

URFO PRACTICE GUIDANCE: A 3 STUDY REVIEW

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OCTOBER 24, 2019 10:00-11:00 PACIFIC TIME

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CONFLICT OF INTEREST

- Dr. Steelman has served as a paid consultant for Medtronic.
- The studies presented were not funded by industry.

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OBJECTIVES

1. Review findings from 3 studies of unintentionally retained foreign objects (URFOs)
2. Discuss challenges to URFO prevention
3. Describe targeted strategies to reduce URFOs

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RETAINED SURGICAL SPONGE



Kahn YA, ASif M, Al-Fadhli W. Intraabdominal gossypiboma. APSP J Case Rep. 2014 May;9(5):17. Used with permission.

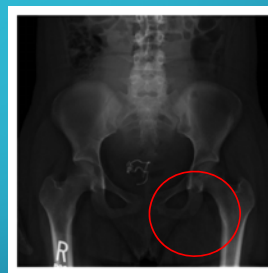
- 8 year old girl
- History of splenectomy, cholecystectomy 2 years prior
- In ED with acute intestinal obstruction
- Exploratory laparotomy
- Sponge obstructing ileum
- Multiple perforations
- Resected the ileum
- High grade fever for 10 days
- 11 days in hospital

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RETAINED SURGICAL ITEMS

- Retained surgical items (e.g. sponges, needles, and instruments) are estimated to occur
 - 1 in 5500 surgeries¹
- Sponges account for 52-69% of retained surgical items.^{1,2,3}



Case Rep Med. 2012; 2012:317856. Published online 2012 Jan 24.
doi: 10.1155/2012/317856
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1. Cima RR, Kollengode A, Gamatz J, Storsveen A, Weisbrod C, Deschamps C. Incidence and Characteristics of Potential and Actual Retained Foreign Object Events in Surgical Patients. *Journal of the American College of Surgeons*. 2008;207(1):80-87. doi:10.1016/j.jamcollsurg.2007.12.047.

2. Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zimmer MJ. Risk Factors for Retained Instruments and Sponges after Surgery. *New England Journal of Medicine* 2003;348(3):229-235.

3. Lincourt, et al. *J Surg Res* 2007

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PATIENT OUTCOMES : CLOSED CLAIMS OF RETAINED SURGICAL ITEM



Colak, et al. Case Rep Surg. 2013;2013:219354.
doi: 10.1155/2013/219354. Used with permission.

- Reoperation 69%
- Readmission/prolonged stay 59%
- Sepsis/infection 43%
- Fistula/bowel obstruction 15%
- Visceral perforation 7%
- Death 2%

1. Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk Factors for Retained Instruments and Sponges after Surgery. New England Journal of Medicine 2003;348(3):229-235.

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EFFECTIVENESS OF COUNTS FOR PREVENTING RETAINED SURGICAL ITEMS

"Every system is perfectly designed to get the results that it gets"
-Paul Batalden

- Historically, the primary intervention for preventing retained items has been manual counting
- Manual sponge counting alone does not prevent retained items
- Counting identifies a retained item **77%** of the time when one is present¹
- Nearly **81%-94%** of retained items occur when counts are reported to be correct^{2,3}



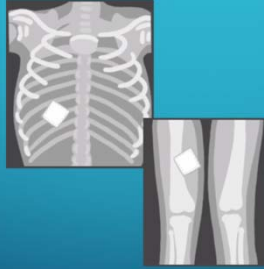
1. Egorova NN, Moskowitz A, Gelljns A, et al. Managing the Prevention of Retained Surgical Instruments. Annals of Surgery 2008;247(1):13-18.
2. Steelman, V.M., Shaw, C., Shine, L., Hardy-Fairbanks, A. Retained surgical sponges: A descriptive study of 319 occurrences and contributing factors from 2012-2017. Patient Safety in Surgery (2018) 12:20.
3. Steelman VM, Shaw C, Shine L, Hardy-Fairbanks AJ. Unintentionally retained foreign objects: A descriptive Study of 308 sentinel events and contributing factors. Jt Comm J Qual Patient Saf. Oct 16, 2018. pii: S1553-7250(18)30304-0

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EFFECTIVENESS OF INTRAOPERATIVE RADIOGRAPHY

Is X-ray a reliable prevention method?



