August 8, 2016

Complications of Care: A Case for MIS Competency

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Disclosure

- The presenters have nothing to disclose

Objectives

- Discuss the evolution and development of minimally invasive surgery (MIS) and procedures
- Identify patient hazards related to the use of monopolar electrosurgery
- Outline national safety initiatives meant to improve outcomes and protect patients
- Understand education and competency assessment to improve staff quality outcomes
- Describe the importance of using technology and standardization to reduce patient injuries

Historical Development of Endoscopy

- Philipp Bozzini (1773-1809) builds Der Lichleiter – the Light Conductor – the first endoscope
  - A sharksin-covered instrument with candle in a metal chimney
  - A mirror inside reflected light from candle through attachments
  - An 1806 paper described his device – an instrument to view internal organs

Verger-Kuhnke, Reuter & Beccaria, 2007

20th Century Laparoscopic Advances

Year	Name	Advancement
1901	Kelling (Germany)	Laparoscopy on dog
1910	Jacobaeus (Sweden)	First used term ‘laparoscopy’
1911	Bernheim (U.S.)	First U.S. laparoscopy
1920	Orndoff (U.S.)	Pyramidal trocar
1929	Kalk (Germany)	135-degree lens system
1934	Ruddock (U.S.)	Bipolar ESU device
1938	Veress (Hungary)	Spring-loaded needle
1970	Semm (Germany)	Auto electronic insufflator
1987	Mouret (France)	First Euro cholecystectomy
1988	McKernan and Saye (U.S.)	First U.S. cholecystectomy

Laparoscopic Surgery Popularized

- GYNs popularized laparoscopic surgery in the 1970s
  - Female sterilization demand
  - "Band-aid" surgery required no hospital stay
- AAGL formed in 1971 to teach/study MIS techniques
- Medicare implemented DRGs (1980s)

Batt, 2007
Kozack, McCarthy & Pokras, 1999
Soderstrom, 2007

Patients Respond

Smaller scars, less pain, quicker recovery = faster return to normal

Why SGO members perform laparoscopy

Reason	2004	2007
Decreased length of stay	74%	85%
Improved quality of life	57%	74%
Patient preference	46%	60%
Improved cosmesis	46%	59%
Improved visualization	18%	41%

Mabrouk, 2009

Patient Hazards

Mechanical

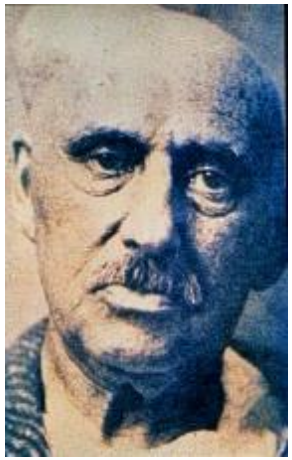
Thermal

- **Complications:** bleeding, perforations, lacerations, infections, dehiscence and occlusions
- **Never-events:** retained foreign objects, wrong site surgery, fires/burns, neuropathies, pressure ischemia, well-leg compartment syndrome

