

Verification of Non-Operative Procedure, Site and Side Critical Components

General Comments

This packet addresses care provided in non-operative sites where invasive procedures are performed: the ED, Dental Office, Primary Care Centers, Wound Care Center, Endoscopy Unit, EP Laboratory, Cardiac Laboratory, Interventional Medical Imaging Areas, PACU, and at the bedside.

Requirements for Scheduling:

- When scheduling
 - The entire procedure name without abbreviations must be included
 - Spinal procedures, (when applicable) must include the anticipated level(s)
 - Additional information that must be provided when known and applicable to the procedure:
 - ** implant/implant system and equipment information
 - ** Specific information on removal of devices
 - ** Information on harvest and donor sites
 - The scheduler from Central Scheduling must verify the information provided by the office by reading it back on the phone in its entirety. Alternatively, the scheduling form completed by the scheduler can be faxed back to the office for their confirmation.

Requirements for Pre-Registration, (when applicable):

- Staff will identify patient per Patient Identification Policy and ask patient what procedure is being done.
- Patient understanding of procedure will be compared with information in pre-registration.
- Any discrepancies – contact supervisor for clarification.

Registration (when applicable):

- Staff member registering will use the Patient Itinerary Report as a guide to confirm patient identity, procedure, site and side, if applicable.
- Any discrepancies identified to be reported to supervisor for further intervention.

Preadmission Testing (when applicable):

- Staff will confirm patient identity, procedure, site and side, if applicable.
- Any discrepancies will be identified and will be reported to the supervisor for further intervention.

Arrival to Patient Care Area:

- Clinical staff reviewing patient will confirm patient identity, procedure, site and side, (if applicable).
- Any discrepancies reported immediately to the physician/clinical affiliate and resolve prior to patient going to area for procedure.

Requirements for the Consent Document:

- Any changes to the consent document what –so-ever, after the patient’s signature has been obtained require the completion of a new document.
- As much as is known about the implant or device to be inserted or removed must be documented on the surgical consent.
- As much as is known about the donor harvest site must be documented on the consent form.

Requirements for the Anesthesia Time Out:

- A “timeout” is conducted immediately prior to performing an anesthesia procedure as a precursor to a procedure or independently.
- Identification of correct site and side(s), if indicated, including presence and visibility for the marked site with anesthesia provider’s initials when laterality is an issue for a pain block. When the anesthetic is administered for a midline spinal procedure, marking is not necessary but the time out is.

Requirements for Site Marking:

- No stray marks should be made on any area other than the intended site/side. Use of arrows, the word “no”, or other written prompts to de-identify a site for surgery is not permitted
- The presence of the physician/clinical affiliate’s initials must be verified after the patient is prepped and draped; the procedure cannot be initiated until this step is completed and every individual present in the room actively validates and verbalizes this
- Only the FDA approved marker available in the hospital may be used for site marking.
- FDA approved markers are available on all clinical units.
- Spine procedures: pre-procedure skin marking for laterality and/or level is required; intraoperative imaging is completed to confirm the exact level/site. A second “timeout” is conducted to correlate the image and intra-spinal markers
- Marking must be completed by the physician/clinical affiliate.
- Not specific to laterality exclusively; also intended to mark operative “site”
- Involves all paired organs, structures, and bilateral procedures
- Site marking must be legible, unambiguous, and be visible when the patient is draped
- If the physician/clinical affiliates initials are N.O., three initials must be utilized
- Marking examples:

- **for a left chest tube insertion procedure, the patient will have a mark and physician/clinical affiliate's initials on the left side of the torso near where the incision will be made
- **for a bilateral repair, marks will be made at both incision sites
- **for internal organs, the skin of the side that would be treated should be marked, if applicable.
- Special Purpose Wrist Band: For procedural sites considered problematic to mark and sensitive for the patient, a wrist band may be used as an alternative to site marking. When the procedure site is the labia or testes, a wristband bearing the following information may be used in lieu of site marking:
 - The wrist band must contain
 - **first and last name of the patient
 - **a second identifier (account number or medical record number)
 - **the name of the anatomical site and side
 - **the name of the procedure
 - **must be applied by the physician/clinical affiliate
 - A patient with such wristband must be positioned in a manner so that the arm bearing the wristband is placed on an arm board and visible during the timeout portion of the procedure. This wristband must be consulted during the timeout.

Requirements for Relevant Images:

- The physician/clinical affiliate is responsible for hanging films or pulling up images in PAC's.
- During the "timeout" for the procedure, a second team member confirms that the image belongs to the patient
 - **first and last name of the patient
 - **second unique identifier-medical record number or account number for an image within the SJH network or date of birth for out of network images
 - **date of study
 - **that the image is displayed in the correct orientation using the markers present on the image

Requirements for the Time Out:

- Must occur after the patient has been prepped and draped and immediately prior to start of the procedure.
- Timeout elements must include:
 - Identification of the patient using 2 patient identifiers which includes the patient's first and last name and either the medical record or account number.
 - Read from the procedure consent the procedure, site (if applicable), and side (if applicable), to the physician or clinical affiliate and any other care providers present for mutual confirmation.

- Identification of correct side and side (s), if indicated, including presence and visibility of marked site with physician/clinical affiliate's initials when laterality is an issue
- Visually confirm the physician/clinical affiliate initials are visible within the prepped and draped area, (when applicable)
- Verbally confirm that the patient's position is correct (if applicable) to the procedure to be performed
- Verbally state to the procedure team general information regarding any supplies, equipment or items, or any other special requirements (i. e., requires interpreter to be present)
- Verbally states to the procedure team the status of available blood products including type and screen, (when applicable)
- Verbally prompts the physician/clinical affiliate to state the antibiotic name, dose and administration time, (when applicable)
- Verbally validates the correct irrigation fluids by reading from the case card or preference card all irrigation fluids dispensed to the field, (when applicable)
- Verbally states as well as prompts the physician/clinical affiliate to articulate safety precautions implemented based on patient history or medication use, (when applicable)
- The timeout will not begin until the entire team (every member present in the room) has ceased activity and is attentive to the nurse, or as otherwise indicated.
- The nurse, or as otherwise indicated will prompt each and every individual present in the room during this timeout to ascertain an active response to:
 - **agreement with the procedure, site and side as known to them
 - **confirmation that the site markings are present and visible, when applicable
 - **that the patient is appropriately positioned relative to the planned surgical procedure
- The identity of each participant must be documented in the medical record.
- The procedure will not begin until all steps have been completed and total agreement has been obtained.
- Complete agreement must be attained prior to the initiating of the procedure. Disagreement or uncertainty by anyone present will result in a temporary cessation of activity and progression of the procedure.
- The coordinator, manager or director will be immediately summoned to resolve the issue. During hours that these individuals are not available, the director or administrator on call will be immediately called for direction/intercession.

