



Hospital Quality Institute Vanguard Award 2016

Sharp HealthCare
8695 Spectrum Center Blvd
San Diego, CA 92123
www.sharp.com

Contact Person:

Patricia Atkins, MS, RN
Vice President, Quality and Patient Safety
Patricia.atkins@sharp.com
858-499-3525

Assistant:

Becky Fritzges
Rebecca.Fritzges@sharp.com
858-499-3115

Title of Application:

Eliminating Wrong-site, Wrong-procedure, and Wrong-patient errors (WSPEs) Through Commitment, Collaboration and Accountability

Topical Area of Focus: Patient Safety

Brief statement by an executive leader in support of the application:

“The wrong kidney removal event in 2012 was absolutely devastating. So, I gathered a multi-speciality group of physicians, executives, and leaders from nursing, procedural areas and IT to examine our pre-procedural processes. What we found at Sharp was similar to what had been reported in the literature. We had weaknesses in scheduling, verification, site marking, time out and a lack of a safety culture. The causal factors were often attributed to rushing, lack of clarity, and policies which allowed physicians to autonomously act outside of generally accepted practice and safety standards. We partnered with the Medical Executive Committees to raise the bar on our safety practices. After four years and many cycles of improvement, we have proven results that reflect highly reliable processes. The improvement work never ends but our teams are more capable and collaborative than ever before. We are proud to share our challenges and successes in hopes of helping other hospitals eliminate WSPEs and the harm that patients suffer.

Dan Gross, DNSc, RN, Executive Vice President, Sharp HealthCare

I. Executive Summary

Sharp HealthCare is the largest healthcare system in San Diego and approximately 300,000 invasive procedures are performed annually in four acute care and three specialty hospitals. Although our overall rate for wrong-site, wrong-procedure, and wrong-patient errors (WSPEs) is better than average, Sharp's goal is to have zero WSPEs.

The Safe Surgical and Procedural Experience Committee (SSPEC) began in 2012 after a significant WSPE. This event and some near misses created a strong call to action and a system-wide team including a multi-specialty group of physicians, executives, and leaders from surgery and procedural areas and IT that examined the enormous complexity of operative and procedural systems. The team created reliable processes in the areas of: scheduling, site-marking, required relevant images, pre-procedural verification, consent, radiologic image error correction, and physician onboarding. In addition, several strategies to improve the safety culture were implemented.

At the beginning of this initiative, a patient experienced a WSPE at Sharp every 71 days on average. We are proud to report that we have achieved 377 days between events. Sustainment strategies are now underway and improvements will continue as teams are more capable and committed than ever to ensure that patients receive the intended procedure 100% of the time.

II. Background and relevance of the problem being addressed and effort undertaken

Few medical errors are as alarming as a Wrong-site, Wrong-procedure, and Wrong-patient errors (WSPEs). Patients are harmed, families are distressed, physicians and staff are traumatized and organizations suffer as trust is eroded internally and within the community. The Joint Commission reports that (WSPEs) continue to occur and they are the most frequently reported sentinel event with 1,196 reports through September 2015¹. A 2006 seminal study found that wrong-site errors occur in approximately 1 out of 112,000 surgical procedures². However, this estimate is based only upon malpractice claims and grossly underestimates the true incidence. Also, this study only includes procedures performed in the operating room. Another study using Veterans Affairs data found that half of WSPEs occurred during procedures outside of the operating room³. In 2011, Mark Chassin, the Joint Commission President estimated that WSPEs occur 40 times every week. In a ten-year analysis at Sharp HealthCare from 2006 to 2016, 28 events were reported and included the following types of WSPEs:

- Wrong lens implant – 7
- Wrong tube/catheter placed – 4
- Wrong side block – 3
- Wrong side incision – 3
- Wrong spine level – 2
- Wrong patient artificial rupture of membranes – 1
- Wrong side stent placed – 1
- Wrong side craniotomy – 1
- Wrong side biopsy – 1
- Wrong side nephrectomy – 1
- Wrong patient for radiation – 1
- Wrong breast lesion removed – 1
- Wrong procedure – 1
- Wrong orthopedic implant – 1

Most of these events did not result in permanent harm to the patient as many were caught and promptly corrected; however, a few resulted in serious, permanent harm. The Joint Commission calls all of these “never events” and only with highly reliable processes, fully engaged teams, and a strong safety culture will these events never occur.

