

Patient Safety and Surgical Errors: Review Article

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Abstract

Patient Safety considered one of the most important issues in medical and surgical field, millions of patients suffer harmful injuries or death every year due to medical errors and behind these numbers lie the stories of many damaged lives and billions of dollars are spent on prolonged hospital stay, corrective procedures, income loss, disability and litigation, resulting from unsafe care.

Keywords: Patient Safety; Medical Errors; Harm

Introduction

Patient safety definition: “The prevention of harm to patients” or avoiding injuries or harm to patients from care that is intended to help them.

Emphasis is placed on the system of care delivery that:

1. Prevent error
2. Learn from error that do occur
3. Built on a culture of safety that involves health care professional organizations and patients.

Adverse event: An injury caused by medical management rather than by underlying disease or condition of the patient.

Complication: The sequelae of diseases such as neuropathy as a complication of diabetes mellitus.

Medical error:

Error of execution: The failure of a planned action to be completed as intended

[slips or laps]

Error of planning: The use of wrong plan to achieve an aim.

Ensuring patient safety: Involves the establishment of operational system and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur.

Patient safety indicators “PSI”

Screen for problems that patients experience as a result of exposure to the health care system.

And that are likely amenable to prevention by changes at the system or provider level.

1. Complication of anesthesia anesthetic overdose, reaction or ETT misplacement
1000 surgery
2. Foreign body left during procedure
3. Iatrogenic Pneumothorax
4. Post-operative hemorrhage or hematoma
5. Post-operative metabolic derangement
6. Post-operative respiratory failure
7. Post-operative PE or DVT
8. Post-operative sepsis
9. Post-operative wound dehiscence
10. Transfusion reaction and many others.

Discussion

Some basic concepts and terms:

- Advances in surgery, anesthesia and postoperative care have led to major declines in surgical mortality.
- This lecture will address some of the more problematic issues directly related to surgery:
 - Anesthesia-related safety complications
 - Wrong site and wrong patient surgery
 - Retained foreign bodies
 - Surgical fires
 - Non-surgical procedural safety.
- Other kind of errors:
 - Medication error

- Diagnostic error
 - Teamwork and communication errors
 - HAI: Including surgical site infection.
- 45% of adverse events “errors” were in surgical patients, of these 17% resulted from negligence and 17% led to permanent disability.
 - 3% of patients who underwent an operation suffered an adverse event (most of which are related to perioperative care) half of these were preventable.
 - Surgery, like the rest of medicine, has traditionally approached safety as matter of individual excellence: a complication was deemed to represent a personal failing on the part of the surgeon.

But the shift in focus to systems improvement has catalyzed major advances in Surgical Safety.

Volume-outcome relationships:

- One early study of lap chole’s showed that injuries to the common bile duct dropped almost 20-fold once surgeons had at least a dozen cases under their belts. After that the learning curve flattened but not by much: the rate of common bile duct injury on the 30th case was still 10 times higher than the rate after 50 cases.
- Obviously, part of the solution to the volume-outcome and learning curve conundrums lies in the development of innovative training model’s, including the use of medical simulation.
- In addition, some surgical and procedural specialties are now requiring minimum volumes for privileging and board certification.

These are the 10 volume-sensitive surgeries:

- Bariatric surgery for weight loss
- Esophageal resection
- Lung resection
- Pancreatic resection
- Rectal cancer surgery
- Carotid endarterectomy
- Open aortic aneurysm repair
- MV repair and replacement
- Hip replacement
- Knee replacement.

- **“Practice makes perfect” theme:** Not years but procedural volume.
- In one study published in 2013;
 - Birkmeyer and colleagues asked bariatric surgeons to submit videotapes of one of their operations.
 - A panel of at least 10 peers, blinded to the identity of the surgeon and the patient outcomes, reviewed each videotape and rated the surgical technique, the rating varied tremendously, with some surgeons deemed to have stellar techniques while others were judged to be mediocre.