State of New York
Department of Health

Office of Health Systems Management
Division of Primary and Acute Care Services

New York State
Surgical and Invasive Procedure Protocol

for

Hospitals ~ Diagnostic and Treatment Centers
Ambulatory Surgery Centers ~ Individual Practitioners

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NEW YORK STATE SURGICAL AND INVASIVE PROCEDURE PROTOCOL

(FOR THE PREVENTION OF WRONG PATIENT, WRONG SITE, WRONG SIDE & WRONG INVASIVE PROCEDURE EVENTS)

I. STATEMENT OF PURPOSE

The State of New York is committed to providing its residents access to quality health care. Hon. George E. Pataki, Governor and Antonia C. Novello M.D., M.P.H., Dr.P.H., Commissioner of Health, continue to work toward a system that reduces medical and surgical errors by commitment to a safe and protected patient care environment. Key to achieving this goal is promoting a culture of safety and strengthening open communication among health care providers, individual practitioners and the patients they serve.

One of the goals of Governor Pataki and Commissioner Novello, is the elimination of wrong patient, wrong site, wrong side and wrong invasive procedures, through the development of comprehensive systems that ensure the correct procedure is done on the correct patient on the correct site. Increased practitioner awareness combined with strong provider protocols and standardization **will enhance** the patient safety measures currently in place.

The New York State Surgical and Invasive Procedure Protocol (NYSSIPP) developed by the Procedural and Surgical Site Verification Panel (PSSVP) is intended for all patient care settings and for all individual practitioners. As new recommendations are developed, NYSSIPP will be updated with evidence-based findings.

II. CHARGE TO THE PANEL

The PSSVP was charged with the development of an enhanced protocol to minimize the potential for wrong patient, wrong site, wrong side and wrong invasive procedures performed in any health care setting in New York State. The panel reviewed the lessons learned from the analysis of occurrence codes 911 and 912 reported to the New York Patient Occurrence Reporting and Tracking System (NYPORTS) from 2003 through 2005, the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) database of reviewable sentinel events and the clinical literature (see references, Appendix A), as well as the collective experiences of the panelists. Application of NYSSIPP is not limited to hospitals and it is not limited to operating rooms.

NYSSIPP represents a consensus of the panel on the current best practices in the area of preventing wrong patient, wrong site, wrong side and wrong invasive procedures. NYSSIPP was developed utilizing JCAHO's Universal Protocol™ as the basis with enhancements derived from review of the NYPORTS database. The PSSVP and the New York State Department of Health (NYSDOH) anticipate that implementation of NYSSIPP will help to further reduce the incidence of wrong patient, wrong site, wrong side, and wrong invasive procedure events in New York State.

III. IMPACT

NYSSIPP is the foundation which hospitals, clinics and individual practitioners are strongly encouraged to build upon and adapt to the setting of care in which it is used. The NYSSIPP stresses the importance of communication among the members of the surgical team and with patients.

Each Article 28 provider of surgical services and/or invasive procedures should implement NYSSIPP and closely evaluate the effectiveness of the recommendations. Compliance monitoring of NYSSIPP should become an integral part of a facility's performance improvement/quality improvement activities. Facilities should address non-compliance in a systematic fashion, and follow-up activities must be documented.

IV. BACKGROUND

In 1999, The Institute of Medicine published a report on medical errors and the impact of errors on patient safety. The report, *To Err Is Human*, generated heightened awareness on the part of providers and consumers. Medical errors remain a subject of national attention.

NYPORTS is a mandatory web-based incident reporting system that has been active since 1998, and is considered a model for state-based adverse event reporting.

Wrong patient, wrong site, wrong side, and wrong invasive procedure events map to one of three reporting NYPORTS codes:

- **Code 911** - Wrong patient, wrong site surgical procedure.
This code is used for surgical procedures performed in the operating room or ambulatory surgical suite only, for surgery that proceeds to surgical incision or beyond.
- **Code 912** - Incorrect procedure or treatment – invasive.
This code is used for incorrect non-OR procedures or treatments or occurrences in the OR that involve error but are not specifically wrong patient or wrong site events.
- **Code 901** – Serious Occurrence Warranting DOH notification.
This code is used for wrong patient, wrong site, wrong side or wrong invasive procedure events in free-standing Article 28 facilities where procedures are performed. Hospitals do not report wrong patient, wrong site, wrong side or wrong invasive procedure events or other OR errors under this code.

The following table provides examples of reportable events and their corresponding NYPORTS code. Note that the appropriate code may depend on the type of facility reporting the event.

