APPENDIX A. SEARCH STRATEGIES

DATABASE SEARCHED & TIME PERIOD COVERED:
PubMed – 1/1/2004-2/2013
LANGUAGE: English

SEARCH #1:
surgery OR surgical OR operating room* OR surgical procedures, operative OR perioperative OR peri-operative OR preoperative OR pre-operative
AND
wrong-site OR wrong-patient* OR wrong*[ti] OR incorrect[ti] OR mistake*[ti] OR never-event* OR "never event" OR "never events" OR Universal Protocol
NOT
animal* NOT (human OR humans)

SEARCH #2:
(surgery OR surgical OR operating room* OR surgical procedures, operative OR perioperative OR peri-operative OR preoperative OR pre-operative
AND
(retain*[ti] OR unretriev*[ti] OR forgot*[ti] OR forget*[ti])
AND
item OR items OR foreign body OR foreign bodies OR fragment* OR instrument* OR tool OR tools OR device* OR sponge* OR screw* OR needle* OR swab* OR knife blade* OR pin OR pins OR scalpel* OR clamp* OR scissors OR towel* OR electrosurgical adapter* OR tweezer* OR forceps OR tip OR tips OR tube OR tubes OR tubing OR scope OR scopes OR ultrasound tissue disruptor* OR bulb OR bulbs OR laser guide* OR guide wire* OR guidewire* OR guide-wire*)
OR "device loss" OR device-loss)
OR
gossypiboma* OR textiloma* OR muslinoma* OR gauzoma* OR "muslin-induced" OR "muslin induced"
NOT
animal* NOT (human OR humans)

SEARCH #3:
surgery OR surgical OR operating room* OR surgical procedures, operative OR perioperative OR peri-operative OR preoperative OR pre-operative
AND
fire OR fires
NOT
animal* NOT (human OR humans)

DATABASE SEARCHED & TIME PERIOD COVERED:
Web of Science – 1/2004-2/2013
LANGUAGE: English

SEARCH STRATEGY:
Topic=(surgery OR surgical OR operating room* OR perioperative OR peri-operative OR preoperative OR pre-operative)
AND
Topic=(wrong-site OR wrong-patient* OR never-event* OR "never event" OR "never events")
OR Title=(wrong OR mistake* OR incorrect*) OR (Title=(retain* OR unretriev* OR forgot* OR forget*) AND Topic=(item OR items OR foreign body OR foreign bodies OR fragment* OR instrument* OR tool OR tools OR device* OR sponge* OR screw* OR needle* OR swab* OR knife blade* OR pin OR pins OR scalpel* OR clamp* OR scissors OR towel* OR electrosurgical adapter* OR tweezer* OR forceps OR tip OR tips OR tube OR tubes OR tubing OR scope OR scopes OR ultrasound tissue disruptor* OR bulb OR bulbs OR laser guide* OR guide wire* OR guidewire* OR guide-wire*)) OR Topic=(fire OR fires) OR Topic=("Universal Protocol")
OR Topic=(gossypiboma*) OR Topic=(textiloma OR muslinoma* OR gauzoma* OR "muslin-induced" OR "muslin induced")

DATABASE SEARCHED & TIME PERIOD COVERED:
CINAHL – 1/2004-2/2013
LANGUAGE: English

SEARCH STRATEGY:
surgery OR surgical OR operating room* OR surgical procedures, operative OR perioperative OR peri-operative OR preoperative OR pre-operative
AND
wrong-site OR wrong-patient* OR never-event* OR "never event" OR "never events" OR "Universal Protocol" OR TI (wrong* OR incorrect OR mistake*) OR (TI (retain* OR unretriev* OR forgot* OR forget*) AND (item OR items OR foreign body OR foreign bodies OR fragment* OR instrument* OR tool OR tools OR device* OR sponge* OR screw* OR needle* OR swab* OR knife blade* OR pin OR pins OR scalpel* OR clamp* OR scissors OR towel* OR electrosurgical adapter* OR tweezer* OR forceps OR tip OR tips OR tube OR tubes OR tubing OR scope OR scopes OR ultrasound tissue disruptor* OR bulb OR bulbs OR laser guide* OR OR guide wire* OR guidewire* OR guide-wire*)) OR fire OR fires
OR gossypiboma* OR textiloma OR muslinoma* OR gauzoma* OR "muslin-induced" OR "muslin induced"