X-rays only identify a retained item 67% of the time when present¹

1. Clini RR, Kollengode A, Garnatz J, Stovveen A, Weisbrod C, Deschamps C. Incidence and Characteristics of Potential and Actual Retained Foreign Object Events in Surgical Patients. *Journal of the American College of Surgeons* 2008;207(1):80-87. doi:10.1016/j.jamcollsurg.2007.12.047.

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POLLING QUESTION #1

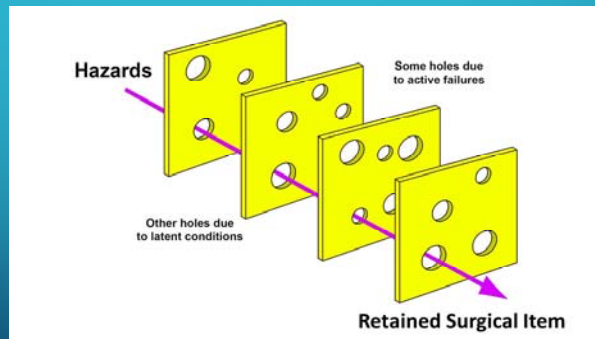
When updating a policy for prevention of retained surgical items, which do you use?

- A. Investigation of an event in your hospital
- B. Published research
- C. Both

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REASON'S SWISS CHEESE MODEL OF ERRORS



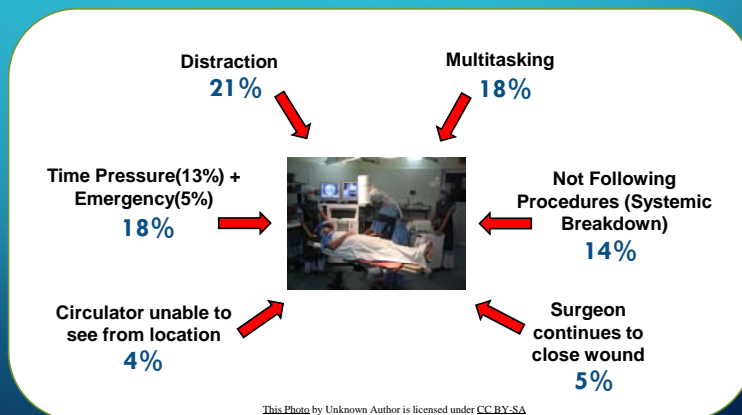
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A PROSPECTIVE RISK ANALYSIS

HEALTHCARE FAILURE MODE AND EFFECT ANALYSIS



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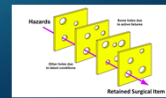
STEELEMAN, V.M., CULLEN, J. AORN J 94 (August 2011) 132-141. © AORN, Inc., 2011. doi: 10.1016/j.aorn.2010.09.034

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USING DATA TO DESIGN SAFER PROCESSES

We can learn from:

- A root cause analysis of single event
 - Requires an adverse event or near miss to occur in the setting
 - Often identifies one cause
- Published evidence about risk in many events
 - Allows us to learn from errors that have occurred elsewhere and the effectiveness of strategies for prevention
 - Identifies numerous contributing factors
 - Can be used to design safer processes before an error occurs in the setting



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RECENTLY PUBLISHED DATA

Retained Surgical Sponges

Steelman, V. M., Shaw, C., Shine, L., & Hardy-Fairbanks, A. J. Retained surgical sponges: a descriptive study of 319 occurrences and contributing factors from 2012 to 2017. *Patient Safety in Surgery*. 2018(June).
Provided as a handout for this presentation.

Retained Instruments and Other Items

Steelman, V. M., Shaw, C., Shine, L., & Hardy-Fairbanks, A. J. Unintentionally retained foreign objects: A descriptive study of 308 sentinel events and contributing factors. *Joint Commission Journal on Quality and Patient Safety*. October 2018; S1553-7250(18), 30304-0.

Retained guidewires

Steelman, V. M., Thenuwara, K., Shaw, C., & Shine, L. Retained guidewires: A descriptive study of 73 sentinel events. *Joint Commission Journal on Quality and Patient Safety*. September 2018; S1553-7250(18), 30256-3.

