Retained Surgical Items (RSI)

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Outline

• Differing definitions
• Different types of items/different causes of retention
• What is known now about RSI
• Current project to identify causes and cures for retained surgical items
  – Project description
  – Early results
Differing definitions

CDPH (SB1301)

• Retention of a foreign object in a patient after surgery or other procedure,
  – excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.
NQF serious reportable events

- **Unintended** retention of a foreign object in a patient after surgery or other invasive procedure,
  - Excluding objects present prior to surgery intentionally left in place (e.g., piece of glass in the foot)
  - Excluding objects intentionally implanted
  - Excluding objects intentionally left in because risk of removal exceeds risk of retention

CHPSO

- Unintended retention of a foreign body after surgery or other invasive procedure
- **And** “near misses”
  - A fragment is generated and retrieved
  - An item *almost* is left in the patient
  - A hazard is identified that could result in a retained surgical item
- Broader to accelerate learning
Types of items/different causes of retention

Two fundamentally different categories

- Counted
  - Count correct
  - Count incorrect
- Not counted
  - Countable
  - Not usually considered countable
Counted items

• Count correct
  — People are not perfect
  — Identify impediments to high performance
    • Interruptions, distractions, intimidation
  — Identify ways to facilitate accuracy
    • Move from counting to accounting
    • Technical solutions
• Count incorrect
  — Team failure?

Not counted items

• Countable
  — Policy change?
  — Adoption of new items
    • Was there a risk evaluation and training?
• Not usually considered countable
  — Largest category of items
  — Little existing knowledge on how to reduce incidence of these
What do we know?

Probable factors that increase risk of RSI

• Emergencies
• Unplanned procedure changes
• Higher body-mass index patients
• Surgical complexity
• Fatigue and work load
  —E.g., late in day, long procedure
• Personnel changes
American College of Surgeons guidelines

- Standardized counting process
  - Actual process may not be same as written policy
- Methodical wound exploration before closure
- Use x-ray detectable items in wound
- Maintain environment conducive to focused performance, clear communication and careful documentation
  - Culture, communication, interruptions/distractions, staff changes
- X-ray or other electronic devices as needed

Sponge accounting

- Verna Gibbs, MD. nothingleftbehind.org
  - Presenting at HASC Track I on May 15
  - Visit web site for loads of useful information, including how to use this method most effectively
- Low tech method to reduce the cognitive load at the end of the case
  - Fill pouches on a hanging bag instead of individually counting
  - All full pouches, all sponges accounted for
- Still need backup when things go wrong (e.g., empty pouch)
Project to identify causes and cures

CHPSO Event Collection Project

- Members only
  - Member list at www.chpso.org/members.php
- Reports are Patient Safety Work Product
  - Confidential
  - Privileged
- Identifiers are removed before sharing information
California Hospital Patient Safety Organization
Retained Surgical Item
Record Review Form

Confidential: Patient Safety Work Product

Event Location and Time (here and when item was left behind, and where and when it was discovered)

Hospital/Clinic Name: [Redacted]
Unit (e.g., OR, ICU, ED, etc.): [Redacted]
Time of Day: 12:00 AM, Day of Week: [Redacted]

Event discovered:
□ Before incision closed □ In OR after closure □ In recovery room □ Same hospitalization
□ After discharge or in a subsequent hospitalization

Patient Information
Age: [Redacted] Sex: [Redacted] Medical Record Number: [Redacted]
Harm: □ None □ Mild □ Moderate □ Severe □ Death

Procedure
Planned Procedure: [Redacted] Actual Procedure: [Redacted]
CPT code(s) for actual (if known): [Redacted] Case length (minutes): [Redacted]
Procedure urgency: □ Elective □ Urgent □ Emergent □ Unknown
Complicating factors: □ Bleeding □ Obesity □ Unexpected deviation from plan

Retained Item
□ Sponge □ Towel □ Needle □ Instrument □ Fragment □ Other

Name/Model Number: [Redacted] Manufacturer: [Redacted]
Size: [Redacted] Other ID(s) (e.g., lot number): [Redacted]

Item left behind: □ Unintentionally □ Unknown □ Intentionally (describe reason):

What factors contributed to the event? (check all that apply)