NUMBER AFTER REMOVAL OF DUPLICATES (PubMed, CINAHL, Web of Science): 3379

DATABASE SEARCHED & TIME PERIOD COVERED:
SCOPUS – 1/2004-2/2013
LANGUAGE: English

SEARCH STRATEGY: #1
surgery OR surgical OR operating room* OR perioperative OR peri-operative OR preoperative
OR pre-operative
AND
wrong-site OR wrong-patient* OR never-event* OR "never event" OR "never events" OR
"Universal Protocol"

SEARCH STRATEGY: #2
surgery OR surgical OR operating room* OR perioperative OR peri-operative OR preoperative
OR pre-operative
AND
TITLE(wrong* OR mistake* OR incorrect)

SEARCH STRATEGY: #3
surgery OR surgical OR operating room* OR perioperative OR peri-operative OR preoperative
OR pre-operative
AND
TITLE(retain* OR unretriev* OR forgot* OR forget*)

SEARCH STRATEGY: #4
surgery OR surgical OR operating room* OR perioperative OR peri-operative OR preoperative
OR pre-operative
AND
fire OR fires

SEARCH STRATEGY: #5
Gossypiboma* OR textiloma OR muslinoma* OR gauzoma* OR "muslin-induced" OR "muslin
induced"

SEARCH STRATEGY: #6
TITLE-ABS-KEY(surgery OR surgical OR operating room* OR perioperative OR peri-operative
OR preoperative OR pre-operative)
AND
TITLE-ABS-KEY(retain* OR unretriev* OR forgot* OR forget*)
AND
TITLE-ABS-KEY(item OR items) OR (TITLE-ABS-KEY(foreign body OR foreign bodies OR
fragment* OR instrument* OR tool OR tools OR device* OR sponge* OR screw* OR needle*
OR swab* OR knife blade*) OR (TITLE-ABS-KEY(pin OR pins OR scalpel* OR clamp*
OR scissors OR towel* OR electrosurgical adapter*) OR (TITLE-ABS-KEY(tweezer* OR
forceps OR tip OR tips OR tube OR tubes OR tubing OR scope OR scopes OR ultrasound tissue
disruptor* OR bulb OR bulbs OR laser guide* OR guide wire* OR guidewire* OR guide-wire*)
OR
TITLE-ABS-KEY(surgery OR surgical OR operating room* OR perioperative OR peri-operative

OR preoperative OR pre-operative)
AND
(TITLE-ABS-KEY("device loss" OR device-loss)

TOTAL AFTER REMOVAL OF DUPLICATES AND DELETION OF "Animal NOT Human" FROM KEYWORDS: 1317

DATABASE SEARCHED & TIME PERIOD COVERED:
IEEE XPlore – 1/2004-2/2013
LANGUAGE: English

SEARCH STRATEGY #1:
surgery OR surgical OR operating room* OR perioperative OR peri-operative OR preoperative OR pre-operative
AND
wrong-site OR wrong-patient* OR never-event* OR "never event" OR "never events" OR "Universal Protocol"

SEARCH STRATEGY #2:
surgery OR surgical OR operating room* OR perioperative OR peri-operative OR preoperative OR pre-operative
AND
wrong OR mistake* OR incorrect

SEARCH STRATEGY #3:
surgery OR surgical OR operating room* OR perioperative OR peri-operative OR preoperative OR pre-operative
AND
retain OR retains OR retaining OR unretriev* OR forgot OR forgotten OR forget OR forgets OR forgetting

SEARCH STRATEGY #4:
surgery OR surgical OR operating room* OR perioperative OR peri-operative OR preoperative OR pre-operative
AND
fire OR fires

SEARCH STRATEGY #5:
surgery OR surgical OR operating room* OR perioperative OR peri-operative OR preoperative OR pre-operative
AND
("device loss" OR device-loss