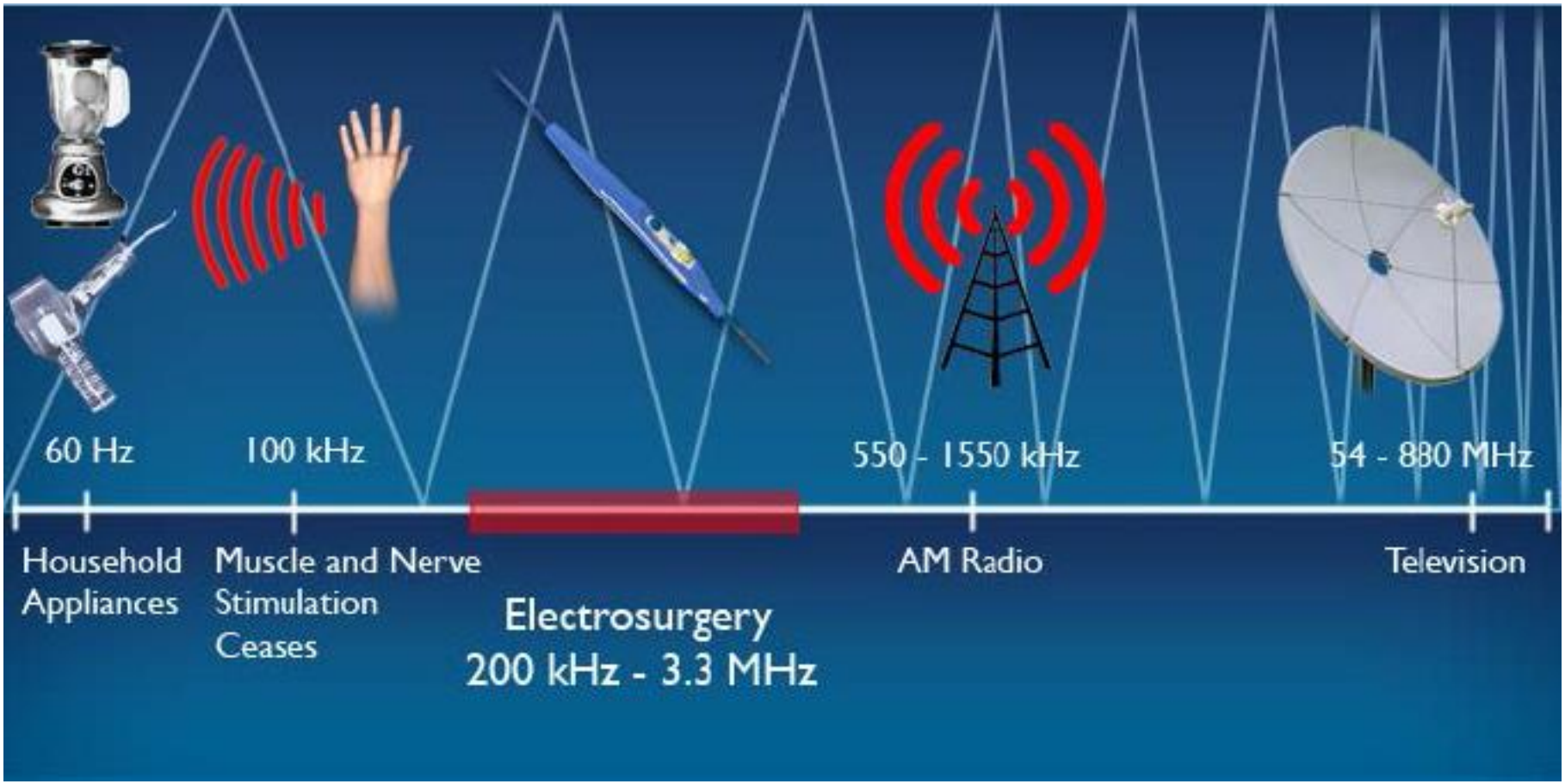
Wu, 2000
Clarke, 2009

Electrosurgery Technology: A Review

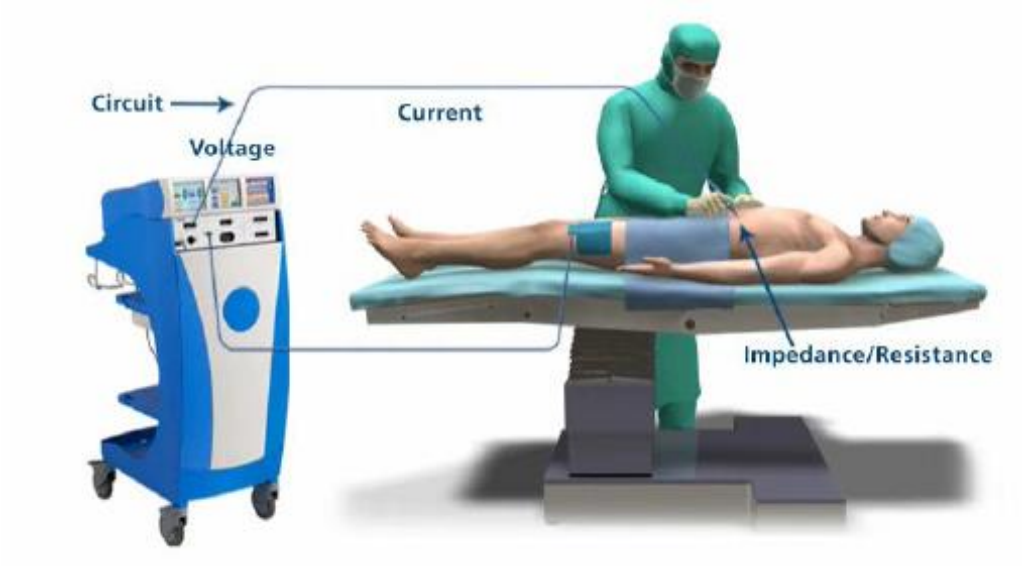
An understanding of the principles of electricity is necessary in order to understand the applications



Frequency Spectrum



Properties of Electricity



Current: Flow of electrons during a period of time, measured in aperes

Circuit: Pathway for the uninterrupted flow of electrons (must be complete/closed to flow)

Impedance: Obstacle to the flow of current measured in ohms

Voltage: Force pushing current through the resistance, measured in volts

Properties of Electricity

Seeks ground! (its source)

Electrosurgery is the use of a radio frequency electric current, used to cut tissue or achieve hemostasis

- **Current is at 300 – 500KHz**
- **Effects the body in heat**

Seeks path of least resistance

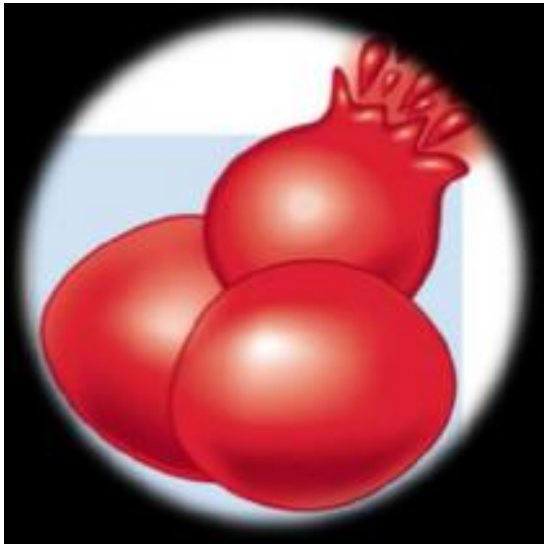
The Fundamental Rule…

Electricity follows the path of least resistance; it is a function of the water content in the cell. As tissue is desiccated, its resistance increases and the electricity seeks alternate routes.