III. Describe the effort, including the scope, process, strategies and tactics utilized, challenges encountered and how they were addressed.

The Safe Surgical and Procedural Experience Committee (SSPEC) was formed in 2012 with the goal of creating highly reliable processes that would support the elimination of WSPEs at Sharp hospitals. The system-wide committee met monthly and initially focused on reviewing the literature and studying the vulnerabilities within Sharp. Sharp leaders reached out to the experts in WSPEs, The Joint Commission Center for Transforming Healthcare and the Pennsylvania Patient Safety Authority, to learn from their experience.

The importance of creating openness and transparency was continuously emphasized. When events and near misses occurred there were forums created to openly discuss them in the spirit of learning without judgment. Our first priority was to create a safe environment to embrace our failures and capture the learning so improvements could be made.

A Broad and Deep Project Scope

- SSPEC was comprised of a multi-professional, system-wide collaboration across 34 inpatient and outpatient surgical and procedural departments
- There was strong physician engagement (over 20% of team membership) crossing several specialties (anesthesia, surgery, cardiology, OB/GYN, orthopedics, and radiology)
- This was a four-year engagement with a focus on sustainment and safety culture
- The scope encompassed the entire procedural process from scheduling to incision.
- The specificity of the standard work was unprecedented

Process, Strategies and Tactics Utilized

Eleven workgroups were formed to address the priorities for improvement. Using Lean Six Sigma tools and processes, improvements were deployed to 34 OR and procedural departments. The following improvements were hardwired:

Process	Improvement
Scheduling	Mandated written/faxed booking form with required fields to reduce scheduling errors; leveraged technology solutions Created immediate feedback to physician offices regarding mistakes via the innovative concept of a real time ‘glitch log’
Site Marking	Clear requirements for challenging situation and real-time monitoring and accountability – See Attachment A for ‘Site Marking Reference Table for Special Circumstances’

Procedures Requiring Relevant Images	Enforcement of specific procedures that require a relevant radiologic image and a hard-stop with an escalation process implemented. See Attachment B & C for 'Procedures Requiring Relevant Imaging Studies' and 'Physician Attestation That An Imaging Study is Not Relevant'.
Pre-procedure Verification Process	Patient engagement and standardized forms for use throughout the system and clarified leadership responsibility for managing these processes
Time Out	Streamlined, standardized and mandated full team engagement
Specific Anesthesia and IR site marking and Time-Out	Clear expectations spelled out in policy for every scenario for Anesthesia and Interventional Radiology
Cath Lab Scheduling	Hard-stop requirements for two-patient identifiers in the Cath Lab scheduling process for both outpatient and inpatient procedures
Consent Process	Standardization of consent forms and consent processes
Radiologic Image Error Correction Process	Implemented a standardized process to correct radiologic images when they are originally incorrect
Physician Onboarding	Defined onboarding process to be implemented throughout Sharp in collaboration with medical staff offices
Safety Culture	<p>Surveyed the staff, leaders and physicians of the surgery and procedural area regarding the culture of communication openness to get a better understanding of perceptions and barriers to speaking up.</p> <p>Focus groups to determine barriers to openness and communication and department-specific leadership actions to address issues</p> <p>An emphasis on transparency and on learning, not judgment, when errors, mistakes and near misses occur</p> <p>A great catch program was leveraged to share stories and recognize individuals who stopped errors before they reached the patient</p> <p>Hand-written thank you notes are sent to staff when they speak up for safety</p>

Challenges Encountered and How They Were Addressed

Numerous challenges were encountered during the transformation of our surgical and procedural safety practices and are outlined below.

Challenge #1: There are hundreds of physicians' offices with varying practices that schedule cases at Sharp hospitals.

How we addressed: We implemented an annual hospital-based luncheon for all physician-office schedulers in order to develop relationships with the schedulers and set expectations for safe scheduling practices. A standard booking form was implemented and a 'GLITCH Log' implemented to capture issues and actions for follow up in real time.