REPORTABLE EVENTS AND CORRESPONDING NYPORTS CODE

Event	Hospital	Diagnostic & Treatment Center
Patient underwent procedure intended for another patient (all wrong patient Operating Room or Ambulatory Suite procedures that proceed to surgical incision or beyond are reported in Code 911; - except endoscopic procedures, which are only reported as 912).	911	901
Patient had surgery to ring finger that was intended for index finger (all wrong site Operating Room or Ambulatory Surgical Suite procedures that proceed to surgical incision or beyond are reported in Code 911; with the exception of endoscopic procedures, which are only reported as code 912).	911	901
Patient had a procedure in the OR on the wrong side of body. A right hip surgery was intended, incision made to left hip before error realized (all wrong site Operating Room or Ambulatory Surgical Suite procedures that proceed to surgical incision or beyond are reported as Code 911).	911	901
Patient went to OR and anesthesia is administered. It is discovered that the wrong patient was brought to Operating Room and the procedure is aborted (procedures that proceed to anesthesia only, despite location, are captured as Code 912).	912	901
Patient had a left mastectomy. Following the procedure, it is discovered that the pathology findings used for the procedure belonged to another patient with the same last name (wrong invasive procedures as a result of error of omission, imaging or pathology reports, despite location, are reported as 912).	912	901
Patient had the wrong intra-ocular lens implanted in an Ambulatory Surgical Suite (all wrong equipment/implant cases are reported as Code 912).	912	901
Patient answered to another patient's name and underwent an upper endoscopy in the Operating Room intended for another patient (all endoscopic procedures, despite location, are reported as Code 912.)	912	901
Patient had wrong side chest tube placement in ED. All wrong surgical or other invasive procedures performed outside the Operating Room or Ambulatory Surgical Suite (e.g., endoscopy, interventional radiology, nursery, ED etc.) are reported as Code 912.	912	901

See NYPORTS Hospital Manual, v4.0 effective June 1, 2005 and NYPORTS Diagnostic and Treatment Center Manual, v1.0, effective June 1, 2006.

In 2000, the NYSDOH impaneled experts to develop guidelines to reduce wrong patient, wrong site, wrong side and wrong invasive procedures. The recommendations of that panel, “The Pre-Operative Protocols for Hospitals, Ambulatory Surgery Centers, and Individual Practitioners”, were published in January 2001. Despite implementation of NYS guidelines, as well as the JCAHO’s Universal Protocol™, these events continue to occur.

Continued national and statewide focus on reducing wrong patient, wrong site, wrong side and wrong invasive procedures prompted New York State Commissioner of Health Antonia Novello, M.D., M.P.H., Dr.P.H. to appoint a second panel, (The Procedural and Surgical Site Verification Panel) to address this ongoing national patient safety issue. Twenty-one experts in medicine, surgery, anesthesia, radiology, nursing, law, quality, and patient safety convened in February 2006 and in July 2006 achieved consensus of the content of NYSSIPP. NYSSIPP replaces the “Pre-Operative Protocols for Hospitals, Ambulatory Surgery Centers, and Individual Practitioners” of 2001.

V. APPLICABILITY OF THE NEW YORK STATE SURGICAL AND INVASIVE PROCEDURE PROTOCOL

Each Article 28 facility must have a policy on surgical and invasive procedures, which may be implemented and maintained in a manner best suited to the individual facility, that at a minimum specifically addresses the following:

- Scheduling
- Consent
- Pre-Operative/Pre-Procedural Verification processes
- Marking of the operative/procedural site
- Exceptions to site marking
- “Time out” immediately before the procedure
- Resolution of discrepancies/disagreements
- Compliance monitoring

This Protocol and its Implementation Guidelines apply to all operative and other invasive procedures that expose patients to more than minimal risk, including procedures done in settings other than the operating room such as a special procedures units, endoscopy units, or interventional radiology suites. Certain routine “minor” procedures such as venipuncture, peripheral IV line placement, insertion of nasogastric tube, or Foley catheter insertion are not within the scope of the Protocol. However, most other procedures that involve puncture or incision of the skin, or insertion of an instrument or foreign material into the body, including, but not limited to, percutaneous aspirations, biopsies, cardiac and vascular catheterizations, and endoscopies are within the scope of this Protocol. In addition, the Protocol is intended to apply to those anesthesia procedures performed either prior to a surgical procedure (e.g. regional nerve blocks – brachial plexus) or independently (e.g. spinal facet blocks).

The PSSVP recognizes that there will be significant diversity in the professional roles of individuals across the spectrum of health care settings utilizing NYSSIPP. It is the intent of the panel that implementation of NYSSIPP will be adapted to the setting and the procedure. This document identifies participants in the procedure as members of the “surgical team” but it is intended to include proceduralists, endoscopists and anyone assisting in any way in a procedure.

VI. COMMUNICATION

Communication among surgical team members and with the patient and family is vitally important. The Protocol addresses many modes of communication among members of the surgical team that are necessary to avoid wrong patient, wrong site, wrong side, wrong procedure events. To decrease role confusion, facilities are encouraged to define the responsibilities of each staff member involved in the procedure. There should be active verbal communication regarding consent, marking, and/or appropriate equipment and supplies. The PSSVP stresses the need for the surgeon, scrubbed staff, anesthesia personnel and the circulating nurse to discuss the planned procedure prior to commencement so that all team members are familiar with the strategies and expectations.

Written documentation of the pre-operative and pre-procedural verification process and “time out” are essential and will provide a means of monitoring compliance with the process.

Patients with physical or cognitive barriers to hearing or to understanding the surgical/procedural process must have whatever aids or support necessary to facilitate understanding. This may include an interpreter and/or guardian in attendance with them at the time consent is obtained and the surgical site is marked.

NYSSIPP requires that the surgery/procedure be stopped if there is any discrepancy in information about the patient or the surgery/procedure to be performed or *any* disagreements regarding the patient, site, surgery/procedure or implant/equipment (provided it is medically appropriate – i.e. a delay must not compromise the patient’s safety or result in clinical deterioration). The discrepancy must be resolved before proceeding.

Whenever possible, having consistent teams will strengthen communication as well as facilitate continuity of care.

In the event of an adverse occurrence, it is important to be aware that Section 405.7(b)(8) of Title 10 of the New York Codes Rules and Regulations requires that a patient be advised of any change in (health) status, including harm or injury, the cause of the change and the recommended course of treatment. The information shall be made available to an appropriate person on the patient’s behalf if the patient is not competent to receive the information and documented in the medical record. Facilities should have policies that address this requirement.

VII. RECOMMENDATIONS OF THE PSSVP

The recommendations of the PSSVP with regard to efforts that should be undertaken to prevent wrong patient, wrong site, wrong side, and wrong invasive procedure occurrences are outlined in NYSSIPP. NYSSIPP is a guideline that hospitals, other health care facilities, and private practices may adopt, adapt and/or enhance to meet individual facility specialty care needs.