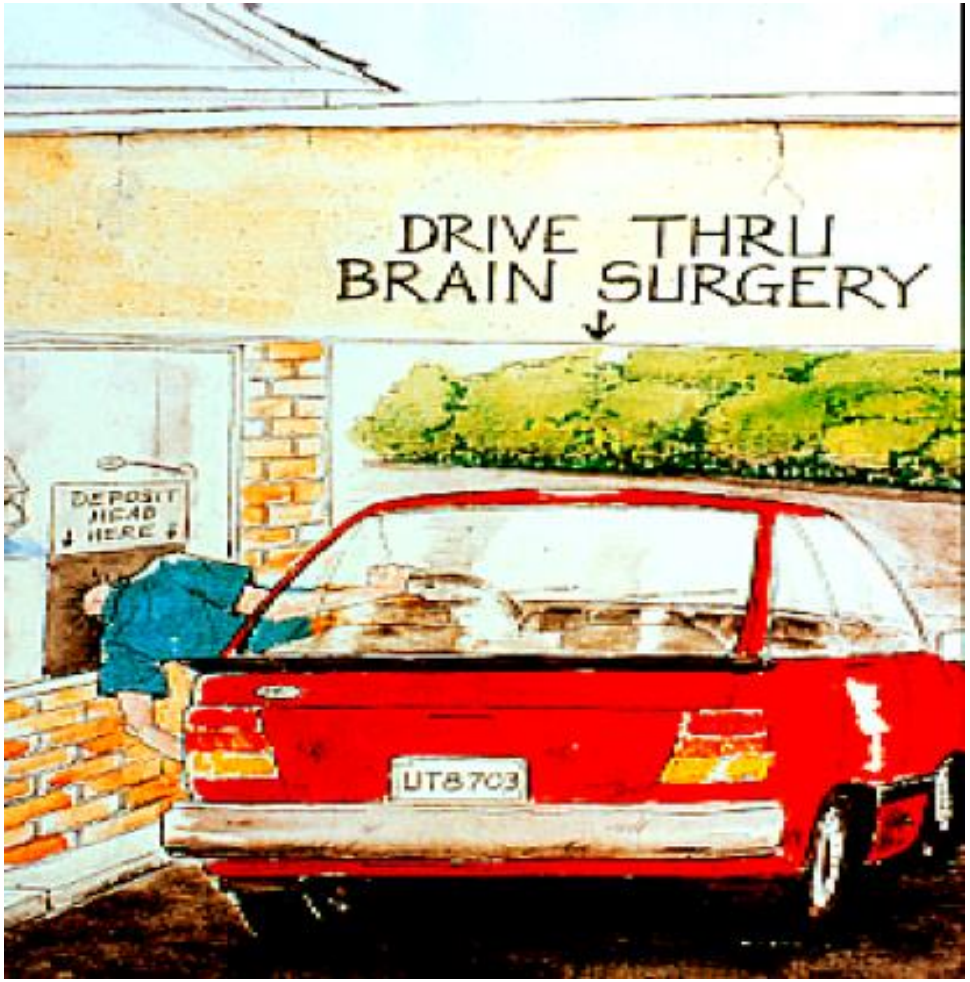
Energy Impact

H20 content in cells

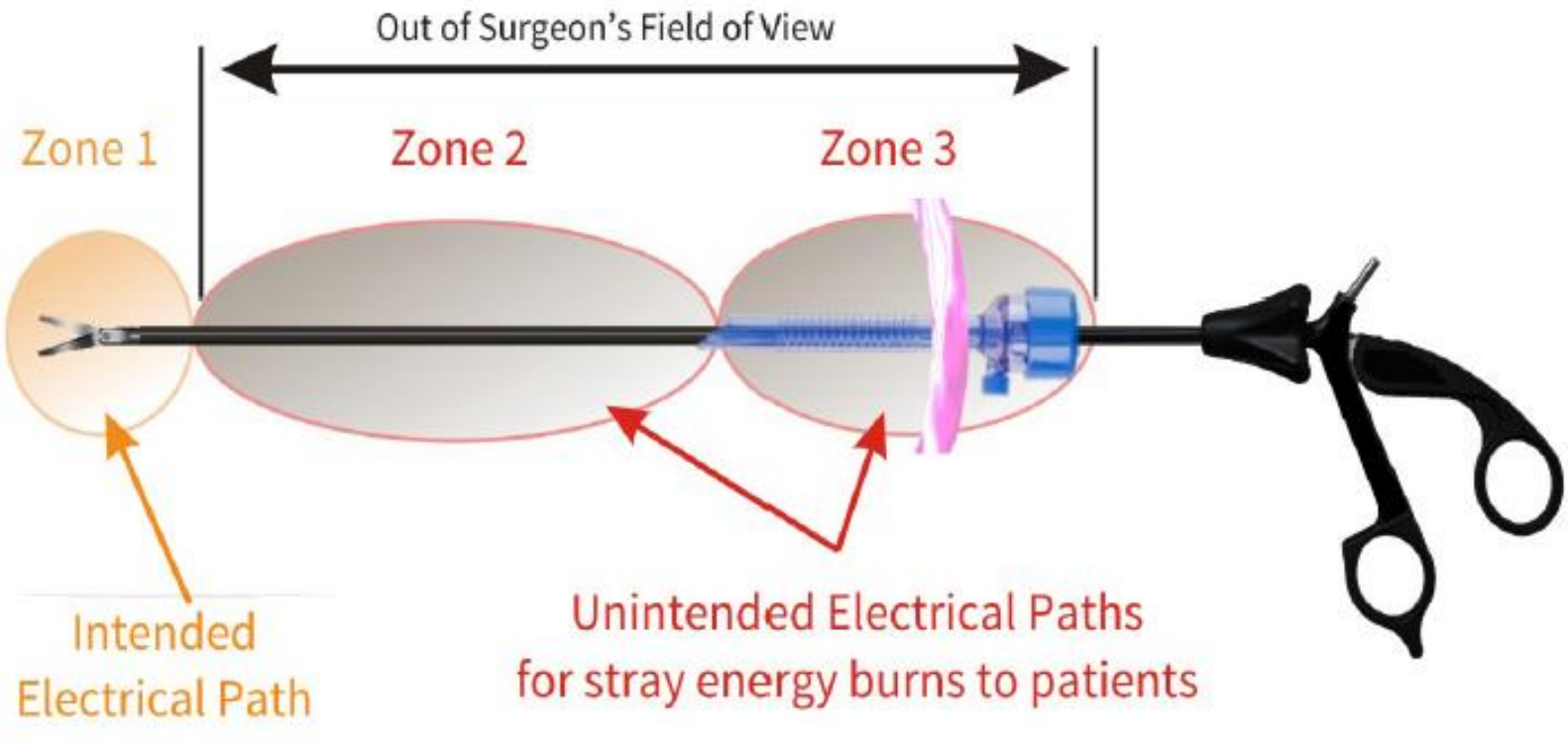
Ablated cells 100 degrees C



Minimally Invasive Surgery



Zones of Patient Injury



Electrosurgery MIS Safety Hazards

- Direct coupling
- Capacitive coupling
- Insulation failure
- Residual heat
- Endosurgical smoke plume

Direct Coupling

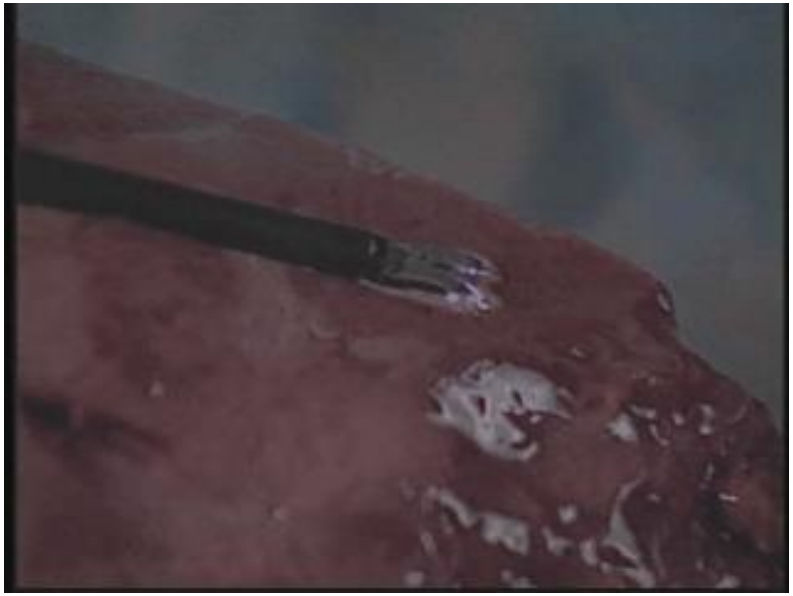
Occurs when electrode is activated close to or in direct contact with conductive object:

- Laparoscope
- Clips
- Instruments

Contact site could be outside the surgeon's field of vision

Capacitive Coupling

Capacitor: Two conductors separated by an insulator



Capacitance: Property of an electrical circuit which enables transfer of a charge from one conductor to another, even through intact insulation

Munro, 2004

Insulation Failure

Insulation compromised

Insulation Failure

Insulation failure in laparoscopic instruments

Paul N. Montero · Thomas N. Robinson · John S. Weaver · Greg V. Stiegmann

Background Electrosurgery is used in virtually every laparoscopic operation. In the early days of laparoscopic surgery, capacitive coupling, associated with hybrid trocars, was thought to be the major cause of laparoscopic electrosurgery injuries. Modern laparoscopy has reduced capacitive coupling, and now insulation failure is thought to be the main cause of electrosurgical complications. The aim of this study was (1) to determine the incidence of insulation failures, (2) to compare the incidence of insulation failure in reusable and disposable instruments, and (3) to determine the location of insulation failures.