Patient safety in anesthesia

- **APSF:** Anesthesia Patient Safety Foundation, which working closely with other professionals, healthcare and industry groups, helped propel the field forward, first by convincing caregivers that the safety problem was real and that it was soluble with the right approach.
- The lessons learned from APSF movement are:
 - **First:** Safety requires strong leadership, characterized by a commitment to openness and willingness to embrace change.
 - **Second:** Learning from past mistakes is an essential part of patient safety. The closed case reviews produced key insights.
 - **Third:** Technology, considered an essential part of the solution. Oximetry, capnography, automated BP monitoring has proven vital to saving lives.
 - **Fourth:** where applicable use of Human Factors engineering and forcing functions can markedly enhance safety.
 - Example of forcing function [changing the anesthesia tubing so that the incorrect gases couldn't be hooked up was crucial, this was a far more effective maneuver than trying to educate or remind anesthesiologists about the possibility of mix-ups.
 - **Finally:** Anesthesia had to grapple with a number of highly visible errors reported in the media. So, in US in 1980s anesthesiologists paid exorbitant rates for malpractice insurance “among the highest in the medical profession”.
 - Now that errors causing patient harm are so unusual in the field of anesthesia, current malpractice premiums fall in the midrange of all specialties, a good example of the “business case for safety”.

Wrong-site/Wrong-patient surgery

- A real story in 1995, Hospital Tampa in Florida the patient [W.K.] a 51-year-old, diabetic man, with severe peripheral vascular disease, developed a gangrenous right leg, which necessitate for amputation in the hospital.

The admitting clerk mistakenly entered into the computer system that Mr. W.K. need a left below-the-knee amputation.

The patient surgeon entered the OR, read the wrong procedure, prepped the wrong leg, and then began to amputate it. The error was discovered partway through the surgery, too late to save the left leg. Of course the gangrenous leg still needed to be removed and few weeks later it was, leaving Mr. W.K. a double amputee.

- A recent systematic review suggests that there is one wrong-site surgery event per 100,000 surgical procedures.

And studies that also considered outpatient surgery and nonsurgical procedures have given higher estimates.

The highest incidence is in otolaryngology procedures accounting for 0.3% to 4.5%.

- The old approach to this problem is just to blame a careless surgeon or nurse who are useless and we should approach the problem from Swiss Cheese Model and bad system. Appreciating this makes clear the need for multidimensional approach aimed at preventing the inevitable human slips from causing irrevocable harm.

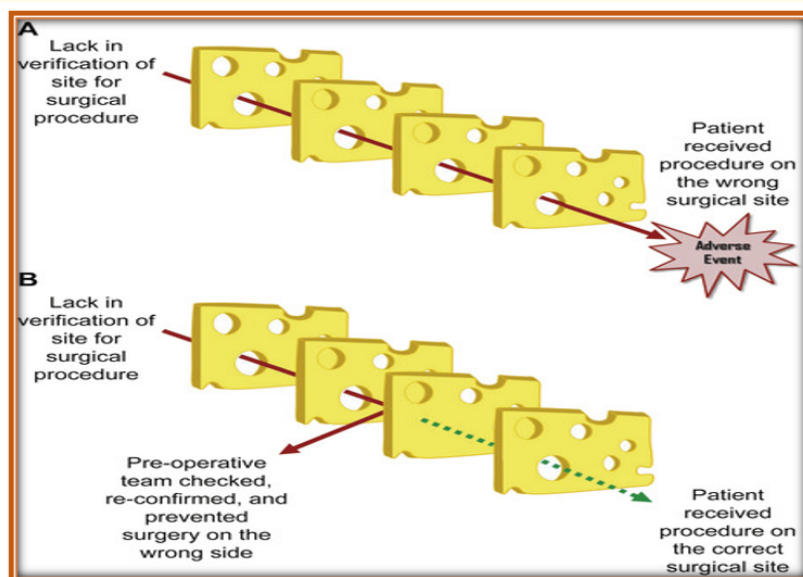


Figure 1: Swiss cheese model.