NEW YORK STATE SURGICAL AND INVASIVE PROCEDURE PROTOCOL

A. SCHEDULING

Scheduling must include:

1. Entire procedure, exact site, level, digit, and side/laterality (including spelling out “Left”, “Right” and “Bilateral” – no abbreviations other than C-Cervical, T-Thoracic, L-Lumbar, S-Sacral *when identifying spinal levels* – e.g. L4-5).
2. Specific information on implant/implant system and/or equipment.
3. Specific information on removal of device.
4. Information on harvest and donor sites.
5. The Operating Room (OR), or the person responsible for accepting requests to schedule procedures, must verify the information provided by the surgeon/physician. The information should be verified in a manner agreed to by both the institution and physicians (read-back, fax, e-mail, etc).

B. CONSENT DOCUMENT

Consent documentation must include:

1. First and last name, date of birth of patient and medical record number of the patient.
2. Name and description of surgery or procedure in terms that are understandable to the patient (correct site/side, level and digit with the side spelled out as “Left”, “Right” or “Bilateral”).
3. No acronyms or abbreviations (except spinal levels noted in section A above).
4. Specific implant/implant system to be placed or device to be removed.
5. Patient/family/guardian/health care agent signature and date.
6. Witness signature and date.
7. Physician signature and date.
8. If the consent is altered or illegible it must be re-done and re-signed by all parties.

C. PRE-OPERATIVE/PRE-PROCEDURAL VERIFICATION PROCESS

Verification of the correct person, procedure site and side must occur (as applicable):

1. At the time the surgery or invasive procedure is scheduled.
2. At the time of admission or entry into the facility.
3. With the patient involved, awake and aware, if possible.
4. Anytime the responsibility for care of the patient is transferred to another caregiver or location in the pre-operative or pre-procedural process.
5. Before the patient leaves the pre-operative area or enters the procedure/surgical room.
6. In ALL clinical settings where invasive procedures are performed, including but not limited to endoscopy suites, catheterization laboratories, interventional radiology suites, intensive care units, labor and delivery areas, emergency departments, etc. There are recognized benefits to applying this to all bedside procedures.

A pre-operative or pre-procedural verification checklist must be utilized to ensure availability and actual review of the following, prior to the start of the procedure:

1. Relevant documentation: History & Physical, signed consent and any other documents required by the organization as part of the pre-operative evaluation process. The consent must be signed by the patient/legal representative, and surgeon.
2. Relevant images, properly labeled and displayed including photographs.
 - In “High Risk” procedures (as determined by the surgeon), the images should be reviewed by the surgeon and radiologist together pre-operatively.
 - Someone other than the primary surgeon confirms the name, date of the study and “Left-Right” orientation.
 - The surgeon is responsible for assessing what films/images are appropriate for viewing before and during the surgery.
 - When intra-operative imaging studies are performed, appropriate consultation should be available for interpretation of intra-operative studies.
3. Relevant diagnostic reports or studies (ultrasound, endoscopy, etc.).
4. Relevant pathology reports.
5. Necessary patient-specific implants and special equipment.
6. Confirm identity using two (2) identifiers, confirm procedure and site marking if appropriate.

D. MARKING THE OPERATIVE/PROCEDURAL SITE

1. The physician/dentist/podiatrist doing the procedure must do the site marking using his/her own initials. Site marking must be legible and unambiguous (see exceptions). Note: If the surgeon’s initials are “N.O.”, utilize three initials.
2. All sites involving laterality (e.g. brain) and/or paired organs, multiple structures (fingers, toes, hernias, lesions) or multiple levels (spine). Make the mark at or near the incision site(s) so that it/they will be visible when the patient is draped. (See following exceptions).
3. For hand and foot surgery, the surgeon must mark the surface(s) of the digit to be operated on, anterior, posterior or both.
4. The appropriate site must be verified before any cast is split. For relevant orthopedic cases, the skin/site should be marked immediately after cast/splint is removed.
5. For surgery of the spine, pre-operative skin marking is required to indicate laterality, when appropriate. A second time out must be performed when the intra-operative imaging is done to confirm the level.
6. When the site or level is not visually identifiable, the surgeon must obtain an intra-operative image, using markers that will not move, to confirm the exact level/site.
7. Do NOT mark any non-operative site(s).
8. The mark must be visible in the operative field after the patient is prepped and draped.
9. The mark must be made using an FDA approved marker that is sufficiently permanent to remain visible after completion of the skin prep. Adhesive site markers should not be used as the sole means of marking the site.

10. In the event of multiple surgical procedures by different surgeons, all relevant surgical sites must be marked prior to the first surgery. The surgeon marking the site(s) must be present for and participate in the "time out" performed for each procedure he/she marks.
11. Marking must take place with the patient/family involved, awake and aware, if possible.
12. If a smaller mark is necessary, such as near the eye in Pediatric Ophthalmology cases, a dot near the eye constitutes the site marking. A special purpose wristband is also an option.
13. A special purpose wristband must be used for patients:
 - who refuse marking,
 - a neonate (as marking may cause a permanent tattoo),
 - problematic surgical site(s) to mark (e.g. perineum or anus) or when marking can be done only after shaving a patient's head prior to a neurosurgical/cranial procedure.
 - The first and last name of the patient, a second identifier, the anatomical site and name of the procedure must be written on the special purpose wristband.
14. Final verification of the site mark must take place during the "time out".