Methods At four major urban hospitals, reusable laparoscopic instruments were checked for insulation failure using a high-voltage porosity detector. Disposable L-hooks were collected following laparoscopic cholecystectomy and similarly evaluated for insulation failure. Instruments were determined to have insulation failure if 2.5 kV crossed the instrument's insulation to create a closed loop circuit. Statistical analysis was performed using Fisher's exact or χ^2 analysis (*denotes significance set at $p < 0.05$).

Results Two hundred twenty-six laparoscopic instruments were tested (165 reusable). Insulation failure occurred more often in reusable (19%; 31/165) than in disposable instruments (3%; 2/61; *$p < 0.01$). When reusable sets were evaluated, 71% (12/17) were found to have at least one instrument with insulation failure. Insulation failure incidence in reusable instruments was similar between hospitals and hospitals that do not routinely check for insulation failures (33%; 7/21; $p = 0.16$). Insulation failure was most common in the distal third of the instruments (54%; 25/46) compared to the middle or proximal third of the instruments (*$p < 0.05$).

Conclusion One in five reusable laparoscopic instruments has insulation failure, a finding that is not altered by whether the hospital routinely checks for insulation defects. Disposable instruments have a lower incidence of insulation failure. The distal third of laparoscopic instruments is the most common site of insulation failure.

Keywords Radiofrequency · Monopolar electrosurgery · Laparoscopic · Insulation failure

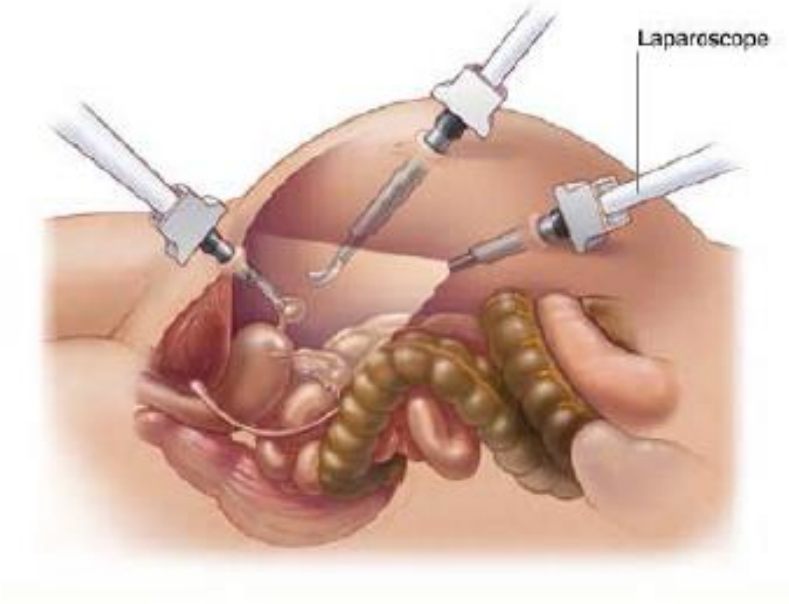
Monopolar radiofrequency electrosurgery is used in virtually every laparoscopic operation. Injury from inadvertent energy transfer has a reported incidence of 1-5 recognized injuries per 1,000 cases [1, 2]. Many such injuries create catastrophic complications [3] and result in medicolegal actions [4].

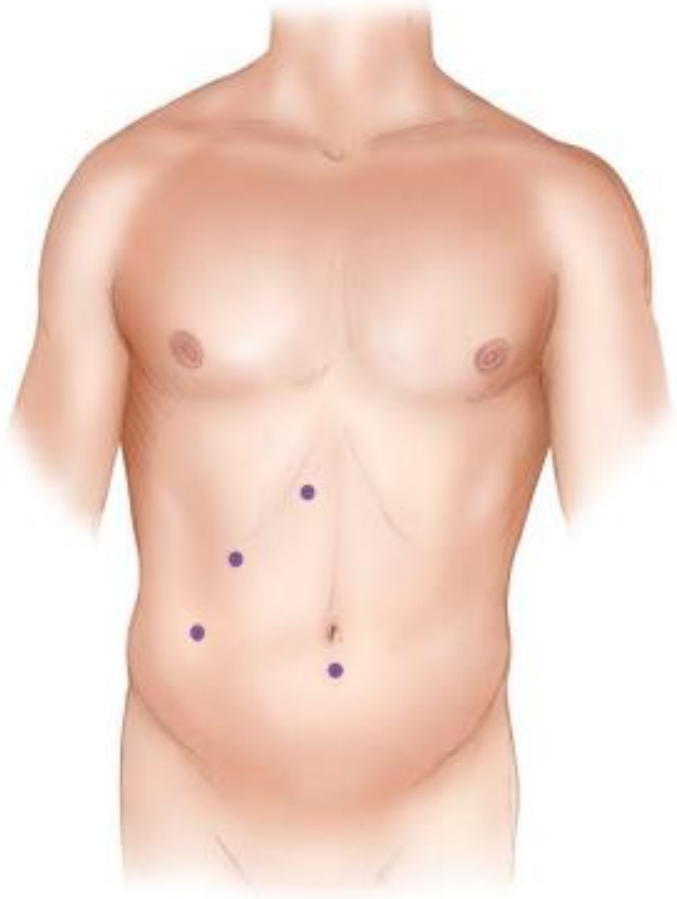
Four types of laparoscopic electrosurgery injury patterns exist: insulation failure, capacitive coupling, direct coupling, and direct application [5, 6]. In the early days of laparoscopic surgery, use of hybrid (a combination of

Conclusions: One in five reusable laparoscopic instruments has insulation failure; a finding that is not altered by whether the hospital routinely checks for insulation defects. Disposable instruments have a lower incidence of insulation failure. The distal third of laparoscopic instruments in the most common site of failure..

