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Patient Safety Initiative Update

- The second annual report, Patient Safety Initiative: 2006 Summary Report (link to http://www.nj.gov/health/ps/documents/ps_report_2006.pdf) was released in January 2008 covering 2006 reporting and Patient Safety Initiative activities. Overall reporting has increased both in terms of the number of reports and the number of hospitals making reports. Falls and pressure ulcers continue to be the most frequently reported events.

- The rules implementing the Patient Safety Act (P.L. 2004, c.9) were approved by the Health Care Administration Board in January 2008 and published in the New Jersey Register in March 2008. Those rules establish a time frame for implementation of the rules for all licensed health care facilities. In addition, the rules define the requirements for each licensed facility to develop a patient safety committee and a patient safety plan.

- Based on approval of the rules, psychiatric, special and comprehensive rehabilitation hospitals began mandatory reporting on April 1, 2008. Those facilities have been notified regarding the initiation of reporting. General hospitals continue to report as required under the earlier system. Additional materials on how to prepare an RCA have been provided to all reporting facilities. A special training session on event reporting and RCA development will be offered in June for special, psychiatric and comprehensive rehabilitation hospitals.

- A revised Mandatory Patient Safety Reporting Requirements for Licensed Health Care Facilities (link to http://www.nj.gov/health/ps/documents/final_directions_march08.pdf) is available on the Patient Safety site. This manual reflects the passage of the rules and the implementation of

the reporting system for all acute care hospitals. The only change in the rules is that hospitals are required to report an event within five days after discovery. The requirement that hospitals report within five days of when the event **should have been discovered** was deleted from the rules.

Invasive Procedures: Wrong Patient, Wrong Site, Wrong Procedure

The Patient Safety Initiative has received reports of Surgery-Related Events from various hospitals across New Jersey. Specifically, there were reports of surgeries and invasive procedures performed on the wrong body part, the wrong patient and incidents where the wrong procedure was conducted. These are errors that can be avoided by consistent use of widely accepted universal protocols. This issue of *Patient Safety Initiative Updates* considers the problem of correct identification for invasive procedures in the operating room as well as other locations.

Ensuring the Correct Surgery and Invasive Procedure

In 2004 the Joint Commission required all accredited organizations to comply with the *Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery*™.[1] The purpose of this protocol is to ensure communication between and among the surgical staff and the patient to verify the correct procedure on the correct patient and the correct site. The main components of this protocol include:

- **Preoperative verification process**: verification of patient's identity, determination that all relevant documents (e.g., history and consent), studies, and images are properly labeled and available before the start of the procedure, and any required equipment or implants are available.

- **Marking the operative site**: an unambiguous mark, such as, initials or "yes", should be placed at or near the incision site in indelible ink that is visible after the patient is prepped and draped.

- **Time out immediately before the start of the procedure**: must be conducted in the location where the procedure will be done and involve the entire operative team; should be documented and include correct patient identity, correct side and site, agreement on procedure being performed, correct patient position, availability of correct implants and any special equipment.

- **Adaptation of the requirements to non-operating room settings, including bedside procedures**: must include verification, site marking, and "time out" procedures.

Second Looks:
Review of Events and RCAs

Despite the presence of a *Universal Protocol* that is available to hospitals and patient care providers, for quite some time now, there are reports of events which demonstrate the protocol is not being consistently applied. The following are some examples of reports and follow-up by those involved.

Events in the Operating Room

1. *A patient was admitted with a diagnosis of a left hip fracture. The patient went to the operating room for surgical repair of his left hip and the surgery was incorrectly started on the right hip. During the preoperative interview the nurse verified the correct surgical site but did not mark it; this failure to mark the correct site created a critical ambiguity that was not corrected. The "time out" procedure was incomplete and conducted while the patient was still in bed and not in the operating room. The fact that the site*

was not marked was clear and obvious to the staff; however this was not corrected during the time out procedure.

Response: To prevent this type of error from reoccurring, the Wrong Procedure/ Wrong Patient policy for this facility was revised and strengthened. The physicians performing the procedure are now required to mark the site with their initials in indelible ink and are responsible for initiating the "time out" and ensuring that it occurs in the location where the procedure is being conducted. The completion of a "time out" is now documented.

2. *A patient was admitted for open reduction and internal fixation of the right fourth finger fracture. During the preoperative interview the correct site was verified and marked "yes" by the physician with the patient. During the patient preparation for surgery, the right hand of the patient was scrubbed with a betadine solution which removed the site mark. The surgeon began the surgery and incorrectly made an incision on the right third finger. The nurse manager recognized the mistake and informed the surgeon, who then closed the incision and initiated the procedure on the correct fourth finger.*

Response: To avoid this type of error from occurring in the future, the markers have been replaced with Association of periOperative Registered Nurses (AORN) indelible markers. All "time out" procedures now include assurance that the site marking is visible after the skin preparation. This facility also initiated a hospital-wide "time out" day and distributed "time out" posters to all the departments and staff in an effort to raise awareness.

Events in a Non-Operating Room Setting

Wrong site, wrong patient, wrong procedure surgery is not just an issue for the operating room; it can occur during any invasive procedure performed in an office, ambulatory setting, or at the bedside.

3. *A patient was scheduled for an esophagogastro-duodenoscopy (EGD) in the endoscopy unit. During the preoperative interview, the nurse questioned the patient about what procedure he was having and the patient replied that he was having a colonoscopy. This information was not*

verified and the "time out" procedure was not performed resulting in a colonoscopy being performed instead of the EGD.

