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/side, 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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