Wrong-site surgery is a stubborn problem across the country. Rhode Island Hospital in Providence has used its well-publicized experience with wrong-site surgery to dissect the process and learn how to prevent these events. The 719-bed hospital, which performs about 25,500 surgical procedures a year, has had 3 wrong-site surgeries in the OR and 2 at the bedside in recent years.

After the most recent incident (sidebar, p 21), Rhode Island Hospital and Newport Hospital, a sister facility in the Lifespan system, volunteered to be the first to work with the Joint Commission’s new Center for Transforming Healthcare (CTHC) on a project to prevent wrong-site surgery. Another Life-span facility, Miriam Hospital, also collaborated on the project.

CTHC aims for breakthroughs on some of health care’s toughest problems, such as hand hygiene and wrong-site surgery, by teaming with hospitals to apply sophisticated quality improvement techniques like Lean Six Sigma.

‘We had a choice’

After the wrong-site incidents, “We had a choice—to let the morale get worse and to feel bad about ourselves and our practice, or to say, ‘We are going to fix this,’” says Rhode Island Hospital’s administrative director of perioperative services, Diane Skorupsi, RN, MS, CNOR, NE-BC.

An update on the project was presented at the Joint Commission Conference on Quality and Patient Safety in June 2010 in Chicago.

The CTHC team worked with the hospital’s project team to use tools such as DMAIC (Define, Measure, Analyze, Improve, Control), failure modes and effects analysis (FMEA), statistical process control, and Lean management.

The CTHC project on wrong-site surgery isn’t finished. “We need to do more work to validate what was learned and the solutions,” says Erin DuPree, MD, a member of the CTHC team. She cautioned hospitals not to think they must adopt the steps taken at Rhode Island Hospital.

Rhode Island Hospital’s perioperative leaders talked with OR Manager about the project so far.

As in other ORs, the ultimate goal is to move away from a hierarchy to a team-based culture that encourages communication to verify the surgical site and the plan for surgery. In the meantime, the process is being standardized to reduce opportunities for error.

Analyzing failure modes

FMEA is an analytical tool for identifying where failures might occur and classifying them by the likelihood and severity of the potential failures.
The Rhode Island team conducted an FMEA to identify potential failure modes in its Universal Protocol process. For example, one failure mode was identifying implants during the briefing. Intraocular lenses are the implant with the highest risk of an error because more than one lens can be ordered per patient, and the lens is patient specific.

In the revised process, the patient and lens are matched through primary source verification: correct patient, correct surgical consent, and correct implant request. The verification is conducted prior to the day of surgery and is reverified during the preoperative briefing on the day of surgery before the time-out.

The perioperative leadership team now uses the FMEA as a working document, Skorupski says, adding potential failure modes and monitoring processes. Each department shares the top 3 risks for failure with the clinical staff and solicits their input.

The team has also conducted FMEAs on specific parts of the process, such as scheduling, preadmission testing, the preop process on the day of surgery, and the intraoperative phase of care.

**A Leaner time-out**

Applying Lean management principles, the team streamlined the time-out. Lean involves analyzing work processes to improve flow and eliminate steps that don’t add value.

Previously, the time-out was cumbersome, Skorupski notes, and wasn’t accomplishing its true purpose—to be a final verification stop before the incision and to promote communication among the OR team members.

Now “we keep the time-out crisp, with the patient identification, procedure, side, and site,” she says.

To streamline the process, the primary documentation and patient information are verified in the preoperative area and again during the briefing in the OR prior to prepping and draping.

**Auditing the process**

Every time-out process is audited for 14 components of surgical site verification. Examples are: Was the surgical site visible? Did the surgeon initiate the time-out? Did the surgeon use the wording specified?

The audits are required by the state health department, which mandated that for every procedure, the site marking and time-out are observed by a licensed clinical professional who is not part of the surgical team. Rhode Island Hospital added a behavioral component to the audits to monitor cultural change and ensure the surgeon initiates the process.

The audits also enable the team to collect detailed data to highlight compliance issues and aspects of the process policies don’t cover as well as to monitor cultural change.

Audits offer opportunities for coaching and teaching.

“Every time a surgeon has to be prompted [to lead the time-out], we see that as an opportunity,” Skorupski says.

Time-out audit results are trended daily and graphs posted so OR personnel can see how they’re doing.

**Key observations**

The hospital’s work with Lean, FMEA, and the audits has led to changes that the leaders think have increased the safety and accountability of the Universal Protocol process.
One finding was the need for OR teams to focus consistently on the briefing and time-out. Root cause analyses at Rhode Island Hospital and other hospitals have found that even with a brief time-out, “there is an opportunity not to be focused,” Skorupski says.