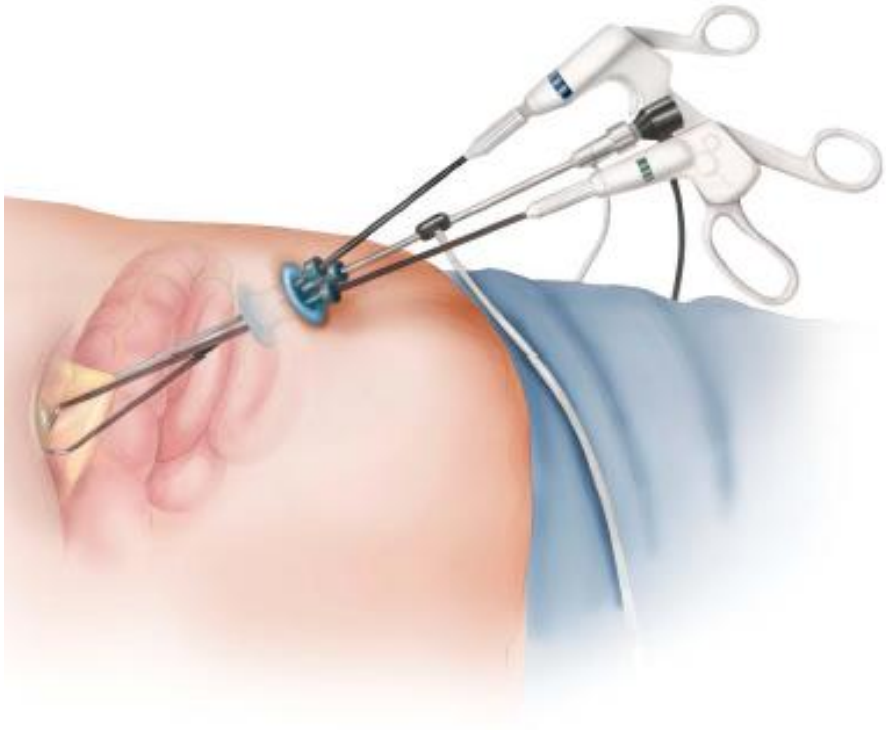
Surgical Endoscopy, July 2009

MIS Access Multiport





Single Port Access



- Single port access popularized by GYNs in 1970s
- New advanced technique for general surgeons and other specialities
- Benefits of one incision over multiple port site incisions seems obvious
- Pioneered at Drexel University in May 2007

Sparrow, 2007

Scopes can not look back on themselves!!

- **90% outside the field of view!**

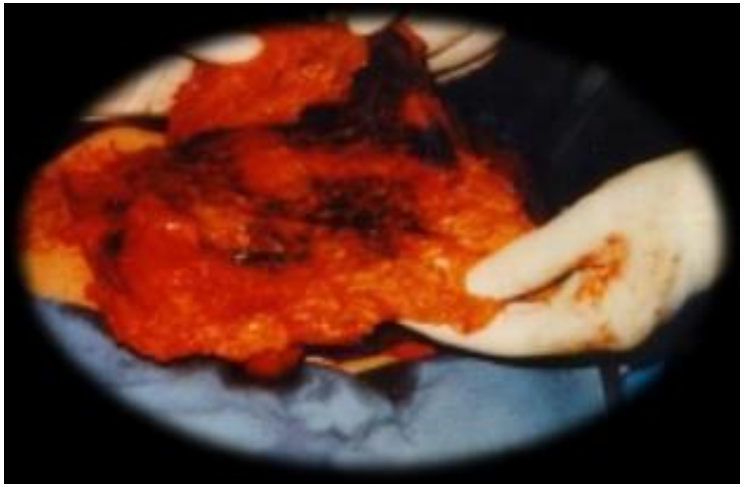
Laparoscopy Instruments

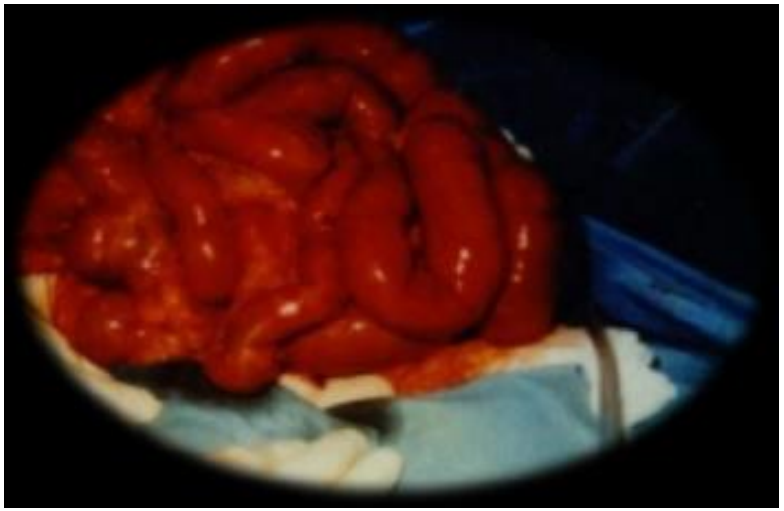
Checked out <u>one</u> lap chole tray, three out of the nine had cuts in the insulation

Dr. Casseres Sages 2004:
1438 conventional laparoscopic instruments

- 18 percent (270 instruments) insulation flaws
- 58 percent had insulation flaws outside the field of view
- 57 not visible to the naked eye

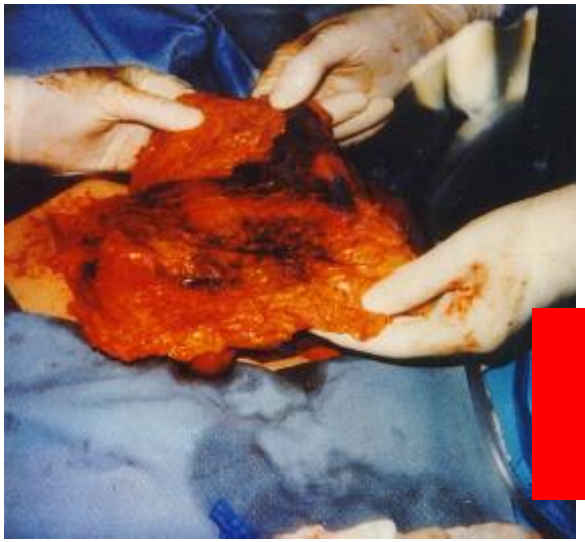
Complications





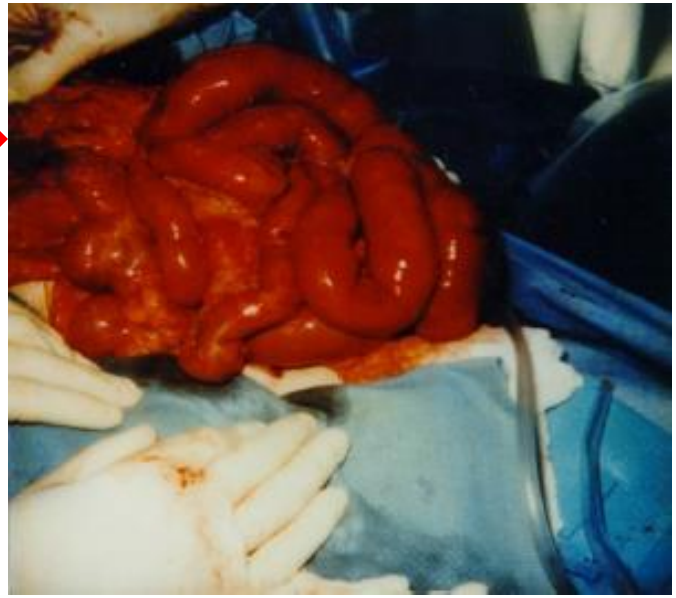
Omentum Burns

- Even with today's antibiotic therapy, the mortality rate from peritonitis is 25 percent