Response: This facility now only accepts written orders for confirmation of procedures. The endoscopy staff was re-educated on the *Universal Protocol* and on conducting a "time out". The "time out" documentation was revised to include the names of those participating in it and requires two signatures verifying the completion of the "time out".

4. *A patient went to the emergency department with dyspnea. The patient was evaluated by a physician who decided that a thoracentesis was needed on the right side; however, he inserted the thoracentsis needle on the left side. The physician immediately realized his mistake and repeated the procedure on the correct side. The correct site was not marked prior to the procedure and a "time out" was not conducted.*

Response: An online *Universal Protocol* education module is being developed and all medical staff are required to complete and pass this module prior to appointment and/or reappointment. Residents and rotating residents would also be required to complete and pass the *Universal Protocol* training. This facility also posted "time out" stop signs throughout the departments starting with the emergency department.

Effective Corrective Actions

Several healthcare organizations have developed recommendations to supplement the Joint Commission's *Universal Protocol* in preventing surgery related events. The Partnership for Health and Accountability in Georgia's *Successful Practices for Correct Site Surgeries/Procedures* recommends that facilities' "time out" procedures include a clear description of which specific procedures require a "time out" and at what point during the procedure a "time out" is required.[2] The policy should designate who is responsible for calling the "time out". The "time out" must include confirmation of correct patient identity, correct site and side, agreement on the procedure to be performed, correct patient position, and availability of correct implants and special equipment. Also, the surgical team must give active confirmation for each of these elements. If there are any discrepancies, there should be a description of the

reconciliation process. Finally, the "time out" must be documented and include signatures indicating that all the team members were in agreement with all the required elements. To help implement the "time out", it is recommended that facilities require the nurse to withhold or hide the scalpel until the "time out" is completed.

The Department of Veterans Affairs, Veteran Health Administration developed "Seven Absolutes to Avoid Surgical Site Errors".[3] These absolutes include having the operating room office schedule each procedure involving laterality with a right or left designation; having the nurse verify each correct surgery site with the operating room schedule and the patient's current medical record; and having the patient verify each surgical site in the presence of a nurse and if possible mark the site. The surgical team should interview the patient; review the patient's current medical record and the results of any diagnostic tests and verbally verify each surgical site and procedure. After the patient is draped, the surgical team must pause and verbally confirm each site prior to incision. The nurse will document the verification process in the patient's medical record.

The New York State Department of Health also developed a policy for surgical and invasive

procedure protocol. This policy incorporates the same standard guidelines as Joint Commission, Veteran Health Administration and Georgia's Partnership Accountability. However, the protocol expands the scope of the policy to include all operative and other invasive procedures performed in the operating room as well as in special procedure units, endoscopy units, and interventional radiology suites.[4] This protocol covers invasive procedures that involve punctures and incisions of the skin, the introduction of any instrument or foreign material into the patient, such as, percutaneous aspirations, biopsies, and catheterizations. The preoperative/pre-procedural verification process is required for invasive procedures in all clinical settings, including endoscopy units, catheterization laboratories, interventional radiology suites, intensive care units, labor and delivery areas, and emergency departments.
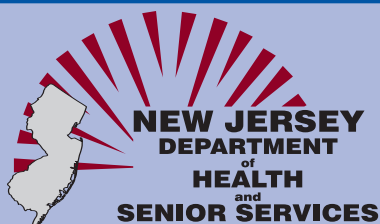
This policy also expands on specific steps within the protocol. During site marking, if the site is not visibly identifiable, the surgeon is to obtain an intraoperative image to mark. When multiple surgical procedures are being performed by different surgeons, all the sites must be marked prior to the start of the initial surgery. Each surgeon must be present for the site marking and participate in the "time out" for each procedure he/she marked. During the "time out" if the procedure is being performed without assistance, the protocol strongly recommends that an observer or assistant participate in the "time out". If a new surgeon arrives and is assuming primary responsibility for the procedure, another "time out" is to be conducted. For procedures that require radiological images to be displayed, a second team member must confirm that the image belongs to the patient, that the image is oriented correctly, and that the proper site is marked. It is also recommended that instruments and equipment not be offered until after the "time out" is performed.

In Conclusion

All facilities and patient care providers performing invasive procedures should adopt the *Universal Protocol* including the "time out" procedure to ensure the safety of their patients. The processes are straightforward but demand strong hospital procedures, effective communication, and constant adherence to the protocols. This is especially true for invasive procedures that occur outside the operating room where this process is not as widely accepted as routine practice.

References

[1] The Joint Commission, "Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery ™" 2003 Available at http://www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf

[2] Partnership for Health and Accountability in Georgia, "Correct Site Surgery/Procedures Successful Practices in Georgia" Available at http://www.gha.org/pha/keyissues/correct-sitesurgery/index.asp

[3] Mathias J, " VHA's Program to Curb Wrong Site Surgery" *OR Manager* 2002 Mar;18(3):7-9

[4] State of New York Department of Health, " New York State Surgical and Invasive Procedure Protocol for Hospital, Diagnostic and Treatment Centers, Ambulatory Surgery Centers, and Individual Practitioners" 2006 Available at http://www.health.state.ny.us/professionals/protocols_and_guidelines/surgical_and_invasive_procedure/docs/protocol.pdf