SEARCH STRATEGY #6:
gossypiboma* OR textiloma OR muslinoma* OR gauzoma* OR "muslin-induced" OR "muslin induced"

NUMBER OF RESULTS: 99

DATABASE SEARCHED & TIME PERIOD COVERED:
Cochrane CENTRAL - 1/2004-2/2013
LANGUAGE: English

SEARCH STRATEGY:
surgery or surgical or operating room* or surgical procedures, operative or perioperative or peri-operative or preoperative or pre-operative:ti,ab,kw
AND
wrong-site or wrong-patient* or wrong* or incorrect or mistake* or never-event* or "never event" or "never events" or Universal Protocol:ti,ab,kw OR "device loss" or device-loss OR gossypiboma* or textiloma* or muslinoma* or gauzoma* or "muslin-induced" or "muslin induced" OR fire or fires
OR
surgery or surgical or operating room* or surgical procedures, operative or perioperative or peri-operative or preoperative or pre-operative:ti,ab,kw
AND
retain* or unretriev* or forgot* or forget*
AND
item or items or foreign body or foreign bodies or fragment* or instrument* or tool or tools or device* or sponge* or screw* or needle* or swab* or knife blade* or pin or pins or scalpel* or clamp* or scissors or towel* or electrosurgical adapter* or tweezer* or forceps or tip or tips or tube or tubes or tubing or scope or scopes or ultrasound tissue disruptor* or bulb or bulbs or laser guide* or guide wire* or guidewire* or guide-wire*

NUMBER OF RESULTS AFTER REMOVAL OF DUPLICATES: 91

NUMBER OF DEDUPLICATED RESULTS ALL ELECTRONIC DATABASES: 4868

APPENDIX B. PEER REVIEW COMMENTS/AUTHOR RESPONSES

Pg.	Comment	Response
P3;L6	word "facilities' misspelled	Corrected
P3	"Key Question #1", may wish to explicitly state/include 'wrong level' as another type of incorrect surgery to go along with wrong site, wrong side, wrong patient, wrong procedure, and wrong implant	We have added 'wrong level surgery' explicitly to the inclusion criteria and have shortened the key questions so that the definitions for all topics are now in the same place (the inclusion criteria).
P5	*"The median prevalence estimate for wrong site surgery across general surgery estimates was 0.9 events per 10,000 surgeries."* The use of the term "general surgery" is unclear. Does this term refer to surgery in general or does it refer to the surgical specialty of "General Surgery"? If the former, the thought process for transition to "spine surgery" is unclear.	We have rephrased the sentence.
P5	*"...surgeons had performed one or more wrong level spine surgeries during their career in recent surveys."* RE: "spine surgeries": does "spine surgeries" refer to procedures performed by orthopedic surgeons, neurosurgeons, or both?	We have clarified the specialty (neurosurgeons in one survey, spine surgeons in the other without further specification).
P9	"a successful legal defense to surgery performed on the incorrect limb is almost impossible" ; this as stated cannot be true and is an interpretation of the "res ipsa" statue. These cases do not imply something is either right or wrong as the authors write in the review, res ipsa cases merely mean that negligence is presumed and therefore it usually is not necessary to prove negligence.	We have replaced the term "almost impossible" with "very difficult".
P9	Reference only The Joint Commission TJC e.g. p9; (which uses the term sentinel events) but not the larger agency The National Quality Forum which is the agency promulgating the larger Serious Reportable Events (SREs) which is what the states follow and which originated the term Never Events in the first place.	We were careful to associate only serious reportable events with the National Quality Forum and sentinel events with The Joint Commission, and believe the paragraph reflects this important distinction.
P10	"other surgical complications". Wrong site surgery, RSI and surgical fires are NOT surgical complications like surgical site infections or anastomotic leaks. They are surgical patient safety problems. Similarly, SSI and UTIs are not classical never events. Never events include things like fires, baby abductions, suicide in hospitals – there are 22 or 24 of them. See NQF list of the nevers. Opinion – making strong recommendations – difficult to do if the evidence is weak which is what one finding from the review overall is…..	Changed as suggested
P43, 3rd para, p55, 4th para	Use of the word "mundane"[implies bias]. These "mundane" problems are the source of the events. These are reviewer opinions, I would recommend just state the finding without the opinion. P.55 4th paragraph – "mundane risks" – these aren't mundane. They are what they are, they are the risks.	We have deleted the term and rephrased the sentences.
P44	Under "VA Subgroup . . .", root causes of 'surgical fires' should be 'wrong-site surgery/incorrect surgery' subgroup header is root causes of wrong site NOT surgical fires	Corrected