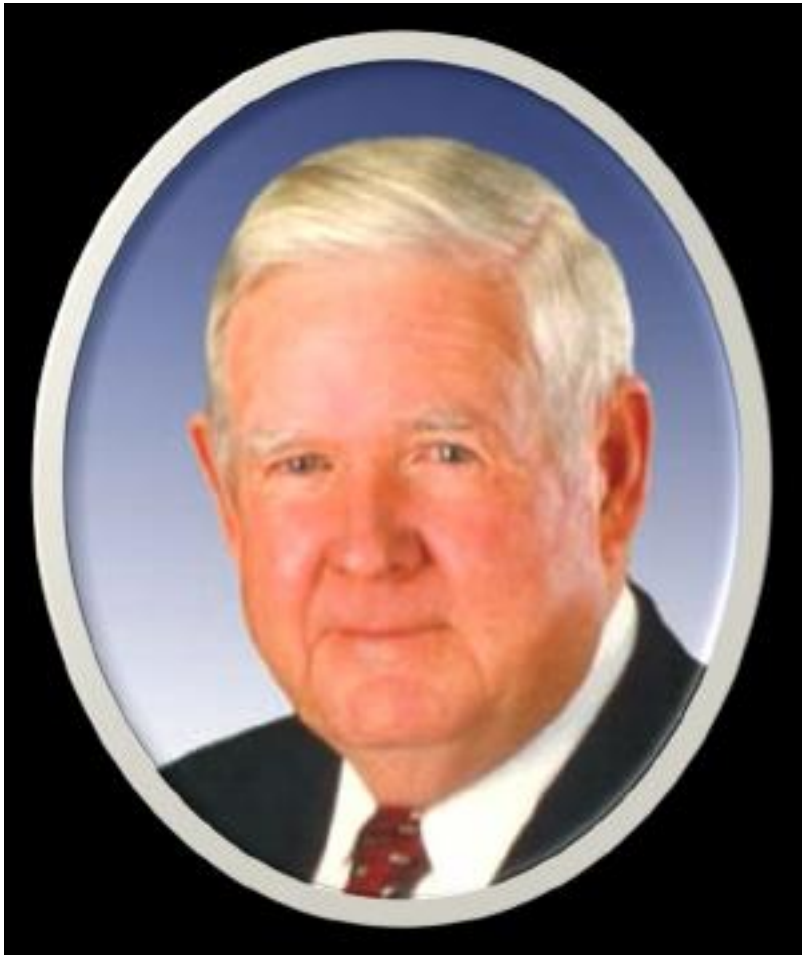
The body's rejection of thermal injury created an inflammatory process

Inflamed small intestine was directly under the injured omentum

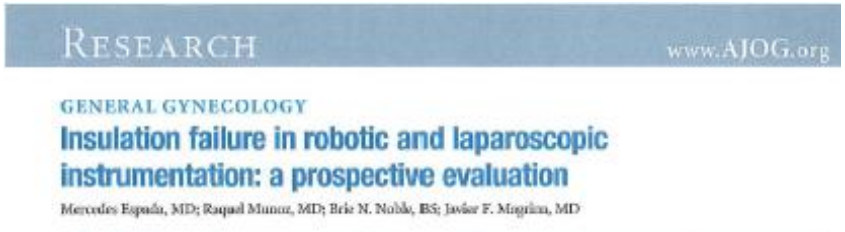


John Murtha Dies

The Washington Post
The 19-term lawmaker died from complications from gallbladder surgery. He had surgery on January 28, 2010. Fellow Democratic Representative Bob Brady said Murtha's large intestine was damaged during the normally routine laparoscopic surgery, causing an infection



In the Literature



RESEARCH www.AJOG.org

GENERAL GYNECOLOGY

Insulation failure in robotic and laparoscopic instrumentation: a prospective evaluation

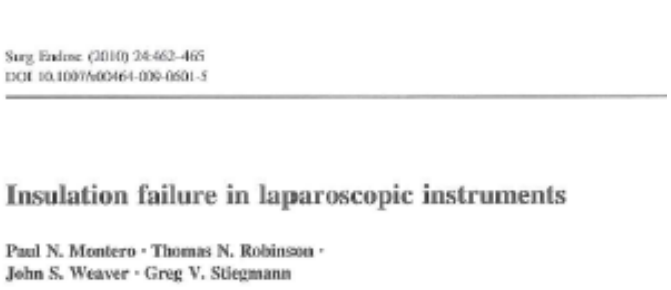
Mercedes Espada, MD; Raquel Munoz, MD; Brie N. Noble, BS; Javier F. Magrina, MD

J Urol 1999 Mar;161(3):887-90

Laparoscopic bowel injury: incidence and clinical presentation.

Bishoff JT, Allaf ME, Kirkels W, Moore RG, Kavoussi LR, Schroder F.

Brady Urological Institute, Johns Hopkins Medical Institutions, Baltimore, Maryland, USA.



Surg Endosc (2010) 24:462–465
DOI 10.1007/s00464-009-0501-5

Insulation failure in laparoscopic instruments

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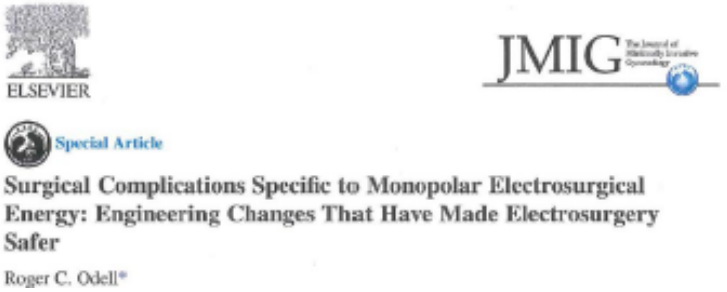
Journal of Minimally Invasive Gynecology (2009) 16, 228–232

THE JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY

Laparoscopic instrument insulation failure: The hidden hazard

Anusch Yazdani, MBBS, FRANZCOG, and Hannah Krause, MBBS, FRANZCOG, CII



ELSEVIER

JMIG The Journal of Minimally Invasive Gynecology

Special Article

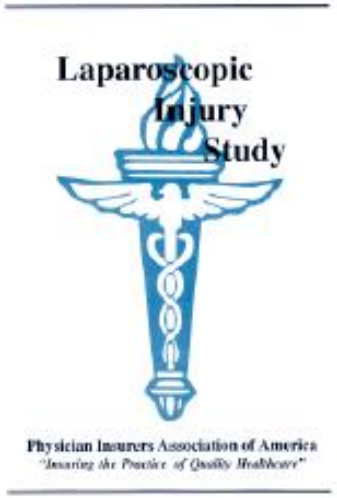
Surgical Complications Specific to Monopolar Electrosurgical Energy: Engineering Changes That Have Made Electrosurgery Safer