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METHODS

- Three descriptive studies
- Retrospective review of events involving unintentionally retained foreign objects voluntarily reported to The Joint Commission (TJC).
- Inclusion criteria
 - Events meeting the TJC definitions of unintentionally retained foreign object and sentinel event.
 - Occurred during surgery, childbirth, wound care, and other invasive procedures.
- Exclusion criteria
 - Surgical sponges intentionally packed for removal later.

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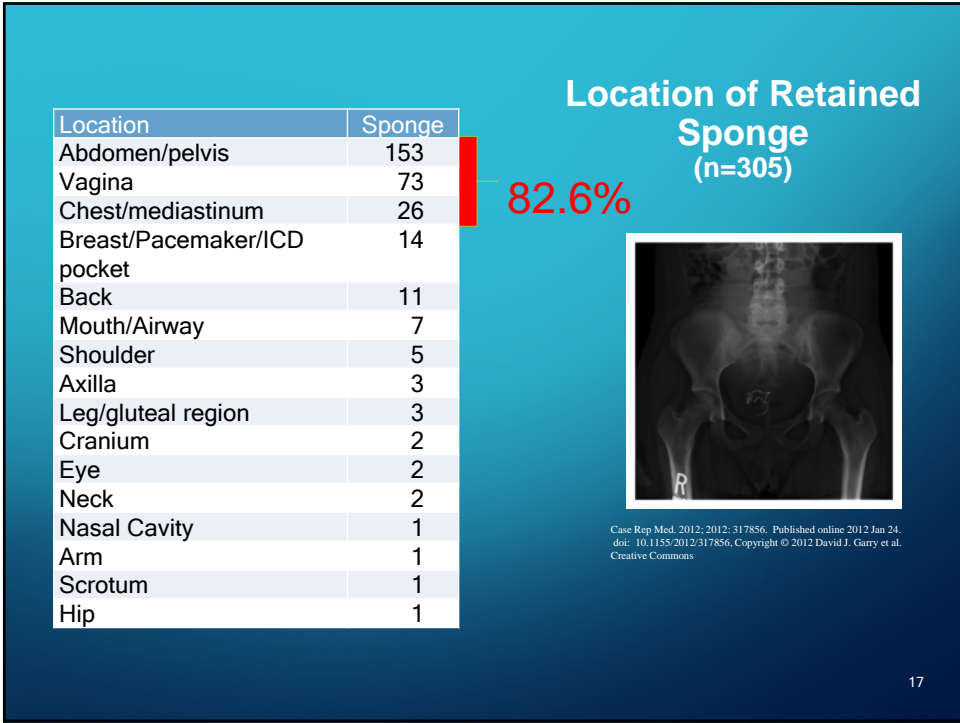
TYPE OF SPONGE (N=319)



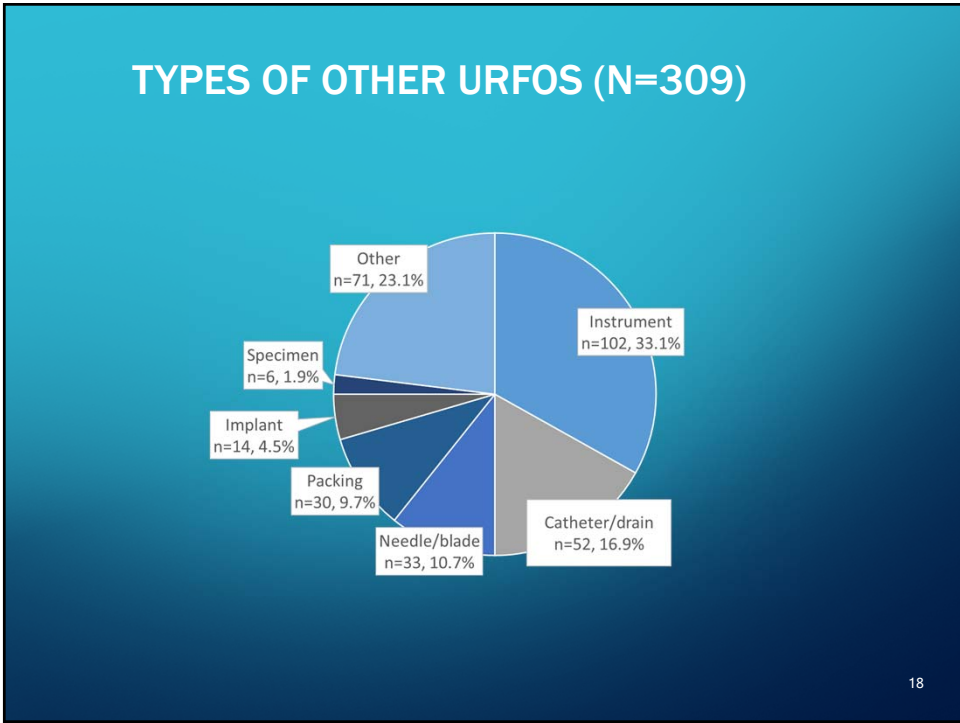
Type of sponge	N	%
Laparotomy	83	26.0
4 X 4/ 4 X 8/ raytec	54	16.9
Towel	11	3.4
Cottonoid	5	1.6
Kerlix	2	0.6
Peanut	1	0.3
Tonsil	1	0.3
4 x 10	1	0.3
2 x 4	1	0.3
Unknown	160	50.2
Total	319	100