In another change, the surgeon must be present in the preoperative holding area for the site verification and marking of the surgical site. The surgeon, with the preop RN, initials the site in the preop area using primary documentation prior to coming to the OR. The surgeon must also initiate and lead the time-out in the OR.

Having the surgeon present in the holding area “has been the key” to getting surgeon buy-in for the process, says the OR’s medical director, Edward Marcaccio, MD.

He also believes the surgeon’s collaboration with the preop nurse in verifying the patient’s primary documents before entering the OR has made the process safer.

“I think nothing was more important than getting the surgeon to the holding area to discuss with the patient and the team where and what exactly the procedure was going to be,” he says. The update for the history and physical also takes place in the holding area.

Surgeons have found there’s a benefit for them—cases tend to start on time when they are in the holding area.

Engaging the team

During the time-out, 3 steps were added to engage the entire team:
• All surgical team members are to view the surgical site.
• The surgeon is to point and touch the site and say: “Can everyone see my mark? This is where I am making my incision.”
• The surgeon asks: “Does anyone have any concerns?”

“One important thing was changing the surgeon’s role to a more active one,” Dr Marcaccio notes. “It is not the surgeon simply nodding when someone else is going through the checklist. The surgeon leads with the elements of the identification and the discussion of the procedure because only the surgeon really knows what the operative plan is.

“Once the surgeons took ownership of the process, I think it really helped to facilitate communication in the OR,” he says.

Leaving room for judgment

The project team also learned site-marking rules can’t be written for every situation. There must be room for judgment and situations that do not fit clear-cut guidelines. Examples are cystoscopy and other procedures conducted through natural orifices.

If a surgeon thinks the site can’t be initialed, the policy states that the surgeon must document why the site can’t be initialed and include a reason beyond stating, “Site not marked.”

“Again, the key is communication throughout,” Skorupski says. “If a patient arrives in the OR, and the site isn’t marked, the surgeon will say, ‘This is where I am going to do my procedure. I did not mark the site because’ and gives a reason. The surgeon then gives the staff an opportunity for feedback and communication.”

Leaders seek input from clinicians to clarify specific situations. Questions are reviewed by the surgical executive committee to provide standardized answers. The management team posts answers to frequently asked questions to guide practice.
“The staff can apply their understanding and use the FAQs to guide them in unfamiliar situations,” Skorupski says. “The policy provides guidelines. Clinicians need to use their critical thinking skills to apply the policy to each situation. Communication is the key. The team must discuss each case and apply the process in an individualized manner.”

For example, recently a patient had 2 procedures by 2 surgeons on a wrist and the nose, raising questions about how to verify and document the sites. The surgical team held a conversation to make sure all members were in agreement about the body parts to be operated on.

“The biggest benefit of the change in the process here is that it is a large step toward a change in the culture from a hierarchy to interactive communication,” she says.

Skorupski says she is confident that the project will demonstrate what she and other leaders have known all along: “This is a great hospital, we are safe, and the community should be glad Rhode Island Hospital is here.”

—Pat Patterson

Representing CTHC on the Rhode Island project were Rick Morrow, a Six Sigma Black Belt; Kate Ranft, a master change agent; and Erin DuPree, MD, a Six Sigma Green Belt. The Rhode Island team included Diane Skorupski, RN; Michele Serino, RN; Dave Pierel, RN; Pat Marshall, RN; Elaine Noren, RN; Rene Chiovitti, RN; and Edward Marcaccio, MD.

Compliance order on wrong-site surgery

In the most recent wrong-site surgery incident at Rhode Island Hospital in October 2009, a surgeon mistakenly performed 2 procedures on the same finger of a patient’s right hand instead of 1 procedure each on 2 fingers of the hand. The state department of health found the site markings and time-outs had not been performed according to policy.

The hospital was placed under a second compliance order and fined $150,000. The compliance order requires the hospital to among other things:
• ensure every surgical site marking and time-out is observed by a licensed clinical professional who is not part of the surgical team
• mandate that surgeons mark the site in the preop area with the assistance of a second licensed professional
• require surgeons to use primary sources such as the consent and history and physical to verify the site
• develop a plan for educating the staff and implementing changes based on data and observations
• conduct mandatory training of surgical site verification procedures
• install video and audio monitoring equipment in all ORs to monitor site marking, time-out, and team dynamics.

Source: Rhode Island Department of Health. www.health.ri.gov