Environment
□ Culture of safety, management □ Physical surroundings (e.g., lighting, noise)
□ Distractions/Interruptions □ Staff qualifications

Staff supervision/supervisor:
□ Clinical supervision □ Managerial supervision

Policies and procedures, includes clinical protocols
□ Presence of policies □ Clarity of policies

Equipment/device:
□ Function □ Design □ Availability □ Maintenance □ Defect or Failure

Incorrect use of equipment/device:
□ Jerking, jiggling, creating a workaround, force-fitting, defeating fall-safe, etc.
□ Selection or use of inappropriate device □ Mis-setting, mis-programming, or otherwise misusing the device

Site:
□ Availability □ Accuracy □ Legibility

Communication:
□ Supervisor/Provider to staff □ Among staff or team members □ Staff to patient (or family)

Human factors
□ Fatigue □ Stress □ Cognitive factors □ Health issues

Other (please describe):

Why do you think that the incident occurred? Any other comments? (use back of page for additional space)

If the item was left behind intentionally, STOP, the form is complete. Otherwise, continue to back of page.
When to report to CHPSO

- **An item is left in the patient that is not supposed to be left there** as part of the procedure. For example, this form would be used for a staple that was dropped into the wound but not for a staple that is properly placed.

- **An item almost is left in the patient.** For example, the count is incorrect and steps are taken to find the item, which is then found in the patient and removed prior to leaving the OR.

- **A fragment is generated and retrieved.** For example, a drill bit breaks in the patient and the pieces are found and removed.

- **You identify a hazard that could result in a retained surgical item.** For example, a new model of retractor has a removable section that could be left behind, but you believe people are not aware of it and that section isn’t being tracked.
Harm Scale (from WHO)

- **None** – no symptoms detected and no treatment is required.
- **Mild** – symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review or minor treatment) is required.
- **Moderate** – intervention is required (e.g., additional operative procedure; additional therapeutic treatment), or increased length of stay occurs, or it caused permanent or long term harm or loss of function.
- **Severe** – life-saving intervention or major surgical/medical intervention is required, or life expectancy is shortened or there is major permanent or long term harm or loss of function
- **Death** – on balance of probabilities, death was caused or brought forward in the short term by the incident.

Common Formats

- PSOs are required to collect data in a standardized manner to the extent practical and appropriate.
- While these are still under development, hospital-specific data elements have been defined.
- Most PSOs are using the AHRQ Common Formats
- Hospitals are not required to use the Common Formats when working with CHPSO, but may find it beneficial to do so.
  - Simpler incident report system terminology updating
  - Better comparability
  - High-quality taxonomy
Common Formats

- Developed by AHRQ with the assistance of the NQF
  - Includes public comment period and hearings
- In partnership with the following Federal agencies/departments:
  - CDC, CMS, FDA, HRSA, Indian Health Service, NIH, NLM, ONC for HIT, Office of Public Health and Science, Substance Abuse and Mental Health Services Administration, DoD, VA

Common Formats

- With review of scores of similar systems (e.g., vendors’ incident report systems, national reporting systems, etc.)
Common Formats

- The common definitions and reporting formats that allow health care providers to collect and submit standardized information regarding patient safety events.
- Represent a “minimal set”—organizations may extend it to meet their needs.

Report flow

1. Event detected
2. Person at scene fills out form
3. Risk management uses form to aid in case review
4. Form sent to CHPSO, optionally RCA as well
5. Aggregation and analysis by CHPSO, with removal of patient, provider and hospital identifiers
Early Results

• 33 unique reports (had some duplicate submissions)

Potential contributing factors

• Urgency  
• Deviation from planned procedure  
• Environment  
• Staff qualifications  
• Equipment/device issues  

• Incorrect use of equipment/device  
• Data  
• Communication  
• Human factors  
• Teamwork
Most common factors

- Staff communication
- Clarity of policies
- Presence of policies
- Staff training
- Distractions/interruptions
- Culture of safety
- Device defect or failure
- Device design
- Device function

Observations

- Bits and pieces predominate
  - Don’t necessarily know how to reduce incidence currently
- Out-of-OR sources area significant
  - Early sepsis treatment
    - More emergency central lines
    - Perhaps less-trained personnel
Questions

• rjaffe@chpso.org
• www.chpso.org
• Nothingleftbehind.org