4th, and 5th on the consent and scheduling documentation.
      iii. Laparoscopic procedures and procedures through a natural body orifice which are intended to treat an internal organ that is “left”, “right”, or “bilateral”.
      iv. If there are “possibles” listed on the informed consent and laterality is indicated, the “possibles” will be marked.
      v. In cases where the surgery is exploratory or unexpected findings occur during the procedure that result in a change in either the procedure or site the following applies:
         - The change in procedure or site must be consistent with the consent by the patient/legal guardian, (or family is the patient is unable to give consent) and verified.
         - All personnel involved in the procedure must stop to perform a second verification noting the change in the procedure or site.
   b. Spine and Other Procedures involving levels (e.g. spine, ribs):
      i. Pre-procedure skin marking of the spinal/other procedure site, anterior or posterior, and general level (cervical, thoracic, lumbar, or rib number) will be marked with the staff surgeon or designee’s initials in a collaborative effort between the staff surgeon or designee and the patient/legal guardian if able.
      ii. Pre-operative imaging will be present during the procedure in the operating room or procedure area.
      iii. High quality intra-operative imaging with opaque instruments marking the specific boney landmarks will be taken and compared with the pre-operative imaging as part of the correct site verification procedure.
      iv. Final verification will be completed by the staff surgeon or designee performing the surgery and requires a comparison between the pre-operative and the intra-operative imaging.
   c. Site Marking Process:
      i. If possible, the patient will be involved in the verification of their surgical site. If the patient is unable to participate in the verification of the operative site, whoever has authority to sign the informed consent for the patient will be asked to participate in the verification process. If a patient refuses to have their surgical/procedure site marked, the staff surgeon or designee will document the patient’s refusal in the patient’s electronic health record. Nursing personnel will document patient’s refusal in the site-marking box on the verification form.
      ii. The staff surgeon or designee (resident, certified physician assistant, or credentialed surgical assistant) who is a member of the operating team will verbally validate the operative side with the patient or guardian, with the consent, and with pertinent diagnostic studies and electronic health records prior to the patient being transported to the operating room.
      iii. Using a skin marker, the staff surgeon or designee will mark the procedure site with his/her initials. The marked initials must be visible through the drape. If a

procedure site cannot be directly marked on the patient's skin, the site will be marked with the staff surgeon or designee's initials on the cast or dressing as close to the procedural site as possible.

iv. When multiple and distinctly different procedures are to be performed in separate anatomical locations (e.g. left femoral nail and right hand debridement), the sites will be numbered on the consent form and the procedure sites will be marked with the appropriate corresponding number.

v. Once the surgical site has been marked, the site-marking icon on Navicare will be clicked off by the staff surgeon or designee.

vi. Completion of the site marking process will be documented on the verification form by the pre-operative nurse or nurse in attendance, CRNA, and the circulating nurse.

vii. If possible, initials marked on the patient will be removed prior to the patient leaving the operating room.

3. Time Out (pause for the cause) Process-prior to the incision
   a. **All personnel involved in the procedure, through active verbal participation, will stop to perform a final verification just prior to the start of the procedure but after the patient has been prepped and draped**. The intra-op team (CRNA, staff surgeon or designee, circulating nurse and scrub personnel) will verbally verify the following:
      i. Patient identity; using two identifiers
      ii. Procedure(s) to be performed (including laterality, multiples, and/or level)
      iii. Correct patient position
      iv. Correct procedure side or site; and
      v. Necessary imaging, equipment, implants, or special requirements (e.g. antibiotic prophylaxis administration).
   b. After verbal verification by all team members, the circulating nurse will document on the verification form with his/her signature that all team members actively participated in the time out (pause for the cause).
   c. The completed verification form will become part of the patient's health record.
   d. In cases where multiple unrelated surgeries are to be performed, the time out (pause for the cause) is repeated prior to each incision or injection, this is especially important when there is a change in the staff surgeon.
   e. A verbal report with an additional pause at the staff to staff level (e.g. staff surgeon to staff surgeon, CRNA to CRNA, etc.) will also occur at any change in the care team at any time throughout the procedure. Staff who may be changed during the procedure and to whom this pause applies includes staff surgeon, anesthesia, circulating nurse and scrub personnel.
   f. Regional Block Anesthetic – Prior to administration of the regional block, the anesthesiologist will verify the correct site and laterality through review of the patient's informed consent, the electronic health record, pre-procedure note, marked procedure site, and through discussion with the patient/legal guardian. The time out (pause for the cause) process is required just prior to the start of the block and requires active verbal participation by the anesthesiologist and one other caregiver.
4. Intra-Op Time Out (pause for the cause) will be conducted
   a. When the approach is midline but the internal approach involves laterality. The staff surgeon or designee will actively verbalize the lateral approach (e.g. right ureter, left bronchus) which will be validated against the consent and verbally confirmed by the rest of the surgical team.
   b. When intra-operative images are taken to mark specific boney landmarks with opaque instruments, the intra-operative images will be compared with pre-operative images as part of the correct site verification procedure.
   c. When implants are a part of the surgery, the verification by the whole care team involved in the procedure will be done when each item/implant is handed to the staff surgeon or designee. The verification will include:

i. Implant specification/type/expiration date
ii. Size
iii. Laterality

5. Occurrence of wrong site, wrong procedure, or wrong patient surgery
Any occurrence of wrong site, wrong procedure, or wrong patient surgery must be reported immediately to the department supervisor and Risk Management or Patient Safety. Such an incident is classified as an Adverse Health Event and/or a Sentinel Event. (see PC-10-72)

B. Invasive and/or Beside Procedures (settings other than the OR)
All patients will be identified and all procedures verified via the process outlined below. All members of the team who are present during the procedure are responsible for verifying the patient and consented procedure(s). All personnel involved in the process must take an active role in this protocol. If at any time, a particular section of the protocol cannot or does not need to be performed (e.g., site marking), the other verification steps still apply. All steps in the process are to be documented on the Bedside or Procedural Area Universal Protocol Form (# 100-900-242) or in the electronic health record. A MINIMUM of one licensed staff person must initial and sign the form attesting to the fact that the protocol was followed.

If a discrepancy is discovered at any time during the steps described below, any member of the care team may "stop the line" and request the staff physician or designee to clarify any aspect of the process or procedure. At no time will the procedure continue if any member of the care team is concerned.

1. Verification of Patient Identification
Per policy PC-01-25, all patients must be identified using a minimum of two identifiers before the start of any procedure or treatment. For invasive procedural and/or bedside procedures, this verification will occur at each of the following points:
    a. Any time the responsibility for care of the patient is transferred from one caregiver to another
    b. before the patient leaves the pre-procedural area for the procedure or is transported from the nursing unit or emergency department, and
    c. before the start of the procedure
2. Verification of Procedure
Prior to the initiation of sedation or start of the procedure the nurse/other will verify the correct procedure to be performed using the order, consent and/or schedule. If possible, the patient/legal guardian may be involved in verbal verification of the procedure to be performed.
3. Imaging Data Verification (if applicable):
If imaging data is used to confirm the procedural site, the staff physician or designee and a member of the procedural team will confirm the images are correct and properly labeled. The nurse/other will document on the verification form who, by name and title, confirmed the imaging data. The use of imaging data during the procedure must be documented on the form. "Not Applicable" or "N/A" should be written if imaging data is not used.
4. Site Marking (if applicable)
    a. Areas that must be marked are:
        i. Laterality (right, left, or bilateral)
        ii. Multiple digits – for hands use thumb, index, long, ring, and small and for toes use great toe, 2nd, 3rd, 4th, and 5th on the consent and scheduling documentation.
        iii. Endoscopic procedures through a natural body orifice that are intended to treat an organ that is "left", "right", or "bilateral" must be marked indicating the exact organ or site/side.
        iv. If there are "possibles" listed on the informed consent and laterality is indicated, the "possibles" will be marked.
        v. In cases where the internal approach involves laterality, the staff physician or

designee will actively verbalize the lateral approach (e.g. right ureter, left bronchus) which is validated against the consent and verbally confirmed by the rest of the team.