Challenge #2: Gaining agreement on which surgical procedures required a radiologic image

How we addressed: We asked each physician supervisory committee to make recommendations for their specialty and sent the final lists to each Medical Executive

Committee until consensus was achieved throughout Sharp. For cases that are challenged, a “case law” log is kept with the rationale for any exception.

Challenge #3: The timing and responsibility of anesthesia block site marking. Some surgeons believed that the surgeon should mark the site rather than the anesthesiologist but that meant that surgeons would have to arrive up to 30-60 minutes earlier and consensus was difficult to obtain.

How we addressed: A specific anesthesia site marking and time out process was created to ensure high reliability for every situation.

Challenge #4: Physicians don’t independently perform the two-patient identifier verification process and instead rely on nurses to perform (e.g. in L&D for artificial rupture of membranes)

How we addressed: Require the presence of an RN, use visual management tactics to clearly identify the patient, and engage the patient in the pre-procedural verification process.

Challenge #5: High variability in the informed consent and numerous languages make informed consent difficult

How we addressed: Mandatory nursing department education regarding the high-risk nature of informed consent and its contribution to WSPEs. Standard consent forms that were translated in several additional languages were created and a standardized two-person verification process was implemented.

Challenge #6: Cardiologists preferred to call the cath lab to schedule inpatients for cases but often didn’t have the patient’s date of birth.

How we addressed: Created a hard stop requiring two patient identifiers during the scheduling process and education to cardiologists regarding the importance of a robust standardized scheduling process.

Challenge #7: When radiologic images are incorrectly labeled with the wrong side (left vs right), the technology does not provide a process to correct the error.

How we addressed: When it was not possible or not in the patient’s best interest to re-take the image, we created a standardized process within the radiology application to note the error. In addition, we are working with the software manufacturers to enable error correction.

IV. Describe the results of the efforts.

Measure 1. Number of WSPEs Events per Year. When SSPEC began in 2012, Sharp was averaging four-to-five WSPEs per year which was consistent with the national average but unacceptable to our goal of zero harm. Figure 1 shows the number of events over time. SSPEC expanded the type of events reported (eg, wrong radiation, wrong rupture of membranes). Despite this increased reporting, Sharp has experienced fewer events in FY2015 and none in FY2016.

Measure 2. Days Since Last WSPEs. When events are relatively rare, the “number of days since” serves as a useful metric. Figure 2 shows the increase in the number of days since last WSPEs moving from an average of 71 days in 2012 to up to 377 days until July 2016. This improvement translates to roughly eight patients who were spared from suffering a WSPEs at Sharp since the improvements were implemented.

Measure 3. The Number of Zero Heroes. Zero Heroes are defined as departments that have had no WSPEs events for greater than one year. At the start of the project, 24 out of 34 departments were Zero Heroes. Today, 33 out of 34 departments are Zero Heroes.

Measure 4. The number of process defects for pre-procedure verification and Time Out processes. The number and types of defects are tracked and summarized to process owners to monitor system vulnerabilities and individual noncompliance.

V. Discuss the significance of the results. How do the results demonstrate outstanding achievement?

The implementation of measures that strive for zero harm and zero defects has changed the mindset that high reliability is possible. Achieving 33 out of 34 units who are Zero Heroes not only recognizes achievement but also keeps everyone inspired to work together as teams to maintain reliable processes.

Other benefits of this project have extended beyond the OR and procedural areas and has resulted in the following:

- Increased transparency in discussing events and near misses across the organization
- Leader development through the use of enhanced accountability systems and sharing best leadership practices such as backing up staff when they speak up for safety and holding physicians accountable to prioritizing patient safety over physician convenience
- Increased focus on safety culture as a necessary component of sustaining change through the use of story-telling, positively recognizing Great Catches, and encouraging staff / physicians involved in an event or near miss to share the story as a way to spread their learning.
- Clear expectations defined through policy, checklists, audit tools, electronic forms in Cerner EMR

VI. Describe sustainability and scaling of the achievements

- The creation of a Safe Surgical and Procedural Experience Dashboard to monitor ongoing sustainment will provide ongoing feedback to operational leaders and help prevent standardized process deterioration
- The development of operational and physician leaders is a major contributing factor to the sustainment of these highly reliable processes. Almost every leader had their

opportunity to come forth and share a lesson learned from either a safety event or near miss during this four-year initiative. Because so many had the opportunity to stand in front of their peers the judgment and shame shifted to mutual support and a desire to learn and improve.