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LOCATION OF INSTRUMENTS AND OTHER RETAINED ITEMS

Location (N=287)	Number
Abdomen/pelvis	83
Vagina	58
Joint (hip/knee/shoulder)	39
Chest/mediastinum	33
Artery/vein	18
Back/coccyx/neck	17
Airway/mouth	13
Leg/foot	7
Arm/axilla	7
Cranium	5
Breast	2
Other	5

74.2%

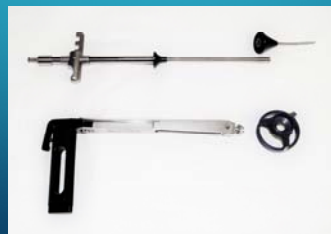
Known in 287 cases.

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TYPES OF RETAINED INSTRUMENTS

- 33.1% of retained instruments were orthopedic
 - Half of these were in joint arthroplasty
- Most frequently identified instrument - part of a uterine manipulator



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RETAINED INSTRUMENTS AND OTHER ITEMS (N=102)

- Drains- most frequently Penrose used during surgery
- Packing was most often placed in the vagina
- Implants included those used in bariatric surgery and for occlusion of the fallopian tubes
- Organs retained were dissected during minimally invasive surgery
 - Gall bladder, stomach, colon, ovary
- The entire list is available in the published manuscript

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HARM FROM RETAINED ITEMS

Category of Harm	Sponge	Other
Unexpected Additional Care/Ext Stay	222	211
Severe Temporary Harm	47	29
Permanent Loss of Function	2	-
Psychological Impact	2	-
Permanent Harm	1	2
Death	1	5

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TIMEFRAME FOR DISCOVERY (243)

Timeframe	Sponge	Other
Operating Room, post-closure	40	37
Hospitalization, post-OR discharge	83	96
Within 7 days of hospital discharge	37	27
>7 days post-discharge	39	25
>30 days post-discharge	44	49



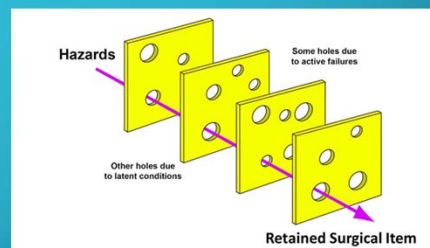
49.4% sponges & 39.3% other retained items were discovered after hospital discharge.

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CONTRIBUTING FACTORS

- 1-12 contributing factors per event
- Sponges- 1430 total
- Instruments & other items -1156 total



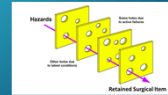
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CONTRIBUTING FACTORS (SPONGES- 1430; OTHER-1156)

Category	Sponge	Other
Human Factors	417	333
Leadership	394	286
Communication	330	253
Operative Care	108	85
Assessment	82	67
Physical Environment	33	72
Information Management	25	36
Performance Improvement	21	5
Other	20	19



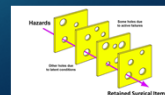
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HUMAN FACTORS – RETAINED ITEMS