- So that the Joint Commission has prompted the use of the Universal Protocol to prevent wrong-site and wrong-patient surgery and procedure by creating a multiple overlapping layers of protection.
 1. **Sign-your-site:** The surgeon marks the surgical site in indelible ink after verifying the correct site. And for success this needs a strong standard policy and enforcement protocols like:
 - a. To mark only the surgical site
 - b. Not to use a mark like [X] and instead to use a double S [SS].
 - c. Double check verification of the correct site mark
 - d. Involve the patient.

- e. Examples of situations that we need an alternative method [like a written process].
 - Patient refused
 - Or Anatomically impossible or impractical to mark the site like mucosal surfaces or perineum.
 - Teeth
 - Premature infant, for whom the mark may cause a permanent tattoo.

2. **Time Out:**

- Need to be effective
 - a. Safety culture
 - b. Good communication “up the authority gradient”
- Should be done before starting the invasive procedure or making the incision.
- Should have the following characteristics.
 - a. Standardized
 - b. Initiated by a designated member of the team
 - c. Involves the immediate members of the procedure team.
 - The surgeon
 - Anesthesiologist
 - Circulating nurse
 - Operating room technician
 - Other....
- The team members agree, at a minimum on the following:
 - Correct patient identity
 - The correct site
 - The procedure to be done
- Document the completion of the time out

3. World health organizations surgical safety checklist:

I. Before induction of anesthesia: with at least nurse and anesthetist.

- Has the patient confirmed his/her identity, site, procedure and consent?
 Yes
- Is the site marked?
 Yes
 Not Applicable
- Is the anesthesia machine and medication check complete?
 Yes
- Is the pulse oximeter on the patient and functioning?
 Yes
- Does the patient have a:
Known allergy?
 Yes No
Difficult airway or respiration risk?
 Yes No
Risk of ≥ 500 ml blood loss (≥ 7 ml/kg in children)
 Yes No If yes 2 IV lines/central access/fluid/blood prepared

II. Before skin incision: with nurse, anesthetist and surgeon

- Confirm all team members have introduced themselves by name and role.
- Confirm the patient's name, procedure and where the incision will be made.
- Has antibiotic prophylaxis been given within the last 60 minutes?
 Yes Not Applicable
- Anticipated Critical Events:
To Surgeon:
 What are the critical or non-routine steps?
 How long will the case take?
 What is the anticipated blood loss?
To Anesthetist:
 Are there any patient-specific concerns?
To Nursing Team:
 Has sterility been confirmed?
 Are there equipment issues or any concerns?
- Is essential imaging displayed?
 Yes Not Applicable

III. Before patient leaves Operating Room: with nurse, anesthetist and surgeon

- Nurse verbally confirms:
 The name of the procedure
 Completion of instrument, sponge and needle counts
 Specimen labeling
 Whether there are any equipment problems to be addressed.
To Surgeon, Anesthetist and Nurse:
 What are the key concerns for recovery and management of this patient?

Figure 2

Notes:

1. The hospitals that use these checklists had 30% fewer patient complications and a nearly 50% lower patient mortality rate than those at control institutions.

2. In Michigan ICU's study found that a checklist-based intervention resulted in major decrease in CLABSI. Leading many people to focus on the checklist as a magic bullet.