- The increased pride in staff and physicians with improved outcomes in contributing to a recommitment to maintaining the standard work. Sharp has an annual awards program and the SSPEC has been awarded Sharp's highest award for safety. This recognition will highlight the work and motivate operational leaders to continue to monitor processes on a daily basis to sustain the gains we have achieved.
- Most importantly, there have been numerous enhanced relationships between OR and procedural leaders, physicians and staff. These improved relationships create an increased trust between disciplines and departments. This increased trust is a necessary component to the fabric of high reliability.

VII. Describe key lessons learned and any advice to colleagues who might try to undertake a similar effort.

Lesson Learned #1:

Executive sponsorship at the highest level is critical to the success of engaging physicians in changing practice habits.

Lesson Learned #2

Outcome-based response to events will limit the learning. A "no-harm, no-foul" way of approaching error management will not allow the rich learning from near misses. Take every error and mistake seriously regardless of the final impact to the patient. Embrace failures – they are a gift of learning.

Lesson Learned #3

A primary barrier to staff speaking up for safety is the uncertainty of whether or not their leader is going to back them up. Leaders need to set expectations for speaking up and then back them up - even when they person speaking up is incorrect.

Lesson Learned #4

Meaningful outcome and process measures provided to key stakeholders is essential to maintain the gain and prevent process deterioration.

Lesson Learned #5

The pre-procedural area is fast-paced and rushing is at the root cause of many WSPEs. The improvement work must encompass processes that are upstream such as ensuring an accurate

and complete History and Physical and an accurate informed consent form. Passing on defects in any process not only creates re-work but also creates rushing and increases risk of errors.

Lesson Learned #6

The use of checklists alone does not prevent errors. The full engagement of a two-person verification process using a checklist prior to the patient crossing the threshold of a procedural area is a robust process that catches errors in time to correct them.

Lesson Learn #7

Creating a safety culture that incorporates not only the requirement of a Time Out but also the expectation that no instruments will be passed to the surgeon or procedural physician until a Time Out is performed. This safety expectation sets a standard and ensures full team engagement. Performing routine observations and audits helps to sustain the compliance.

References:

1. Joint Commission Updates Sentinel Event Statistics. Published 11/18/2015.
https://www.ecri.org/components/HRCAlerts/Pages/HRCAlerts111815_Joint.aspx
2. Kwaan MR, Studdert DM, Zinner MJ, Gawande AA. Incidence, patterns, and prevention of wrong-site surgery. Arch Surg. 2006 Apr;141(4):353-7.
3. Neily J, Mills PD, Eldridge N, et al. Arch Surg. 2009;144:1028-1034.
Incorrect surgical procedures within and outside of the operating room.