P53	consider placing column headings on all Tables, even if continued from previous page	Table column headings are now repeated throughout the report.
P88	not foreign objects, use surgical items	We have used the term "surgical item" in the text throughout, however the evidence tables display the original wording by the study authors, e.g., one of the included guidelines is called "Prevention of unintentionally retained foreign objects during vaginal deliveries by Institute for Clinical Systems Improvement (ICSI)".
P93	Perhaps in the Discussion and Summary framing the dialogue around what do we know; what gaps in knowledge require more research; and what can we do right now to improve performance based on the available evidence.	We have extended the discussion and provide more examples of approaches to prevent wrong site surgery, retained surgical items, and surgical fires that have been suggested in the literature which should be investigated in future studies to determine their effectiveness in preventing the events.
P94	reviewers make an assumption that because events of RSI occur at various times the reason there are a small number of root causes is because the timing of occurrence from discovery makes it "impossible" to reconstruct the contributing factors. This is not the case. For cases when the timeline to discovery is only days or hours there is difficulty in discovering the contributing factors. These failures lie in social, behavorial, educational gaps in the performance of RCAs and the investigations of the root causes.	We have revised the wording to say that the long time to discovery makes it "more difficult", rather than "impossible" to identify the root causes.
P97	"record" (4th paragraph) and "search" (5th paragraph) misspelled	Spelling has been corrected in these instances.
P97	Regarding "Recommendations for Future Research", are there any plans to obtain aggregate data regarding root cause analyses from The Joint Commission?	We are not aware of an ongoing project.
P97	TJC is a VOLUNTARY reporting agency, NOT mandatory p. 97 3rd paragraph and its writings on these sentinel events are "interpretations" actually of NQF or state laws.	We have revised the sentence as suggested.
P97	A recommendation from the report should be to perform studies or require reporting on near miss events/ close calls. Because these events are rare more information can be obtained from close calls which are rarely reported making for a thin evidence base.	We have added the suggestion to the future research section.
P98	wrong-site surgery incidence summarized as 0.09, inconsistent with report stating 0.9 per 10,000 cases	Corrected