E. EXCEPTIONS TO SITE MARKING

1. Single organ cases, which do not involve laterality (e.g., hysterectomy, appendectomy).
2. Spinal block for pain management or epidural does not require an intra-operative marker if fluoroscopy is used. However, it does require skin marking.
3. Interventional cases for which the catheter/instrument insertion site is not predetermined (e.g., cardiac catheterization).
4. Dental cases, where the operative tooth number or name(s) can be indicated on documentation or the operative tooth (teeth) including laterality can be marked on the dental radiographs or dental diagram.
5. Endoscopic or other procedures done through a midline orifice.
6. Situations in which the primary pathology itself is plainly visible (single laceration).
7. When the operative pathology has been identified by real time imaging in the immediate pre-operative period such as for frameless stereotactic neurosurgical procedures or microcalcifications in a breast biopsy.
8. Life threatening emergency when any delay in initiating the surgery would compromise the safety or outcome of the patient (e.g. ruptured aortic aneurysm).
9. When movement of a patient to create a marking would compromise the safety or outcome of the procedure (e.g. movement of a patient with an unstable spine fracture.)

NOTE: A practitioner is NOT exempt from the site-marking requirement when he or she is in continuous attendance with the patient (from the time of the decision to do the procedure through the conduct of the procedure). The requirement for "time out" applies as well. This is based reports of wrong-sided procedures being done despite the continued presence of the person performing the procedure from time to decision to completion of the procedure.

F. "TIME OUT" IMMEDIATELY BEFORE STARTING THE PROCEDURE

Purpose: To conduct a final verification of the correct patient, site/site, procedure and, as applicable, implants.

The "time out" must be conducted in the location where the procedure will be done, after the patient is prepped and draped and just before starting the procedure. This applies to all invasive procedures performed in all settings. All work should cease during the "time out" to allow all members of the team to focus on the "time out". For instances when the procedure is being performed without assistance, it is strongly advised to enlist an observer or assistant to participate in the "time out". It must involve the entire operative/procedural team, use "active communication", and be documented. The "time out" is a standardized procedure, and documentation indicates the procedure was followed in its entirety without deviation.

"Time out" includes the following:

1. Identification of the patient using 2 patient identifiers, such as, name (first and last) and a second identifier as determined by the organization.
2. Identification of the correct site and side(s).
3. Procedure to be performed and proper patient position.
4. Availability of correct implants and any special equipment or special requirements.
5. Verification of the wristband and chart takes place as the patient is brought into the room and before the "time out". The "time out" requires that all participants agree on the information and does not require checking the wristband at that time.
6. Radiological review, when germane to the case (see below).

The above information should be confirmed with the medical record and should be documented along with the identification of those who participated in the "time out".

Additional Confirmatory "Time out" should be undertaken if a new surgeon arrives and is assuming primary responsibility for the case, or if the patient/operative site is re-draped. The name of the patient and the procedure should be verified during this second "time out".

Radiological Review: The surgeon performing the operation is responsible for determining that the images to be displayed are relevant to the surgery. A second team member confirms that the image belongs to the patient (first and last names and second identifier) and that the image is displayed in the correct orientation, using markers on the image. The team confirms the site and side of the lesion as part of the "time out".

- For spinal cases in which an intra-operative image is used to determine the spinal level, a second "time out" must be performed to review the image and correlate with intra-spinal markers.

Procedures Performed Outside the OR: The person(s) performing the procedure must conduct and document the "time out" confirming all of the above information with another person when possible.

For Surgical Procedures: Instruments/equipment are not offered until after the "time out" is performed.



the procedure if there is any discrepancy in information identified by any member of the surgical team. Resolve the discrepancy or disagreement before proceeding.

Required Policy and Procedure

All organizations must have a policy and procedure that incorporates the contents of NYSSIPP, and ensures that the requirements for patient identification, site marking, pre-operative/pre-procedural verification, and “time out” are consistently followed whenever invasive procedures are performed, including, but not limited to procedures performed in the operating room, radiology, obstetrics/labor and delivery, emergency departments, cardiac catheterization lab, clinical units, and out-patient areas. The institutional policy and procedure must specify the actions to be taken when a discrepancy occurs at any step in the process.

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REFERENCES

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New York State Surgical and Invasive Procedure Protocol (NYSSIPP) - FAQ

Topics

- Applicability
- Consent
- Pre-Operative/Pre Procedural Verification Process
- Scheduling
- Site Marking
- Time Out
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Applicability

Is the New York State Surgical and Invasive Procedure Protocol (NYSSIPP) considered a standard of care within NYS?

New York State Surgical and Invasive Procedure Protocol (NYSSIPP) became the standard of care within NYS, on March 1, 2007 for Hospitals, Diagnostic and Treatment Centers, and individual practitioners.

What is the scope of the New York State Surgical and Invasive Procedure Protocol (NYSSIPP)?

The New York State Surgical and Invasive Procedure Protocol (NYSSIPP) applies to all operative and invasive procedures including endoscopy, general surgery or interventional radiology. Other procedures that involve puncture or incision of the skin, or insertion of an instrument or foreign material into the body are within the scope of the protocol. This protocol also applies to those anesthesia procedures either prior to a surgical procedure or independent of a surgical procedure such as spinal facet blocks. Example: Certain "minor" procedures such as venipuncture, peripheral IV placement, insertion of nasogastric tube and foley catheter insertion are not within the scope of the protocol.

What are the accountability expectations of the DOH with respect to the protocol?

It is to be considered a standard of care, which can involve alternative processes that meet or exceed the standards in the protocol. Article 28 facilities will be held accountable to the protocol when investigations into future wrong procedural events are done.

What are the expectations of the protocol for smaller hospitals?

These standards of care are to be followed by all Article 28 facilities regardless of size.

Is an Extra Corporal Shockwave Lithotripsy (ESWL) procedure considered invasive?

Yes, as noted under 'Scope' section of the New York State Surgical and Invasive Procedure Protocol (NYSSIPP).

Does the New York State Surgical and Invasive Procedure Protocol (NYSSIPP) mandate compliance monitoring?

Yes. Facilities should make routine compliance monitoring of areas that perform applicable procedures an integral part of their quality improvement activities including addressing non-compliance.

Scheduling

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Is the surgeon responsible for making sure the correct procedure is scheduled? If not, who is?

This is determined by the hospital. The intent is not to micromanage these processes. One suggestion was that the individuals who make these arrangements should utilize a verification system to ensure the correct procedure is scheduled and follow up phone conversations with written fax or letter.

During the scheduling process, what information regarding an implant to be placed or device to be removed should be included?