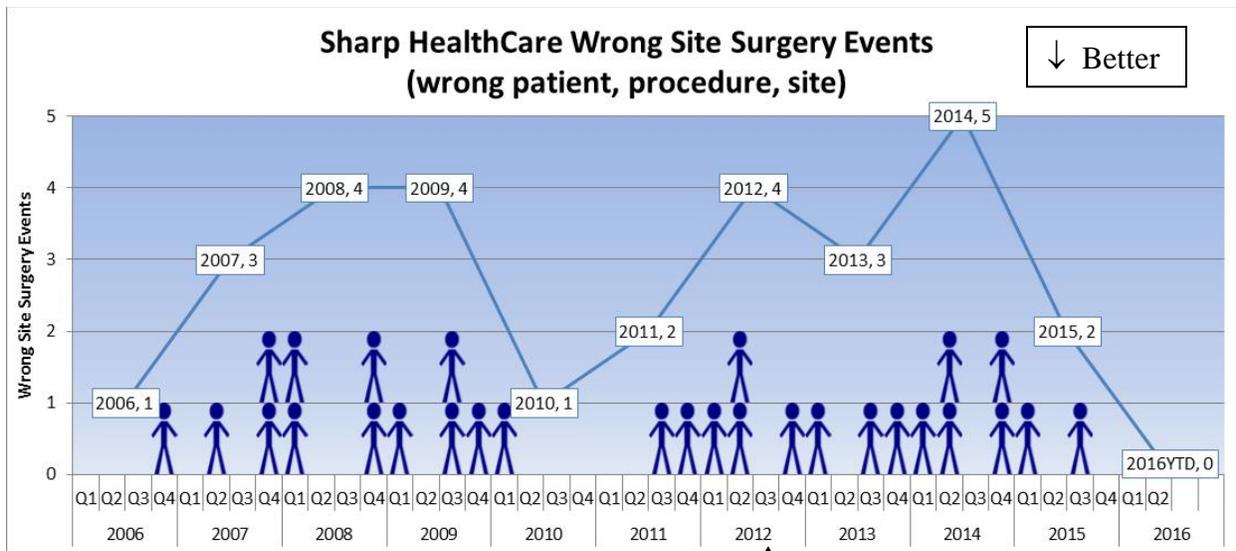


Figure 1

SSPEC began and definition of WSPE expanded to all procedural areas and included any procedure that was unintended

Q: Why use the stick figure icon?

A: To keep the focus on the patient and the harm they suffer.  = One patient harmed through a WSPE (each patient harm event also represents family and care team individuals who suffer distress aka 'second victims')

Q: Why the increase in 2014?

A: SSPEC expanded the definition of WSPE to include all procedural areas, anesthesia, wrong lens size, and any deviation from the intended procedure and in doing so captured additional events that previously may not have been reported.