--	One strategy that we have tried might prove useful in reinforcing procedures and processes aimed at preventing the three index events discussed. We have added **brief discussion of an "emergency procedure"** to our team briefings. This might include such items as the location of the closest fire alarm pull, closest extinguisher, characteristics of available extinguishers, highlighting standard procedures for an cavity sweep at the conclusion of an operation, operating procedures for our RF detector, indications for cavity radiography prior to wound closure, etc. Such frequent "refreshers" on risk mitigation and emergency procedures might serve to keep team members focused on preventing these "never" events.	The approach appears very useful and will hopefully be evaluated in a future research study.
--	Not that is currently available. I personally am publishing a manuscript for surgeons to outline how human cognitive error, lack of effective system safety nets, and poor crisis training leads to these events and worse case scenarios. Additionally, there are aviation studies that outline the effective methodology that the aviation industry does cockpit training and literature in surgery to show that the effects of MTT in its current format may not lead to longevity. This has to be a continued process and health care staff have to understand how human error negatively effects patient care. These are almost always mistakes and not malevolent errors.	A review of the aviation literature was beyond the scope of this review but we have added a reference to the literature and the rationale for the approach to the discussion section.
--	Also, I recently chatted with Verna Gibbs who reminded me that unless we are including things such as bullets, or other non-surgical products, we need to always refer to these items as RETAINED SURGICAL ITEMS and not retained FOREIGN Bodies, so we can keep the literature straight.	See comment above
--	Just as I mentioned above. This is an excellent dissertation of the frequency and risks for these events as noted in the available literature, but there is a lot of non-medical literature that goes thru human factors-cognitive error, systems approaches to safety and the like, which will be summarized in a publication aimed for surgical trainees and surgical teams to go out in a few months. The fact that there are retained surgical items still occurring is a testament to that fact. Not sure which is worse: having a "correct" count w/ a RSI or a surgeon closing the wound in spite of the team telling him there is something missing. This pattern used to be common in aviation, but they have virtually eliminated these issues w/ recurrent training. If we continue w/ the same old adage that we just need more protocols and more technology, this may just get worse.	See comment re aviation literature above
--	Huge undertaking. Clearly the wrong site surgery literature is more expansive. All are clearly described however superficial. Retained surgical items include 4 classes of items – soft goods, (which includes sponges) sharps, instruments and small miscellaneous items and un-retrieved device fragments (UDFs). There is no evidence reviewed on the UDFs which is a FDA reportable event. The synthesis and inclusion of information on surgical fires needs more work also. This category usually includes fires that occur in or on a patient and would include OR burns. There is no information presented on OR burns.	Unretrieved device fragments were included in the literature review (e.g., see included studies Chen et al., 2011; Lincourt et al., 2007). We have revised the inclusion criteria to make this more explicit. OR burns are included in the review if they occurred in conjunction with fires but we discussed with the technical expert panel that fire-unrelated burns are outside the scope of this review.

--	There is some evidence by word choice of opinion which may reflect bias, e.g. "small number of studies"; how many is small? What do the reviewers mean by small?	We have replaced the description with the actual number of identified studies.
--	Seems to this reviewer that the Guidelines section is very thin because of the strict application of only Guidelines from the National Guideline Clearinghouse. I think clinicians use guidelines from published papers and articles and don't rely on these consensus driven formally submitted documents. It makes the body of the available information on corrective actions appear much sparser than it really is when allowing for other guidelines and protocols from other sources e.g. ASA, ECRI, AORN, websites and safety projects. There is an unpublished draft of the VA RSI dataset which has been assembled for publication but has notyet been completed that this reviewer will provide to the project if requested.	We used the Institute of Medicine definition of when advice and recommendations can be called a guideline. Using this definition, recommendations and guidance without reference to being informed by a systematic review are not guidelines. A supplemental Google search on "Surgical Safety Guidelines," did not reveal any additional guidelines meeting our criteria, most of the items returned were references to WHO checklist. There was one guideline identified, Surgical Safety Checklist In Obstetrics and Gynaecology, from the Society of Obstetricians and Gynaecologists of Canada, which is listed in the National Guideline Clearinghouse. However, this guideline covers applying the surgical checklist for procedures in this specialty and is not focused on reducing wrong site surgery, and therefore it was excluded from our review. The searches on "Wrong Site Surgery Guideline" and "Retained Foreign Objects Surgery Guideline" did not identify any guidelines beyond those included in the review already. The search on "Fires Surgical" identified an updated clinical guidance document for preventing and managing surgical fires, which was developed by ECRI. While it summarizes information for clinicians (educational materials, videos and posters) it does not reference a systematic review as informing the recommendation, and hence does not meet the IOM definition of a guideline.
--	is the use of the word "incidences" as a plural noun as in "primary outcomes were <u>incidences</u>" correct? If this is standard terminology in these types of evidence reports ok, but seemed strange to this reviewer.	We have replaced the term "incidences" where the term 'event incidents' was applicable.
--	Similarly, the word "surgeries" is discouraged (even though widely used) e.g. p43, paragraph 5. Not the plural of an operation. Should use procedures or operations. Surgery is not a procedure, it's a discipline and a philosophy. One would not say – psychiatries when asking about psychiatric visits.	We have replaced the term "surgeries" throughout the text with the term "surgical procedures" but have kept the evidence tables as extracted from the original papers.