Minnesota Patient Safety Alert

May 11, 2012

Implant Verification

Background

Close to 40% of wrong surgeries/procedures reported under the Minnesota Adverse Event Reporting Law last year (October 7, 2010-October 6, 2011) were related to wrong implants.

Review of reported wrong procedure events involving implants indicated issues with verification of the correct implant at each step of the process including:

- Scheduling
- Requesting the implant(s)
- Pulling the implant(s) prior to case
- Team Briefing
- Pre-procedure verification
- Time Out
- Selecting implant(s) from case cart

In January of 2007, a Minnesota Safety Alert was issued related to preventing wrong eye/wrong lens procedures: http://www.mnhospitals.org/inc/data/pdfs/Alert_Advisory_1-9-07.pdf.

The Minnesota Department of Health and Minnesota Hospital Association have reviewed: 1) the root cause analyses from wrong procedure events occurring this past year involving implants; and 2) national and local best practices to develop a set of recommendations for implant verification. The recommendations include verifications steps for:

1. Intraocular implants (IOL)
2. Other implants — when implant is known prior to the case
3. Other implants — when implant is not known prior to the case, e.g. hip or knee replacements.

The resulting recommendations are outlined beginning 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 Rachel Jokela, Adverse Health Event Program Director, MN Department of Health, Rachel.Jokela@state.mn.us or (651) 201-5807.

Implant Verification Recommendations

May 11, 2012

These recommendations are intended to provide guidance to improve the consistency of implant verification practices across Minnesota hospitals and ambulatory surgical centers and address issues identified through the reporting of wrong procedures related to incorrect implants. The recommendations are not intended to address all implant related clinical and regulatory requirements.

Implants — Intraocular lens (IOL)

Verification of correct intraocular lens placement (IOL)

- The facility has a process in place to require ordering providers to submit IOL requests in writing.
- IOL requests must be received prior to case prep, at minimum, for the case to proceed.
- IOL requests include, at a minimum, the following key IOL information:
    - Date of surgery
    - Patient
    - Surgeon
    - Right vs. Left
    - Posterior vs. anterior
    - Model #
    - Diopter

- If the facility does not receive a written IOL request prior to case prep (ideally received earlier in the process) with completed key IOL information, the case does not move forward.

- If the surgeon selects the IOL for the case from the supply area, the written request including the key IOL information still needs to be completed by the surgeon prior to case prep.

- A process is in place to verify the correct lens at the following times, at minimum:
    - Selection of IOL implants for case from supply area
        - Verification: Verify correct lens against source documents such as the implant request form, patient's medical record, surgical notes.
    - Pre-operative team briefing
        - Verification: Verify implant is available for case.
    - Time Out process
        - Verification: Verify implant is available in the room for case.
    - Opening the implant to the sterile field.
        - Verification: 1) confirm the implant packaging against source documents, such as the implant request form; 2) read aloud the implant information from the packaging; and 3) show the packaging information to the surgeon.

- The source documents, such as the implant request form, and selected implant are kept together after selection of the IOL for the case.

- The facility requires that only one lens (per operative eye) per case is in the procedure room. If the surgeon requests more than one option, as soon as a decision is made on the correct lens for the case, the second lens is placed out of sight in a pre-designated area.

Implants — If implant is known prior to procedure (non-IOL procedures)

- The facility has a process in place to require ordering providers to submit implant requests in writing.

- Implant requests include, at a minimum, the following key information:
    - Date of surgery
    - Patient
    - Surgeon
    - Implant and specifications the facility will need to order or pull the implant for the case
    - Right vs. Left, if applicable
    - For breast implants: Saline vs. Silicone

- If the facility does not receive a written implant request prior to case prep (ideally received earlier in the process) with completed key information, the case does not move forward.

- A process is in place to verify the correct implant at the following times, at minimum:
    - Selection of implants for case from supply area, if applicable
        - Verification: Verify correct implant against source documents such as the implant request form, patient's medical record, surgical notes.
    - Pre-operative team briefing
        - Verification: Verify implant is available for case.
    - Time Out process
        - Verification: Verify implant is available in room for case.
    - Opening the implant to the sterile field.
        - Verification: 1) confirm the implant packaging against source documents, such as the implant request form; 2) read aloud the implant information from the packaging, including laterality if applicable; and 3) show the packaging information to the surgeon.

- The facility requires that only the implant needed for the case is in the procedure room. If the surgeon requests more than one option, as soon as a decision is made on the correct implant for the case, additional implants are placed out of sight in a pre-designated area.

- The facility has developed an orientation for vendors involved in selecting implants for procedures which includes expectations for the vendor's role in implant verification.

- The facility requires that vendors complete orientation prior to handling implants prior to, or during, a case.

- If a vendor selects the implant for the case, the implant is handed off to a member of the procedure team who completes verification of the implant against source documents.

- The vendor does not introduce the implant to the sterile field.

Implants — If correct implant is not known prior to procedure (e.g., need to trial multiple knee components during procedure prior to final implant selection):

- The facility has a process in place to require ordering providers to submit implant requests in writing.

- Implant requests include, at a minimum, the following key information:
    - Date of surgery
    - Patient
    - Surgeon
    - Right vs. Left, if applicable
    - Which implant options to have available

- If the facility does not receive a written implant request prior to case prep (ideally received earlier in the process) with completed key information, the case does not move forward.

- A process is in place to verify the correct implant at the following times, at minimum:
    - Selection of implants for case from supply area, if applicable
        - Verification: Verify correct implant against source documents such as the implant request form, patient's medical record, surgical notes.
    - Pre-operative team briefing
        - Verification: Verify implant is available for case.
    - Time Out process
        - Verification: Verify implant is available in room for case.
    - Selection of implant from case cart, if applicable
        - Verification: Verify correct implant against source documents such as the implant request form.
    - Opening the implant to the sterile field.
        - Verification: 1) confirm the implant packaging against source documents, such as the implant request form; 2) read aloud the implant information from the packaging, including laterality if applicable; and 3) show the packaging information to the surgeon.

- If cart is in procedure room with multiple implants, ideally only the cart with the correct side implants (L vs. R) is in the room. If carts are not able to be separated (L vs. R) due to storage or other issues, left and right components are clearly separated and labeled on the cart.

- The facility has developed an orientation for vendors involved in selecting implants for procedures which includes expectations for the vendor's role in implant verification.

- The facility requires that vendors complete orientation prior to handling implants prior to, or during, a case.

- If a vendor selects the implant for the case, the implant is handed off to a member of the procedure team who completes verification of the implant against source documents.

- The vendor does not introduce the implant to the sterile field.