As much that is known about the implant or device to be removed should be included at the time of scheduling such as name of device, brand name, size, etc.

Does the information for scheduling need to be verified by the operating room (OR)?

Yes. The person in the operating room or department responsible for accepting scheduling requests, must verify the information provided by the surgeon/physician. Both parties must mutually agree upon the method of verification.

Should information on surgical approach be included for scheduling?

Yes. The entire procedure including the exact site, level, etc. must be written out. Example: If the approach for a laproscopic or open cholecystectomy is known at the time of scheduling, the approach should be included.

The New York State Surgical and Invasive Procedure Protocol (NYSSIPP) language regarding scheduling says that the entire procedure with exact site, level, digit, side/laterality with no abbreviations should be indicated. Does that apply to the consent form only? The use of acronyms on the schedule is not specifically addressed. Procedures such as electroconvulsive therapy (ECT), eosphagogastroduodenoscopy (EGD), or coronary artery bypass graph (CABG) are commonly referred to by the acronym in verbal and written communication.

Acronyms and/or abbreviations must not be used on the schedule except as noted (C-Cervical, T-Thoracic, L-Lumbar, or S-Sacral).

Can you verify what information should be included on the schedule regarding 'donor/recovery sites'? Example: skin grafting, the surgeon may not have identified recovery site at the time of booking.

If it is not known at the time of booking, it can be added later with confirmation from the physician's office and scheduler in the operating room.

Does the reservation/booking form have to have the same wording or description of the procedure as the wording on the consent form? Example: scheduled for a McBride procedure and consent states cutting of bone and tissue and internal fixation device.

What you are referring to is what we call the Scheduling & the Consent Document. The "name and description of the procedure" are to be in terms that are understandable to the patient with correct site/side, level and digit with the side spelled out as left, right, or bilateral. In your example, the consent has to say; "left or right", joint name, McBride procedure- cutting of the bone and tissue with internal fixation device plus all of the other specifications under

consent. The operating room schedule can have technical terminology but the consent MUST have both, the technical procedure/surgical name and the laymen's terms.

Consent

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What should be done if there is a minor change that needs to be made to the consent?

The consent form must be redone, even for a minor change.

How should the name and description of surgery or procedure be handled on the consent form?

The medical terminology should be listed first – then the laymen's term for the procedure. For example, left femoral herniorrhaphy – repair a weakness of the wall of the left groin. At least one NYS Hospital and Medical Staff has identified that they will have the patient or guardian complete the informed consent including procedure before signing. This will both increase patient involvement in the process and demonstrate understanding of the procedure.

For recovery or donor sites, on consents, the final determination is not always known pre-operatively. How specific is the requirement?

As much as is known at the time of consent should be written about the donor site(s). If it is known that they are going to take a saphenous vein graft (SVG) from either leg than it should state "saphenous vein graft (SVG) from left, right or both legs." If the radial artery is going to be the donor graft then write "right radial artery donor graft". For skin grafts: "Split thickness donor skin grafts from left thigh, any other potential place that the grafts may be taken from, etc."

With reference the word implant, how specific does the information for the consent document need to be?

As much that is known about the implant at the time of the consent. If the company name is known by the physician at the time of the consent then yes it should be written on the consent.

The clinical name of the procedure also needs to be included on the consent form for the purpose of correct coding, so would it be acceptable to include a line on the form, in the area where the procedure is written, that states "The terms describing this procedure listed in this consent form have been explained and are understood by the patient"?

No. On the same line should be the actual layman's terms that the patient can understand. This may be a struggle in some cases. Examples: 1) herniorrhaphy – repair of a weakness in the wall of the groin. 2) laminectomy – removal of a piece of bone in the spine. 3) abdomino-perineal resection – removal of the large intestine, rectum and anus with an opening placed in the abdominal wall.

Is a witness to the consent required?

The New York State Surgical and Invasive Procedure Protocol (NYSSIPP) does not address having a witness sign the consent. There is no regulatory or statutory requirement for a witness. It is however, common practice. The surgeon's and the patient's signature prior to the surgery are both requirements.

Pre-Operative/Pre Procedural Verification Process

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When a procedure is performed outside of the operating room do the films need to be viewed in the patient's room?

No, not if there is not a view box or monitor in the room. The film must be viewed where it is best viewed closest to the place that the procedure/surgery is being performed.

Does the new protocol require the pre-operative process to be done on all bedside procedures?

Yes, if they are considered invasive, as defined in the New York State Surgical and Invasive Procedure Protocol (NYSSIPP).

Who is responsible for putting up the correct x-rays in the operating room (OR)?

The facility is to make this determination, and the surgeon is responsible to make sure they are the correct films.

On survey, what proof would DOH require that compliance to the protocol is being assessed?

Each facility has to determine what Quality Assurance (QA) monitoring and documentation is done both in and out of the operating room (OR). One suggestion was that 'real-time' and 'retrospective' monitoring be done and include all expectations for documentation as outlined in the protocol.

Who should confirm the patient's name, date of the study and "Left- Right" orientation of the films for viewing in the operating room?

A physician assistant, attending physician, nurse practitioner, resident, registered professional or nurse can verify the portions of the image that are in writing. The purpose of the second person in the Radiological review is to VERIFY that the first and last name of the patient and their date of birth, or second identifier, is correct, the date of the study, and the x-ray or image is displayed in the correct orientation, using markers on the image that indicate Left (L) or Right (R). No diagnostic evaluation is required for this verification.

With regard to the pre-operative verification process, where it calls for radiology and surgical review pre-operatively in high risk cases, who decides what is a high risk case and what is the protocol for outside films?

The surgeon defines what he/she considers "high risk" and then consults with the radiology service prior to the procedure. With the New York State Surgical and Invasive Procedure Protocol (NYSSIPP) as a base, the executive committee of the medical staff may decide to make the determination that certain procedures are "high risk" and enforce those procedures for all surgeons doing them. Outside films are either retaken and reviewed by the surgeon and radiologist or reviewed by the surgeon and radiologist at the facility in which the operation is to be performed.