Roger C. Odell*

Legal Implications

Physician Insurers Association

- Trocars: 31.10 percent
- Clips: 8.96 percent
- Cautery (electrosurgery): 5.38 percent
- Scissors/scalpel: 3 percent
- Veress needle: 8.17 percent
- Unknown: 37.05 percent
- Miscellaneous: 6.34 percent

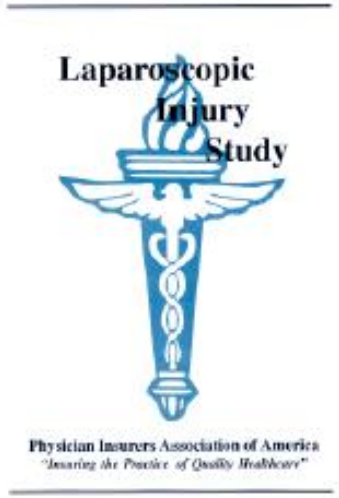


PIAA – 2000

Legal Implications

1990 – 1994 = $42,271,068

1995 – 1999 = $104,000,000



STUDY METHODOLOGY

The need to conduct a special study on laparoscopic injuries was indicated by the high frequency of claims reported in a relatively short period. A comparison of five-year increments reveals this increasing frequency. From 1990-1994, there were 750 laparoscopic claims with a total of $42,271,068 of indemnity paid reported to the PIAA. From 1995-1999, 1426 claims were reported to the database with a total indemnity paid of over $104 million. Laparoscopic surgery is being performed by a variety of medical specialties in the diagnostic and therapeutic processes. The data elements selected to be captured on the survey instrument were compiled after review of the nature of the injuries. The survey was conducted during the summer of 1999 and all forms were completed and returned in October. A copy of the survey is included in this report as Appendix B.

The study encompasses cases involving the laparoscopic injuries resulting in medical malpractice claims. The study includes paid claims, claims that have not been resolved and those claims without a payment to the plaintiff. Information was collected on several focal areas including the specialty and certification status of the named defendant and financial information pertaining to total indemnity. Claimant information was also captured, including patient age and gender. Other information requested included the primary procedure, diagnosis, device causing the injury and the outcome of the patient. Severity was assessed using the NAIC severity code system ranging from one indicating emotional injury only to nine indicating patient death (refer to Appendix C).

Claims

PIAA – 2000

Special Precautions for Laparoscopy

- Ensure proper connection
- Multi-foot pedal access
- Low voltage cutting waveform when possible
- Avoid open circuit activation
- Examine electrodes for impaired insulation
- Instrument limited life use
- Instrument testing: scan, active electrode shielding

ECRI, 2014

Accidents Have Occurred

Even the smallest devices can be hazardous!

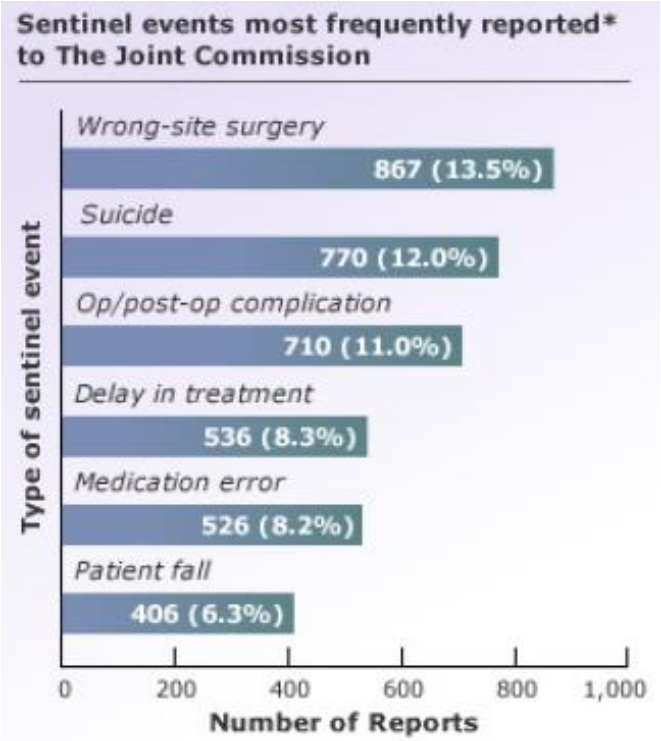
Global Safety Initiatives

- Complex equipment and complicated procedures increase the importance of teamwork
- World Health Organization (WHO) estimates half of reported complications are preventable
  - Identify safety concerns
  - Build safety into technology
  - Promote checklists and teamwork

Haynes, 2009

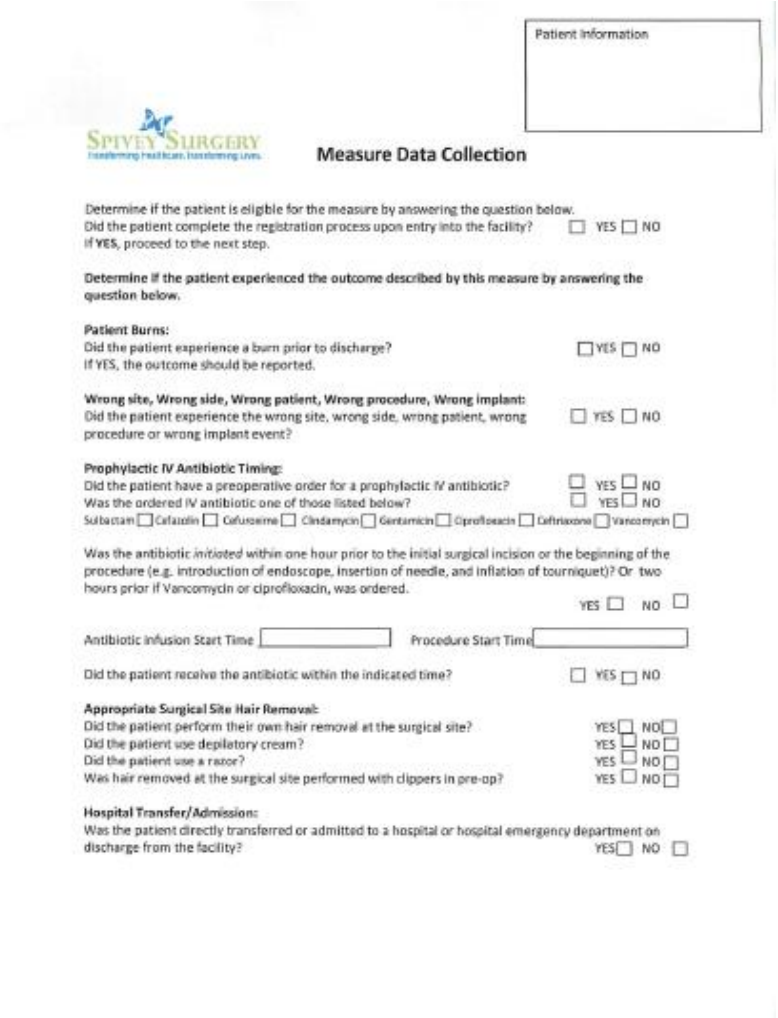
Patient Safety

- The Joint Commission has required hospitals report “sentinel events” since 1995
- Sentinel events are “an unexpected event involving death or serious injury”
- The NQF’s “Never Events” are considered sentinel events by the Joint Commission



