Minnesota Patient Safety Alert

March 16, 2011

Spine Level Localization

Background

Approximately 30 percent of wrong-site surgeries reported under the Minnesota Adverse Event Reporting Law are wrong level spine procedures.

Review of reported wrong level spine procedures indicates that key localization issues include:

1) There are issues that make placing the radiopaque instrument for intra-operative imaging prone to misinterpretation. These include: abnormal anatomy (segmentation anomalies, arthritic changes); specific placement and/or movement of the marker; and patient size limiting quality of imaging.
2) The radiopaque instrument used to identify the current level for intra-operative imaging is often removed prior to placing a durable mark at that level resulting in the misinterpretation of the X-ray when it is available to be viewed in the room.

In November 2010, a work group of Minnesota spine surgeons met to review the findings from reported events and to develop recommendations to address identified key issues associated with wrong level spine procedures. The resulting recommendations are outlined on page two of this safety alert.

For more information on this alert, contact Julie Apold, MHA director of patient safety, at japold@mnhospitals.org or (651) 641-1121 or toll-free at (800) 462-5393 or Diane Rydrych, Assistant Director, Division of Health Policy, MN Department of Health, (651) 201-3564.

Spinal Level Localization Recommendation

These recommendations are intended to provide guidance to improve the consistency of identifying spine levels for surgical procedures in Minnesota hospitals and to address issues identified through the reporting of wrong level spine procedures through the Minnesota Adverse Health Care Event Reporting Law. The recommendations are not intended to address all clinical and regulatory requirements related to surgical procedures.

- Appropriate pre-operative images, as determined by the person performing the procedure, are available for the case:
  - Good quality image
  - Available prior to induction of anesthesia
  - Immediately available for viewing throughout the case
  - If in the clinical judgment of the surgeon there are abnormalities or questions about the films, surgeons are encouraged to conduct a review of preoperative images with an attending radiologist.

- Site marking is completed using appropriate source documents.
  - Marking indicates:
    - Anterior or posterior approach
    - General level, i.e. cervical, lumbar, thoracic
    - Laterality, if applicable
  - Time-Out occurs just prior to incision and includes:
    - Procedure
    - Laterality, if applicable
    - Level

There are two options as the next step in the process:

Option 1	*or*	Option 2
➢ Real-time intra-operative imaging, such as fluoroscopy or stereotactic navigation, is used to verify proper placement of instruments. ➢ A pause is conducted before executing the procedure. o At a minimum, the person performing the procedure must verbalize the level and the procedure team confirms against source documents.		If real-time intra-operative imaging is not used, the spine level is localized by following the process below: ➢ ***Following incision and exposure of the vertebrae***, a fixed anatomic structure is marked with a radiopaque instrument/marker by the surgeon and correct placement confirmed by intraoperative imaging (unless pre-existing landmarks are obvious and sufficient): o Radiopaque instrument/marker should remain visible to surgeon throughout the case (when applicable, e.g., cases in which pre-existing landmarks are not obvious and sufficient) **or,** o If removeable radiopaque instrument is used during imaging, a durable mark or marker should be placed at the precise location as the instrument and should be placed at the same time the radiopaque instrument is placed. o Instrument/marker should be placed on a stable anatomic structure. ➢ After mark/er is placed and imaging available, the individual ultimately responsible for the procedure performs the count of the vertebrae to verify correct level. *Any discrepancies between the count, images and mark/er are resolved prior to continuing with the procedure.* ➢ A pause is conducted before executing the procedure. o At a minimum, the person performing the procedure must identify the marked level on the image, verbalize the level and the OR team confirm against source documents.