Does the surgical and radiological review of these high risk studies need to be face-to-face?

In this day of Picture Archive and Communication System (PACS), it does not need to be face-to-face but it does need to be synchronous or simultaneous. They both need to be looking at the images at the same time so it is "reviewed together".

Our facility identified craniotomy/burr holes as high risk procedures. If it is two in the morning and there is no radiologist in the building what do we do? The patient may be bleeding, so can we write a note stating it is life or death and waive the radiologist reviewing the film.

If it is a true emergency and no radiologist is in the facility then it is proper treatment to proceed without the surgeon/radiologist review. A radiology resident, if present, can be part of the review. The "time out" will verify the correct patient, correct site and side, the procedure to be performed, proper patient position, availability of correct implants and special equipment radiological review, etc. Documentation should follow both for the "time out" as well as the inability to do the radiologist/surgeon review.

In high risk procedures, is it acceptable for the surgeon and radiologist to review images over the telephone while both are reviewing the same images are on Picture Archive and Communication System (PACS), or is a face to face review required?

Over the phone is acceptable, as long as they are viewing the same picture simultaneously.

Site Marking

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The New York State Surgical and Invasive Procedure Protocol (NYSSIPP) indicates the physician/dentist/podiatrist doing the procedure must do the marking using his/her own initials. During your state educational sessions you indicated that someone other than attending physician performing the procedure, such as a resident/fellow who would be an involved active participant in the surgery/procedure, could do the site marking. Would you clarify this and comment on the situation where some of our hospitals that do not have residents, but have PA's that act as first assistants. Are these PA's allowed to mark the surgical site?

We indicated that someone other than the primary surgeon may be "doing the operation". For example, NOT a student who is holding a retractor or the scrub tech that cuts the sutures but someone who is significantly involved. There are procedures that may be done by physician assistant's (PA's) and nurse practitioners (NP's) where a physician is not involved, as in the example of a chest tube, and they can mark the site. In so marking, they are being acknowledged as performing a significant part of the procedure and they will be there at the start of the procedure. A physician assistant (PA) may be taking the vein grafts for a coronary artery bypass graph (CABG) and he/she can mark the appropriate leg. A physician assistant (PA), however, is not doing the craniotomy, but a senior resident may be doing a significant part of the procedure and as long as he/she is there at the start they can mark their own initials.

At what point should the site marking occur?

Marking can be done as early as the day before as long as all the requirements are met.

Can the patient receive sedation for the regional block prior to the surgeon initialing the patient's surgical site?

Yes. Utilizing the New York State Surgical and Invasive Procedure Protocol (NYSSIPP) applies to blocks, as they are an invasive procedure. The anesthesia team will initial the site of the block after the pre-procedural verification and the "time out", then give the block when the patient is properly sedated.

In the case of multiple radiation treatments, does the site have to be marked at each visit?

Radiation therapy is considered invasive so the New York State Surgical and Invasive Procedure Protocol (NYSSIPP) does apply. You would do a "time out" each time assuring the correct patient, correct site and side, correct procedure, etc. are in place. Because the tattoo "site marking" is in place for the exact site for radiation, the technician or radiologist does not need to mark the site. Remember when the radiological studies are reviewed every five days, the second person confirms that the image belongs to the patient first and last names and second identifier and that the image is displayed in the correct orientation, using (left/right) markers on the image.

Do labia and/or ovarian sites need to be marked?

The labia would fall under problematic sites to mark requiring use of a special purpose wristband. Ovarian site(s) if it is unilateral or bilateral need to be marked with initials of the physician.

For multiple surgical procedures is it permissible for the surgeon doing the second procedure to mark the site after completion of the first procedure, prior to the re-draping?

No. All surgical sites must be marked prior to the first surgery and the surgeon marking the site(s) must participate in the "time out" performed for each procedure he/she marks.

Since the intended level for injection is not always possible for intrathecal analgesia and epidural analgesia during labor, must skin marking be done with the intended level?

When the anesthetic is necessary for a midline spinal procedure, example: epidural of the lower half of the body, the level of the block does not make a clinical difference and marking is not necessary. However, if the procedure involves laterality, as in pain block, then it does require marking.

If a surgical procedure is bilateral, for example: bilateral myringotomy with insertion of tubes or bilateral inguinal hernia repair, does the surgeon need to initial both the right and left side; or does the bilateral nature of the procedure eliminate the question of laterality?

No. Both sites in a bilateral procedure must be marked by the surgeon. According to New York State Surgical and Invasive Procedure Protocol (NYSSIPP), all sites involving laterality, for example: brain and/or paired organs, multiple structures as fingers, toes, hernias, lesions, or multiple levels must be marked.

In what circumstance would it be acceptable to sedate and prepare a patient for the operating room prior to the surgeon marking the site?

It is expected that almost all patients can be fully awake and participate in the marking of their surgical site. However, there are patients coming to the OR from the ICU or patients who may not have capacity to understand their circumstances or suffer from severe anxiety. When it is in the best interest of the patient and the outcome of the patient, it is permissible to provide sedation to a patient prior to the marking of the site. It is imperative, however, that the circumstances and the indication for such treatment be documented in the patients chart.

When there is a remote incision that is not the final surgical site, which area should be marked? One example would be a groin incision for an endoscopic carotid endarterectomy. If the intended surgical site is marked, that may not be visible when the patient is draped.

When the access point for surgery bears no relation to the actual surgical site AND there is no clinical reason to access a particular site/vessel, for example: gortex graft or known aneurysm, a mark is not necessary at the access site. In such cases it does put greater emphasis on the need to STOP, FULL "TIME OUT" and AGREEMENT OF ALL PARTICIPANTS ON THE SITE(S) immediately prior to the surgery.

If a patient is undergoing a left colon resection or a right hemicolectomy, are the physicians required to mark pre-operatively, reaffirm at the "time out" or both?

Both. Make the mark at or near the incision site so that it/they will be visible when the patient is draped. A right or left hemicolectomy is a good example of a surgery that does require marking. "Time out" and the corresponding documentation apply to all surgical and invasive procedures.