For the best outcome of this tool (checklist) we need two important associated concepts:

- Safety culture
- Teamwork training

Retained sponges and instruments

- The term retained sponges also called gossypibomas from the latin gossypium=cotton boma=concealment.
- Is used as a catchall phrase for all manner of surgical paraphernalia left behind after surgery.
- In one 16 year study found that 2/3 of retained foreign bodies is actual sponges, while the remaining 1/3 were surgical instruments.
- The overall incidence of retained sponges 1/10,000 surgeries and the overall incidence of retained foreign object rate is 1/5500 operations.
- Some systematic solutions are:
 1. Sponges with loops that were attached to 2 in metal ring. The ring then hung outside the operative field while sponges were placed inside the field around 1940.
 2. 1960s manufactures, producing a surgical sponge with an embedded radiopaque thread, meant to show upon x-rays and to do a post-operative x-ray in case of doubt or in high-risk cases.
 - Emergency surgery
 - Prolonged surgery
 - Surgery on obese patient
 - Surgery that required a real-time change in clinical strategy

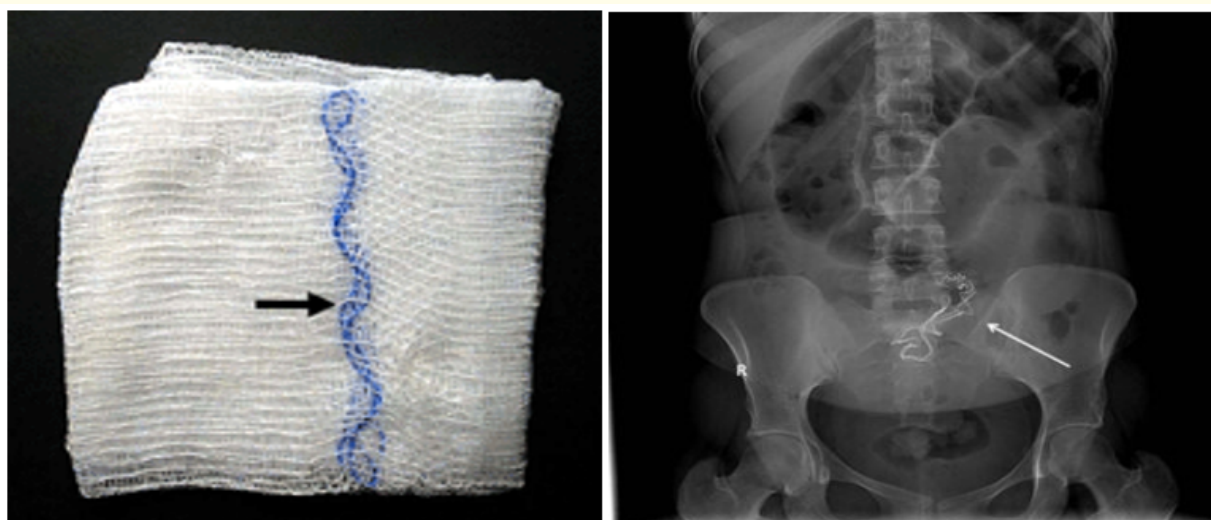


Figure 3

3. A standard protocol that requires four (4) separate counts.
 - a. When the instruments are set up and the sponges are unpacked
 - b. When the surgery begins and the items are called for and used.
 - c. At the time of closure
 - d. During external suturing

But due to:

1. Chaotic and pressure circumstances in most busy OR's.
2. Frequent changes in personnel
3. Reluctance of the nurses to admit to the fallacy of an earlier count.



Create situations in which the count fail

4. New technology: some companies have developed bar-coded sponges, while others have embedded their sponges with radio-frequency ID (RFID) tags that cause a detector wand to beep when the surgeon waves it over the field before closure and considered as cost effective than other models.
5. Others built automatic "sponge counters" resembling toll booth coin machines which can be loaded up and checked after every surgery.

Surgical fires

- It has been estimated that there are between 50 and 200 such Fires annually in the United States. Leading to morbidity in 20% of cases [often severe including tracheal or pulmonary burns] and one or two deaths.
- What is the fire safety triangle?
 - **Ignition source:** Like electrocautery and lasers
 - **Fuel source:** Gaze, drapes, even ETT
 - **Oxidizers:** O₂ and sometimes nitrous oxide

Prevention maneuvers

1. **For the ignition source:** Should be stored away from the patient and their tips should be visualized while hot and, for
2. **For fuel source:** Time should be allowed for alcohol-based prep solutions to dry prior to draping patients.
3. **For oxidizers source:** For oxygen concentrations should be kept to the lowest safe amount, and cautery around the

airway should be used sparingly and only after the anesthesiologist is warned so that he or she can turn down the O₂.