Subcategory	Sponge	Other
Medical staff peer review/ credentialing	126	108
Staff orientation/in-service education	94	98
Competency assessment	49	-
Staff supervision	13	8
Resident supervision	9	5
Staffing levels/skill mix	6	4
Other human factor issues	120	110



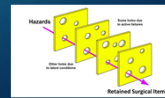
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LEADERSHIP- RETAINED ITEMS

Subcategory	Sponge	Other
Compliance with policies & procedures	205	94
Policies & procedures	129	160
Organizational culture	31	7
Directing departments/services	11	10
Nursing leadership	3	3
Medical staff - Other	3	12
Other leadership issues	12	-



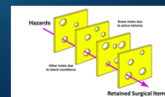
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COMMUNICATION

Subcategory	Sponge	Other
With physician	153	104
Among staff	92	91
Oral communication	54	24
Written/electronic communication	14	13
With administration	13	9
Other communication issues	4	12



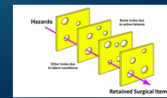
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OTHER CATEGORIES OF CONTRIBUTING FACTORS

Category	Sponge	Other
Operative Care	108	85
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Physical Environment	33	72
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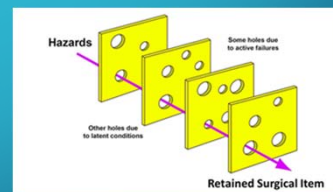
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RECOMMENDATIONS FOR PREVENTION

- Feel vulnerable – you are at risk
- Establish an interdisciplinary team
- Develop a comprehensive program for prevention
 - The count is not the primary intervention for prevention



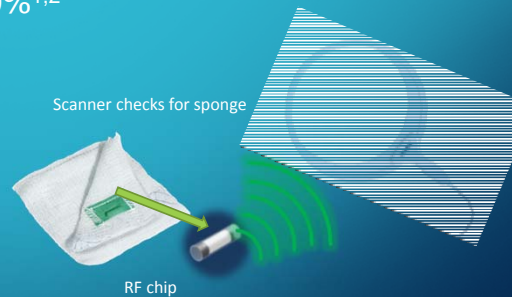
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RADIOFREQUENCY SPONGE DETECTION

- More effective than counts^{1,2}
 - Sensitivity: 98.1%; 100%^{1,2}
 - Counts are 77%³
 - X-Ray 67%⁴
- More cost effective than counts^{5,6}



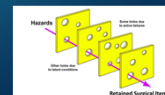
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6. Steelman, V.M., Schaapveld, A.G., Storm, H. et al. The Effect of radiofrequency technology on time spent searching for surgical sponges and associated costs. *AORN J.* 2019; 109(6):718-727.

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RECOMMENDATIONS FOR PREVENTION - HUMAN FACTORS

- Provide team training
- Minimize distractions and interruptions
- Account for objects inserted in the wound
- Methodologically explore the surgical site prior to closure
- Verify integrity of objects upon removal
- Educate about risks and risk reduction



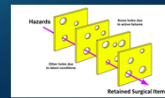
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RECOMMENDATIONS FOR PREVENTION - LEADERSHIP

- Prioritize a culture of safety
- Encourage reporting of events and near misses
- Conduct a proactive risk assessment
- Implement policies and procedures based upon the risk assessment
- Audit and provide feedback of compliance with policies and procedures
- Allocate resources for education, training, credentialing, and audit and feedback



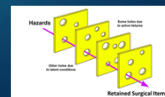
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CONDUCT A RISK ASSESSMENT

- Internal data
 - Type of surgeries performed
 - Processes in place
 - Events
 - Near misses
- Published evidence
 - The published studies presented



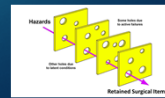
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RECOMMENDATIONS FOR PREVENTION - COMMUNICATION

- Use a white board to communicate insertion of devices
 - (e.g. vascular clamp, item in vagina)
- Verbally acknowledge removal of objects
- Discuss removal of objects during standardized debriefing after procedures
- Discuss need for packing removal during handoff
- Provide written orders for packing removal