Fluoroscopic procedures are particularly challenging to reduce wrong side intervention. Does the state have any recommendations for these challenging cases?

Though not part of the New York State Surgical and Invasive Procedure Protocol (NYSSIPP), the use of Right or Left radio-opaque markers being placed on the skin adjacent to the exact surgical or procedural site is a good process change. We agree with your concept of marking the correct side and site of the "main therapeutic event".

Do all surgeons who are performing one of multiple surgical interventions scheduled in one day, have to mark their own sites prior to the first procedure?

Yes, unless another practitioner agrees to mark the site, and will be present for that procedure's "time out".

One scenario mentioned was that a team does an unofficial "time out" most often in the pre-op area with the patient alert and awake and discuss the right procedure and site with the patient. The surgeon may or may not be present. Then after the patient has been anesthetized, the official "time out" takes place with the surgeon and marking is done.

The protocol calls for the patient being alert and awake at the time of the official "time out" whenever possible, with all team members absolutely present. In this scenario, the patient would not be aware of marking. Only the practitioner doing the procedure is permitted to do the marking- unless we have a multiple procedure issue on an individual, and another surgeon/part of the same day's operation(s) marks and then participates in the "time out" for that surgeon's procedure.

Has any facility shared information about a pen that does not disappear after prepping or that is visible on dark skin?

While the New York State Department of Health does not have any connection to any manufacturer, the Department of Health is aware that marking darker skin can be challenging.

What is the intent for marking the nerve root? The anesthesiologist does the block at the time they see the patient. The process for doing nerve root blocks is that they are done by the anesthesiologist, at the time the patient is seen by the anesthesiologist. They are not marked and then done later. For example, the anesthesiologist would see the patient, mark his initials then insert the needle.

Nerve blocks are done for different reasons and in different settings. When a unilateral block is planned, it should be marked/initialed in discussion with the patient. Distractions occur frequently in the health care setting, with much activity outside of the operating room. Marking of all unilateral procedures is necessary to reduce the risk of a quick, simple needle/injection being done on the wrong side while rushing to move on to the next procedure. Rushing has been identified as the #1 situation resulting in wrong site/side procedures. Please note that continuous attendance is no longer an exemption.

Can a regional block be performed as in epidural, interscalene, axillary, popliteal or fossa block before the patient has talked to the surgeon?

Yes. A block can be performed before the patient talks to the surgeon, and marked with the initials of the practitioner. The surgeon will then initial his or her initials prior to the "time out".

For carotid angiogram, when an intended site is determined, do you have any solutions or recommendations on how to mark the site/side since access can be obtained from the right or left groin and the carotid area is also draped?

Marking isn't the issue here. It is the "time out" where they confirm the patient and procedure. Access site doesn't impact the vessel that will be injected and studied.

How do you mark internal organs/sites if you do a procedure laproscopically? Example: the left ovary.

You could mark the skin of the side that would be treated or use a special purpose wristband. For spinal procedures, an internal marker, with second "time out", is the expectation.

Wrist Band

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When is a special purpose alternative wristband appropriate for the patient?

A special purpose wristband is an alternative to marking in those special cases when site identification is necessary, but either the patient reuses site marking, is a neonate (marking may cause a permanent tattoo) or when the anatomical location makes marking either difficult or not readily visible during surgical preparation or during the "time out".

When is marking not required?

Marking is not required when:

- a) There is a single lesion to be repaired in an openly visible position. Example: open fracture humerus of tibia to be repaired; single open laceration to be repaired.
- b) Entry is via a midline orifice and the structure to undergo a procedure is also midline and/or directly in view of the physician performing the procedure.

What are hospitals using for the Special Purpose wristband? Any information available on purchasing?

Facilities ought to be able to get the special purpose wristbands from whoever currently provides their regular wristbands. They should pick one that meets their needs.

Time Out

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For procedures done outside of the operating room, is it mandated that the "time out" be done with another person?

No. However, when a procedure is being done without assistance it is strongly advised that the person enlist an observer or assistant to participate in the "time out".

If the patient is having an upper endoscopy and colonoscopy done by the same physician, what is the criterion for the "time out"?

The "time out" for both can be done at the same time since the endoscopist is the same for both procedures.

Is a "time out" required for Computerized Tomography (CT) procedures with contrast?

Yes. The New York State Surgical and Invasive Procedure Protocol (NYSSIPP) applies to all Computerized Tomography (CT) procedures with contrast including the "time out". You want to make sure that a full "time out" is done, that you have the correct patient first and last names, the second ID, correct side and site of the procedure that is to be scanned, correct contrast agent, route and dose.

A patient having a surgical procedure is brought into the operating room with an anesthesiologist, two RNs, and tech present. The Anesthesiologist performs a spinal anesthetic. The surgeon then comes into the room to perform the surgical procedure. Are two "time out" procedures required? One before the spinal (with the anesthesiologist and staff in the room at that time), and one before the surgery with the entire team?

Surgeon then comes into the room to perform the surgical procedure. Are two "time out" procedures required? One before the spinal (with the anesthesiologist and staff in the room at that time), and one before the surgery with the entire team?

Yes. Each procedure has its own "time out". What does "each procedure" mean is the next question? In this case it is easy. The spinal would be one procedure and the surgery the other. Suppose the patient also has a tubal ligation? That would be done by the same surgeon and part of the original "time out". The "time out" needs to be done by the surgeon doing the procedure so if he/she is present at the beginning it can be done then. If he/she is not present at the beginning and the procedure is not included in the "time out", then it needs to be done prior to the procedure.

Does the state consider a pap test to fall under New York State Surgical and Invasive Procedure Protocol (NYSSIPP)? [Revised December 12, 2008]

The answer to this questions has changed as of 12/12/08. The NYSSIPP does not apply in all its detail to Pap smears. It would be appropriate, however, to include a step in your process for this procedure that verify's labeling of specimens.

Does the surgeon need to be present during the needle localization for a biopsy?

No, as long as the radiologist and any other staff deemed appropriate are present.

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