b. Spine and other procedures involving levels (e.g. spine, ribs)
   i. Pre-procedure skin marking of the spinal/other incisional site, anterior or posterior, and general level (cervical, thoracic, lumbar, or rib number) will be marked only with the staff physician or designee's initials in a collaborative effort between the staff physician or designee and the patient/legal guardian if able.
   ii. If applicable, pre-procedure imaging will be in the procedure room or procedure area.

c. Site Marking Process
   i. If possible, the patient will be verbally involved in marking their procedure site. If a patient refuses to have their procedure site marked, the staff physician or designee will document the patient's refusal in the patient's electronic health record. Nursing/other will document patient's refusal in the site-marking box on the verification form.
   ii. The staff physician or designee (resident, certified physician assistant, or credentialed surgical assistant) who is a member of the procedure team will verbally validate the procedural site with the patient or guardian, if able, with the consent, and with pertinent diagnostic studies and/or electronic health records prior to the start of the procedure.
   iii. Using a skin marker, the staff physician or designee will mark the procedure site with his/her initials. The marked initials must be visible through the drape. If a procedural site cannot be directly marked on the patient's skin, the site will be marked with the staff physician or designee's initials on the cast or dressing as close to the procedural site as possible.
   iv. When multiple and distinctly different procedures are to be performed in separate anatomical locations (e.g. left chest tube insertion and right Steinman pin insertion), the sites will be numbered on the consent form and the procedure sites marked with the appropriate corresponding number.
   v. Completion of the site marking process will be documented on the verification form by the designated member of the care team (e.g. nurse, other).
   vi. If possible, initials marked on the patient will be removed at the conclusion of the procedure.

5. Time Out (pause for the cause) will be conducted
   a. Prior to incision or start of the procedure an RN or MD will verbally confirm the following:
      i. Patient identity; using two identifiers
      ii. Procedure(s) to be performed (including laterality, multiples, and/or level)
      iii. Correct patient position
      iv. Correct procedure side or site; and
      v. Necessary imaging, equipment, implants, or special requirements (e.g. antibiotic prophylaxis administration).
   b. When there is only one person involved in the procedure (other than the patient), the individual doing the procedure must still perform the Time Out (pause for the cause) process as described above.
   c. In cases where multiple anatomically unrelated procedures are to be performed, the Time Out (pause for the cause) is repeated prior to each incision or injection.
   d. When implants are part of the procedure. Verification by the whole care team involved in the procedure will be done when each item/implant is handed to the staff physician or designee. The verification will involve:
      i. Implant specification/type/expiration date
      ii. Size (if applicable)
      iii. Laterality (if applicable)

e. Verification will be documented on the verification form with the responsible individual's signature or initials.
f. The completed verification form will become a part of the patient's health record

6. Regional Block Anesthetic
   Prior to administration of a regional block, the anesthesiologist will verify the correct site and laterality through review of the patient's informed consent, the electronic health record, pre-procedure note and/or marked procedure site, and through discussion with the patient/legal guardian. The Time Out (pause for the cause) process is required just prior to the start of the block and requires active verbal participation by the anesthesiologist and one other caregiver who is present during the procedure.
7. Occurrence of wrong site, wrong procedure, or wrong patient surgery
   Any occurrence of wrong site, wrong procedure, or wrong patient surgery must be reported immediately to the department supervisor and Risk Management or Patient Safety. Such an incident is classified as an Adverse Health Event and/or a Sentinel Event. (see PC-10-72)

IV. DEFINITIONS

See Definitions and Specifications in the Policy Section

V. COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

VI. ATTACHMENTS NOT APPLICABLE

VII. OTHER RESOURCES

Internal
Surgical Services Verification (Form #100-800-738)
Bedside or Procedural Area Universal Protocol (Form # 100-900-242)
PC-01-05 Patient Identification
PC-10-40 Informed Consent Prior to Treatment or Surgical Procedures
PC-09-50 Procedural Sedation/Analgesia.
PC-10-72 Sentinel and Adverse Health Event Management

VIII. APPROVAL(S)

Judy Moseley
Vice President Patient Care Services

IX. ENDORSEMENT

Patient Care Committee: December 2006
Medical Executive Committee: December 2006