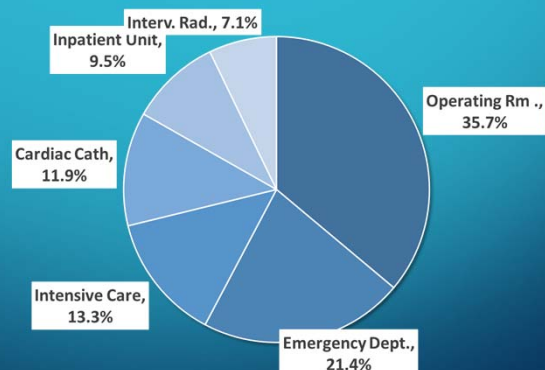
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RETAINED GUIDEWIRES (N=73)

Department Where Guidewire Was Retained (42 reports)



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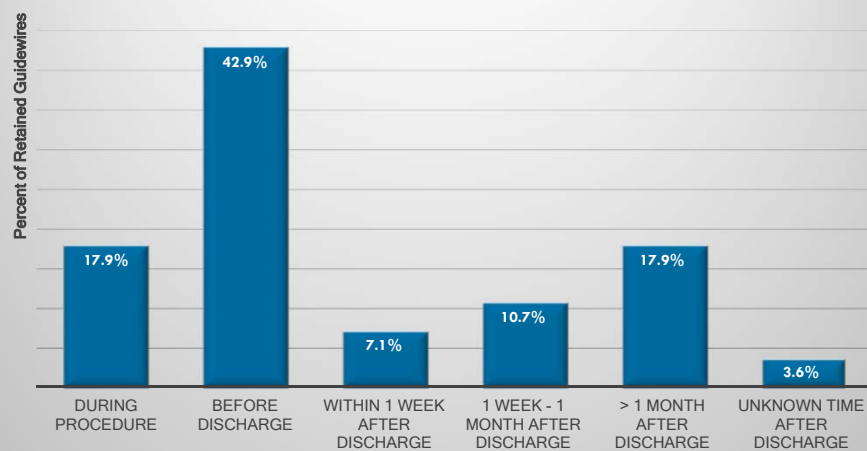
TYPE OF GUIDEWIRE DEVICE (N=73)

Type of device	n	%
Vascular catheters	63	86.3
Central line	42	57.5
PICC	8	11.0
Dialysis catheter	5	6.8
Cardiac catheter	4	5.5
Angio-Seal™	2	2.7
Midline catheter	1	1.4
Port	1	1.4
Surgical procedures	6	8.2
Knee arthroscopy	5	6.8
Breast biopsy	1	1.4
Drainage tubes	4	5.5
Biliary drain	1	1.4
Urinary (neph., suprapubic, stent)	3	4.1

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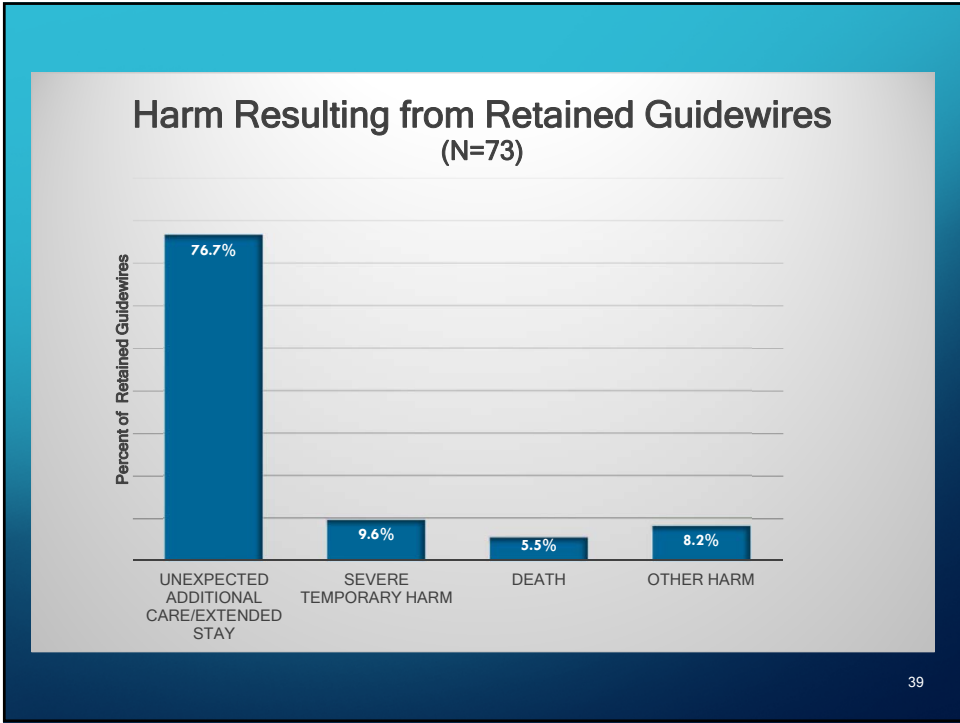
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Time to Discovery of Retained Guidewire (n=56)