- **In case of fire in the OR:**
 - All personnel should be immediately notified.
 - If the fire involving the airway the flow of gas should be turned off and the airway cooled with normal saline.
 - For fire in other location do smothering with water, saline or by physical means is advised and the use of carbon dioxide fire extinguisher should be reserved for persistent flames.

Safety in nonsurgical bedside procedures

- Like thoracentesis and central line placement, paracentesis, LP...
- With a complication rate somewhat high:
 - 6% thoracentesis result in a pneumothorax, 1/3 of it require a chest tube replacement.
 - CV line complications like [Pneumothorax, thrombosis and infection] exceeding 15%.

- **Strategies to decrease the procedures risks are:**

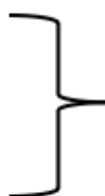
1. **Education and skill building**

By developing of formal curricula and competency-based assessment strategies including forbidding learners from performing procedures independently until they have been deemed competent.

By using of simulation to enhance both teaching and assessment of procedures.

2. **Ensure correct patient and correct-site procedures by:**

- Site marking
- Time out
- Informed Consent
- Checklist



Creating a Universal Protocol for bedside procedures

3. **Adjunctive technologies**

- The use of bedside ultrasound
- The availability of PICC: Peripherally inserted central catheter to avoid the need for subclavian or jugular puncture to access to the central circulation.

4. **Procedure services:**

- By limited number of physicians, who receive additional training in the relevant procedures, and commit to spending significant time on the service advantages:
 - A better trained and skilled personnel
 - A more implementation of standard protocols
 - Freeing clinicians from other distractions while performing procedures.
 - Responsibility for educating trainees.

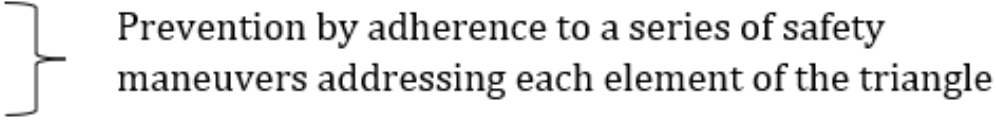
These services represent a major advance in patient safety and should be implemented widely.

Conclusion

Key points:

1. **Patient safety issues in surgery include those common to other fields:**
 - Medication errors
 - Health care associated infection
 - Diagnostic errors
 - Communication mishaps
 - And others specific to surgery
 - Wrong-site surgery
 - Retained Sponges
 - OR Fires
2. Evidence for volume-outcome relationship in many surgical areas and the importance of simulator training.
3. The important strategy to prevent wrong-site and wrong-patient errors is the application of a Universal Protocol which include:
 - a. Sign-your-site
 - b. Preprocedural time out
 - c. Teamwork training
 - d. Use of checklists

4. To prevent the rare but hazardous surgical error, retained sponges and other surgical instruments are:
 - a. Sponge count “multiple levels”
 - b. X-ray
 - c. A more robust detection technology such as RFID is increasing

5. Surgical Fires resulted from the interaction of the elements of the Fire Safety Triangle:
 - a. Ignition Source
 - b. Fuel Source
 - c. Oxidizer

Prevention by adherence to a series of safety maneuvers addressing each element of the triangle

6. To enhance the safety of a non-surgical bedside procedures:
 - a. Robust competency-based training
 - b. Bedside ultrasound
 - c. Implementing checklists and timeouts
 - d. Dedicated procedure service

7. All these preventive safety measures lie under the main safety principles:
 - a. Standardization: Create predictability and consistency in your work flow
 - b. System thinking
 - c. Human factor engineering
 - d. Learning from mistakes [1-3].

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