

Preventing Surgical Stapler Adverse Events: A Simulation-Based Curriculum

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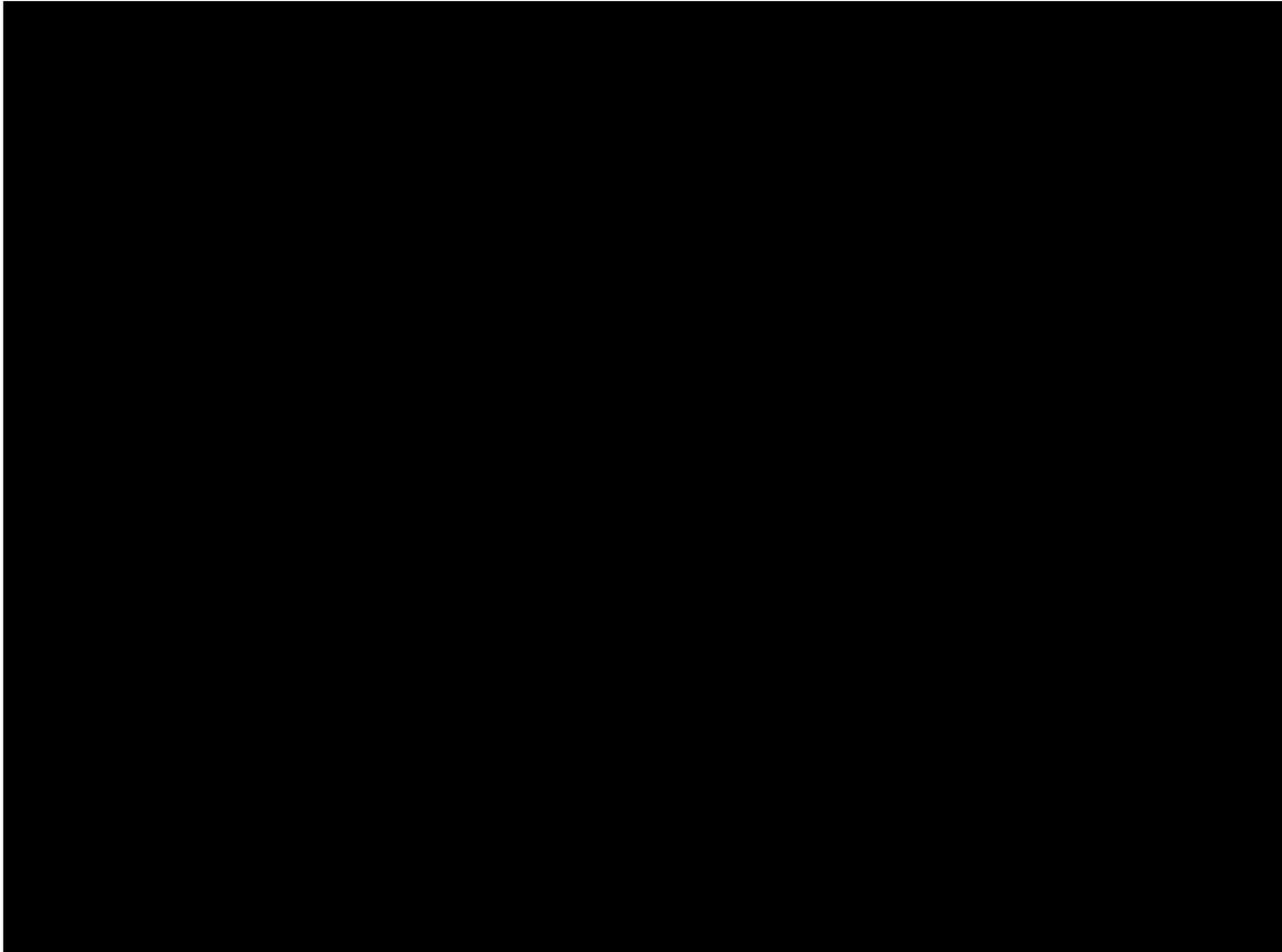
June 10, 2014



Part I

SURGICAL STAPLER RISKS

What Can Go Wrong?