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285 CONTRIBUTING FACTORS TO RETAINED GUIDEWIRES

Category	Count
Human factors	98
Leadership	72
Communication	42
Assessment	29
Physical Environment	13
Operative Care	11
Information Management	9
Health information technology-related	6
Information Management	9

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CONTRIBUTING FACTORS TO RETAINED GUIDEWIRES

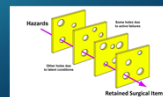
Human Factors (98)	#
Action inconsistent with organizational expectations	37
Other human factor issues (i.e. distraction, fatigue, drift)	30
Inadequate in-service, education, orientation, or competencies	23
Resident/staff supervision	8
Leadership (72)	#
Inadequate policies & procedures	35
Non-compliance with policies & procedures	23
Organizational culture - failure to enforce accountability	5
Ineffective resource allocation	3
Other leadership issues	6

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CONTRIBUTING FACTORS TO RETAINED GUIDEWIRES – COMMUNICATION

Communication (42)	#
With physician (i.e. failure to inform physician)	21
Among staff (i.e. peer to peer)	15
Written communication	3
With administration	3



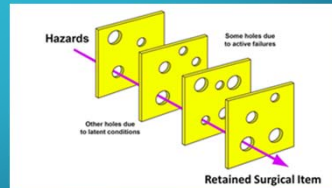
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RECOMMENDATIONS FOR PREVENTION

- Feel vulnerable – you are at risk
- Establish an interdisciplinary team
- Conduct a risk assessment
- Develop a comprehensive program for prevention
 - Focus on team roles



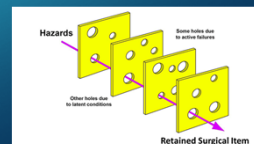
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RECOMMENDATIONS FOR PREVENTION – HUMAN FACTORS

- Educate about the risks
- Train using simulation, forced error detection, competency evaluation
- Credential providers
- Insertion checklist including guidewire removal
- Use a 2-person verification of removal, document
- Standardize kits to remove clutter
- Collaborate with manufacturers
 - Strengthen integrity
 - Color code
 - Reminder in kits



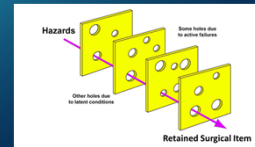
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RECOMMENDATIONS FOR PREVENTION – HUMAN FACTORS - LEADERSHIP

- Implement policies and procedures requiring 2-person verification of removal and integrity
- Audit and feedback of compliance
- Allocate resources
 - Education/training
 - Audit & feedback
 - Standardization of insertion kits



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RECOMMENDATIONS FOR PREVENTION – COMMUNICATION

- Verbally acknowledge guidewire removal and integrity
- Document removal & integrity
- Implement a best practice alert of required documentation and when X-Ray needed
- When ordering X-Ray indicate guidewire/fragment removed
- Implement high priority alert & verbal report from radiologist if guidewire/fragment identified on X-Ray

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SUMMARY

- Retained surgical items continue to occur.
- These events can seriously harm patients.
- Many contributing factors have been identified.
- Counting is ineffective.
- A comprehensive interdisciplinary program for prevention is needed.
- A risk assessment should be conducted.
 - Based upon internal data and published evidence.
 - The studies presented serve as important source of evidence

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PRIMARY REFERENCES

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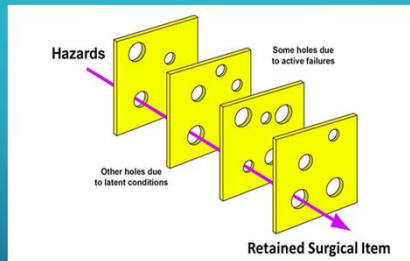
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