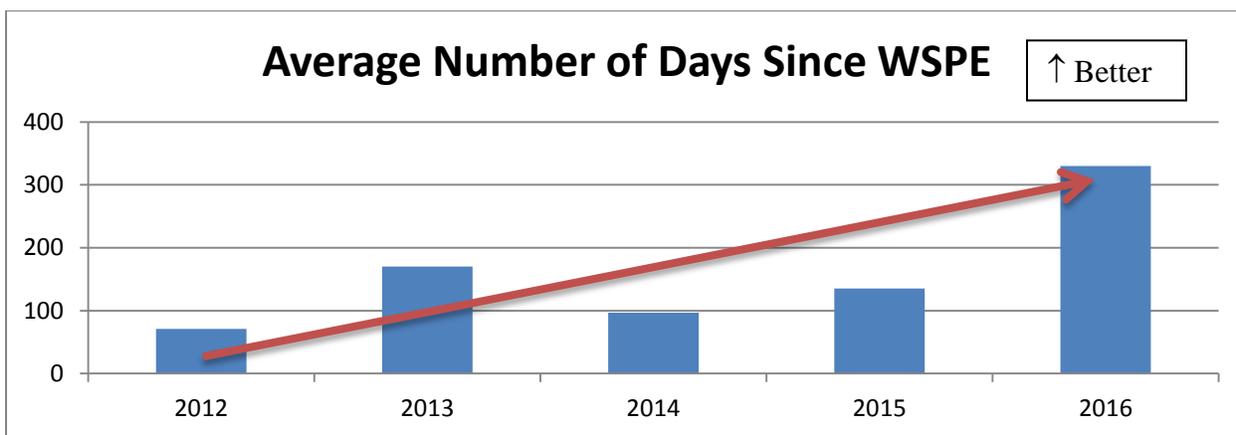


Figure 2

ATTACHMENT A – SITE MARKING REFERENCE TABLE FOR SPECIAL CIRCUMSTANCES

Special Circumstance	Approved Alternative
Internal organs surgery with mid-line or natural orifice approach	Placement of the physician’s initials near the incision on the side indicating laterality (e.g. right thyroid lobectomy, initials placed on right neck).
Spine Surgery/Procedures	Initial general site and include vertebral level and approach (anterior or posterior). If unable to position patient to mark site, use a gray armband with two patient identifiers, procedure and site and side.*
Bandaged areas	Remove bandage and initial site if no risk of injury to patient; otherwise use a gray armband with two patient identifiers, procedure and site.
Mucosal Surface	If site will NOT be visible after prepping and draping, use a gray armband with two patient identifiers, procedure and site.
Perineal area	If site will NOT be visible after prepping and draping, use a gray armband with two patient identifiers, procedure and site.
Premature infants	Initial site or use a gray armband with two patient identifiers, procedure and site.
Cranial surgery	Place initials directly on head/face. Part the patient’s hair if necessary.
Hand/Foot digit surgery	Place initials at the base of the finger/toes and place dot using skin marker on the individual joint/s as intended.
Dental surgery	Initial the dental radiogram or dental diagram and have radiograph and/or diagram available in room at start of surgery. If unable to view radiograph, use a gray armband with two patient identifiers, procedure and site.
Eye Surgery	Initial forehead over the operative site to indicate laterality. If unable to mark face, or surgical drape will cover incision, use a gray armband with two patient identifiers, procedure and site and side.
ENT Surgery	Initial site region on face or neck. Gray armband may be used if not possible to initial site.
Abdominal Surgery	Place initials at or near incision on side indicating laterality.
Legs and Arms	Place initials at incision site on planned limb.
Two sites involved in one operative procedure (e.g. multiple traumas, skin graft from one site to another)	Initial both sites by respective physicians if more than one physician involved. The time-out must be repeated intra-operatively for every additional procedure performed on the same patient.

ATTACHMENT B



**Procedures Requiring Relevant Imaging Studies
Updated April, 2013
(Revised November, 2013)**

The respective Supervisory Committees throughout Sharp HealthCare have determined that the following procedures require an imaging study to be present prior to the start of the case.

As of December 1, 2012, if the imaging study is not present, the patient will not be transported to the procedure room and the case will be delayed.

If a procedure is based on ultrasound alone, the ultrasound report is required to be present rather than the imaging study.

Bilateral procedures do not require images with the exception of Lumpectomies and Joint Replacement of the Fingers/Toes

An attestation form is required to be completed if it is determined that an imaging study is not relevant for one of the procedures below. The attestation form will be reviewed by Medical Staff Leadership.

Alphabetized by Procedure Name	
A - K	L - Z
Adrenalectomy	Lumpectomy / Mastectomy
Aneurysm Repair	Nephrectomy (transplant nephrectomy does NOT require images)
BrainLab / Medtronic Image Guided Endoscopic Sinus Surgery	Orchiectomy
Chest Tube	Osteoplastic Flap
Endoscopic Sinus Surgery- In General	Spine (Any Procedure Performed on the Spine)
Endarterectomy	Thoracotomy
Fractures (All) - If fluoroscopy is planned prior to the initial skin incision, then no images are necessary.	Ureterectomy
Intracranial Procedures (All)	Vascular bypass
Joint Replacement (Any)	VATS (Video-Assisted Thoracoscopic Surgery)

ATTACHMENT C



**Physician Attestation
That An Imaging Study is Not Relevant for
A Procedure Requiring an Image**

Supervisory Committees at Sharp HealthCare have determined that the procedure you have scheduled requires an imaging study to be present prior to the start of the case. Contact Sharp Surgical Scheduling Dept. for the complete list.

An attestation form is required to be completed if it is determined that an imaging study is NOT relevant for this procedure.

If you believe that an imaging study is not relevant to this particular case, please indicate the reason why. The Chief Medical Officer (CMO) and the Department Chair will review the form and either agrees that an image is not helpful or may determine that the case is not allowed to proceed. Contact your CMO for questions.

Check one:

The imaging study is negative and the procedure is based on physical findings

Other (explain) _____

Signed: _____, MD Date: _____

Please Print:

Physician: _____

Procedure: _____

Patient: _____ DOB ___/___/___

Internal review:

Approved Denied

CMO (print): _____ Signature: _____

By signing above, I attest that the department chair and I have reviewed this case and agree on the above marked decision

Please return this form to the OR Manager or Fax to the Sharp Surgery Scheduling Dept.