Background: Literature

- Low reported rates of malfunction, but potentially catastrophic results
- Reports to FDA MAUDE database 2003-2012: 97 deaths, 3,436 injuries, and 2,817 malfunctions
- May be due to device malfunction or use error



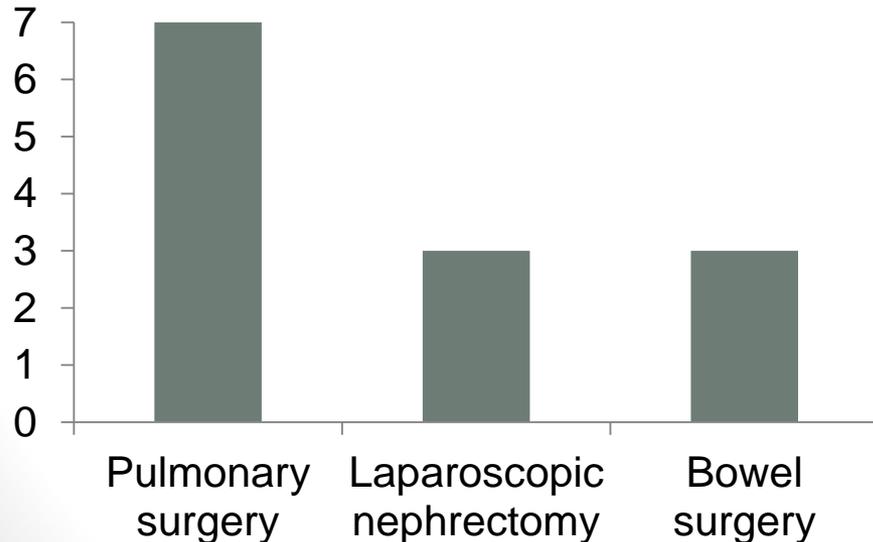
Stapler Failure Modes

- **Division without ligation**
 - Missing stapler cartridge
 - Missing staples
 - Overriding safety mechanism and firing used cartridge
- **Malformed staple lines**
 - Firing over existing staples/clips
 - Incomplete firing stroke
 - Manufacturing defect
- **Stapler locking** before or after firing leading to tissue injury when stapler is removed
- **Partial or no cutting**
- **Damage of nearby tissue** during stapler insertion or removal

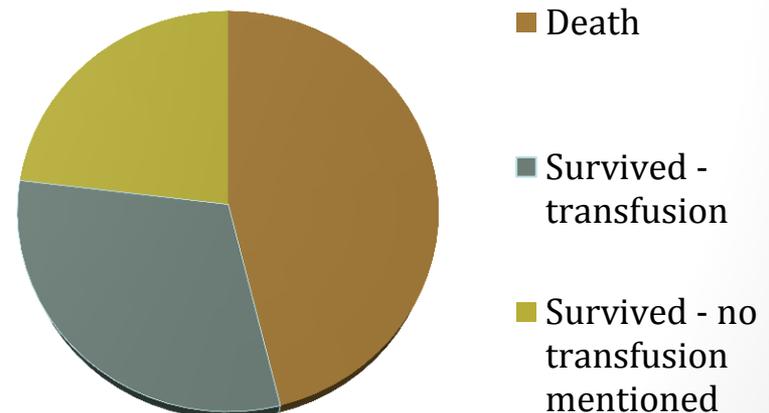
Background: Spot RCA Database

- 12 relevant RCAs (13 events) involving non-skin closure surgical staplers

Type of Surgery



Patient Outcome



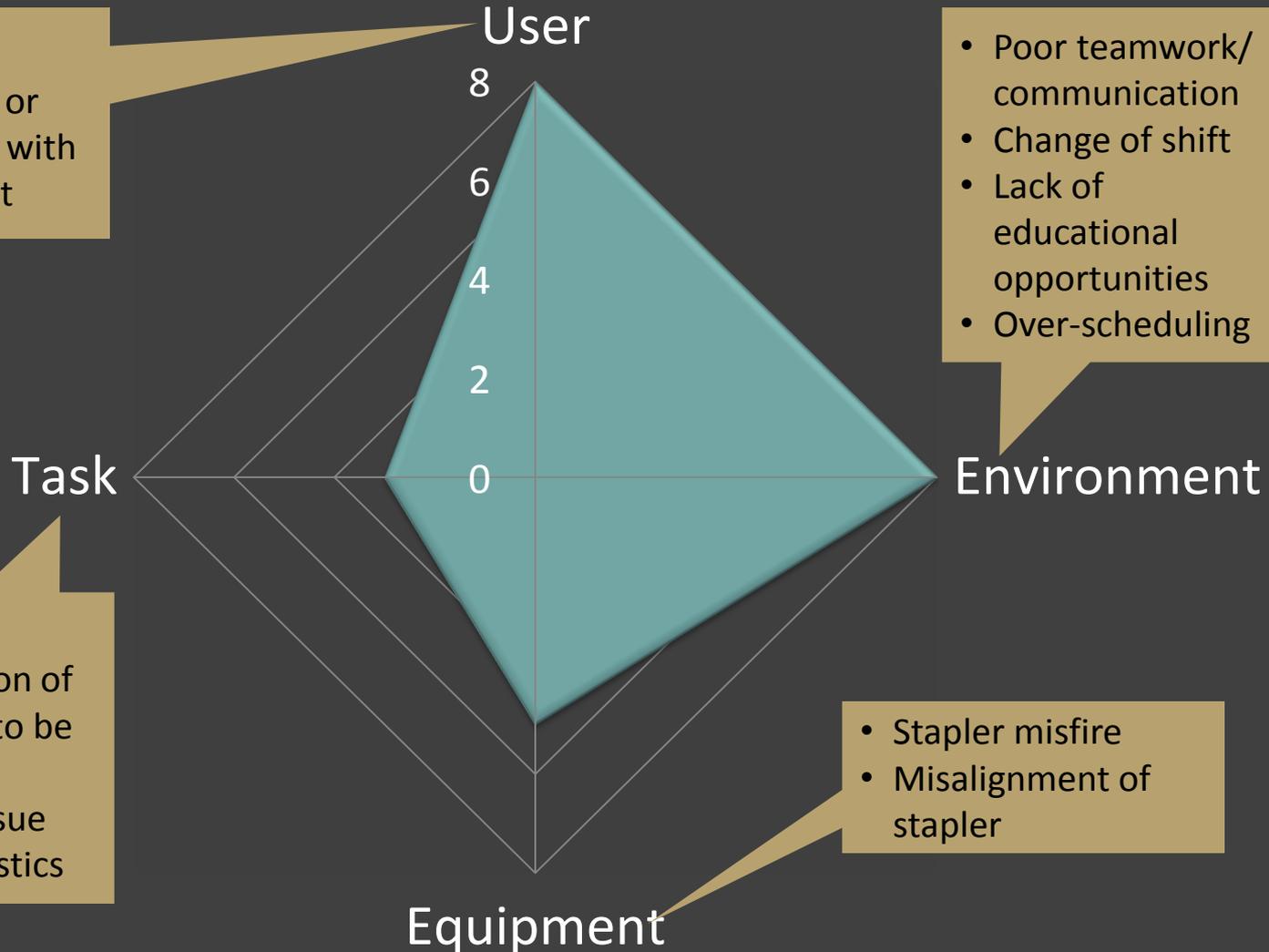
Stapler Event Root Causes

- Lack of education or familiarity with instrument

- Poor teamwork/communication
- Change of shift
- Lack of educational opportunities
- Over-scheduling

- Poor visualization of structure to be stapled
- Friable tissue characteristics

- Stapler misfire
- Misalignment of stapler



Hazard Avoidance and Mitigation

Prior to surgery:

- **Evaluate** potential devices prior to purchase
- Ensure surgeons have their **preferred devices**
- Implement **systematic training** on surgical devices
- Make provisions for **practice time**

Hazard Avoidance and Mitigation

During surgery:

- **Identify** devices, use issues, and possible adverse outcomes during preoperative briefing
- Establish **proximal control** and **pause** (“Step Back”) prior to stapling large blood vessel
- **Examine** stapler prior to firing
- Avoid **stapling over clips** or existing staple line
- **Visually inspect** staple line prior to dividing tissue
- Avoid **forcefully freeing** the tissue if stapler locks up
- Utilize standardized procedure for **investigation of misfires**



Part II

SIMULATION-BASED TRAINING

Learning Gap



- No systematic training program for surgical devices
- “See one, do one, teach one”
- No routine trial of new devices
- No provisions for routine practice with surgical devices

Training Objectives

- Familiarize users with correct operation of tool
- Teach users best practices
- Teach users possible failure modes and responses
- Demonstrate severe failures



Methodology

- Participants: Surgeons, nurses, technicians
- Site: Required clinical team training events
- Design: Optional hands-on activity
 - Initial survey
 - Surgical stapler simulation activity
 - Post-training survey



Pre-Training Survey

- Demographics
- Training/Experience
- Stapler ease of use
- Experiences with stapler failures
- Knowledge of stapler failure modes

Pre-Training Survey

- Demographics
 - Gender
 - Age
 - Height/weight
 - Dominant hand
 - Glove size
 - Specialty
 - Most common case with stapling device
- Training/Experience
- Stapler ease of use
- Experiences with stapler failures
- Knowledge of stapler failure modes

Pre-Training Survey

- Demographics
- Training/Experience
 - Year most recent training completed
 - Last time you used a surgical stapler
 - Frequency of use of various models
 - Did you have specific stapler training during your residency?
Have you since?
- Stapler ease of use
- Experiences with stapler failures
- Knowledge of stapler failure modes

Pre-Training Survey

- Demographics
- Training/Experience
- Stapler ease of use
 - How easy/difficult to you find it to close a surgical stapler?
Fire a surgical stapler?
 - Have you ever required assistance with using a surgical stapler?
- Experiences with stapler failures
- Knowledge of stapler failure modes

Pre-Training Survey

- Demographics
- Training/Experience
- Stapler ease of use
- Experiences with stapler failures
 - Have you ever encountered failures with surgical staplers?
 - Did you report the failure and secure the stapler?
 - Have you ever heard of other people encountering failures?
- Knowledge of stapler failure modes

Pre-Training Survey

- Demographics
- Training/Experience
- Stapler ease of use
- Experiences with stapler failures
- Knowledge of stapler failure modes
 - If you were advising residents, what stapler problems would you tell them to look out for?
 - What would you advise them to do to avoid these problems?

Post-Training Survey

- Knowledge of stapler failure modes
 - If you were advising residents, what stapler problems would you tell them to look out for?
 - What would you advise them to do to avoid these problems?
- As a result of training...
 - I am more aware of possible stapler problems
 - I am more proactive regarding stapler safety
- This training...
 - Would be beneficial to other surgeons
 - Was worthwhile



Strongly
Disagree

Neither Agree
nor Disagree

Strongly
Agree

Summary

- Low reported rates of adverse events related to surgical staplers, but outcome may be catastrophic
- Simulation is a good medium for training because hazards may be demonstrated without risk to patients or providers
- Stapler simulation training will be piloted at clinical team training events in the VA



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Thank you