AHRQ – 2014

Data Collection Tool



Patient Information

SPIVEY SURGERY

Measure Data Collection

Determine if the patient is eligible for the measure by answering the question below.
Did the patient complete the registration process upon entry into the facility? ☐ YES ☐ NO
If **YES**, proceed to the next step.

Determine if the patient experienced the outcome described by this measure by answering the question below.

Patient Burns:
Did the patient experience a burn prior to discharge? ☐ YES ☐ NO
If YES, the outcome should be reported.

Wrong site, Wrong side, Wrong patient, Wrong procedure, Wrong implant:
Did the patient experience the wrong site, wrong side, wrong patient, wrong procedure or wrong implant event? ☐ YES ☐ NO

Prophylactic IV Antibiotic Timing:
Did the patient have a preoperative order for a prophylactic IV antibiotic? ☐ YES ☐ NO
Was the ordered IV antibiotic one of those listed below? ☐ YES ☐ NO
Sulbactam ☐ Cefazolin ☐ Cefuroxime ☐ Clindamycin ☐ Gentamicin ☐ Ciprofloxacin ☐ Ceftriaxone ☐ Vancomycin ☐

Was the antibiotic *initiated* within one hour prior to the initial surgical incision or the beginning of the procedure (e.g. introduction of endoscope, insertion of needle, and inflation of tourniquet)? Or two hours prior if Vancomycin or ciprofloxacin, was ordered.
YES ☐ NO ☐

Antibiotic Infusion Start Time _____ Procedure Start Time _____

Did the patient receive the antibiotic within the indicated time? ☐ YES ☐ NO

Appropriate Surgical Site Hair Removal:
Did the patient perform their own hair removal at the surgical site? YES ☐ NO ☐
Did the patient use depilatory cream? YES ☐ NO ☐
Did the patient use a razor? YES ☐ NO ☐
Was hair removed at the surgical site performed with clippers in pre-op? YES ☐ NO ☐

Hospital Transfer/Admission:
Was the patient directly transferred or admitted to a hospital or hospital emergency department on discharge from the facility? YES ☐ NO ☐

Patient Safety

The BIG "Guys"

- U.S. federal government
  - Health and Human Services
    - AHRQ
    - CMS

New – CMS Final Rule to Improve Quality of Care

- Effective FY15 (October 1, 2014)
  - CMS Pay for Performance plan
  - Includes Hospital Acquired Condition (HAC) Reduction Program, which focuses on complications that are high cost, frequency and are PREVENTABLE
  - Penalizes low-performing hospitals
  - Encourages improvement-monetary incentives

CMS, 2014

New – CMS Final Rule to Improve Quality of Care

- HAC score calculated from two domains:
  - Domain 1 uses AHRQ patient safety indicator (90)
    - 43 percent of Domain 1 is Accidental Puncture and Laceration rate
    - 50 percent of APLs from stray energy burns (Bishoff – Johns Hopkins)
  - Domain 2 – Average of two hospital acquired infection measures

Indicator	Description	Weight
PSI-03	Pressure Ulcer Rate	13.57%
PSI-06	Iatrogenic Pneumothorax Rate	6.14%
PSI-07	Central Venous Catheter-Related Blood Stream Infection Rate	9.31%
PSI-08	Postoperative Hip Fracture Rate	0.05%
PSI-12	Postoperative Pulmonary Emobolism or Deep Vein Thrombosis Rate	22.09%
PSI-13	Postoperative Sepsis Rate	5.36%
PSI-14	Postoperative Wound Dehiscence Rate	1.59%
PSI-15	Accidental Puncture or Laceration Rate (APL)	42.89%
	SUM	100%

CMS, 2014

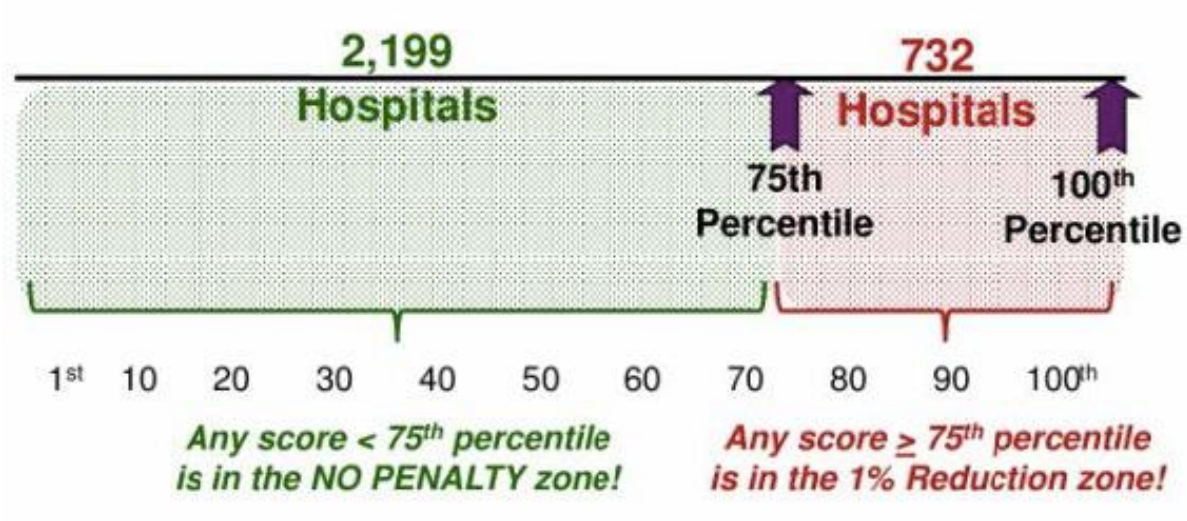
APL Rate/1000 Discharges

- **VA rate at 4.29% per 1,000 patients**

AHRQ, 2014

New – CMS Final Rule to Improve Quality of Care

- **732 hospitals penalized in first year**



- **HAC Reduction Program score distribution**

CMS, 2014

Hospital Acquired Condition Reduction Program

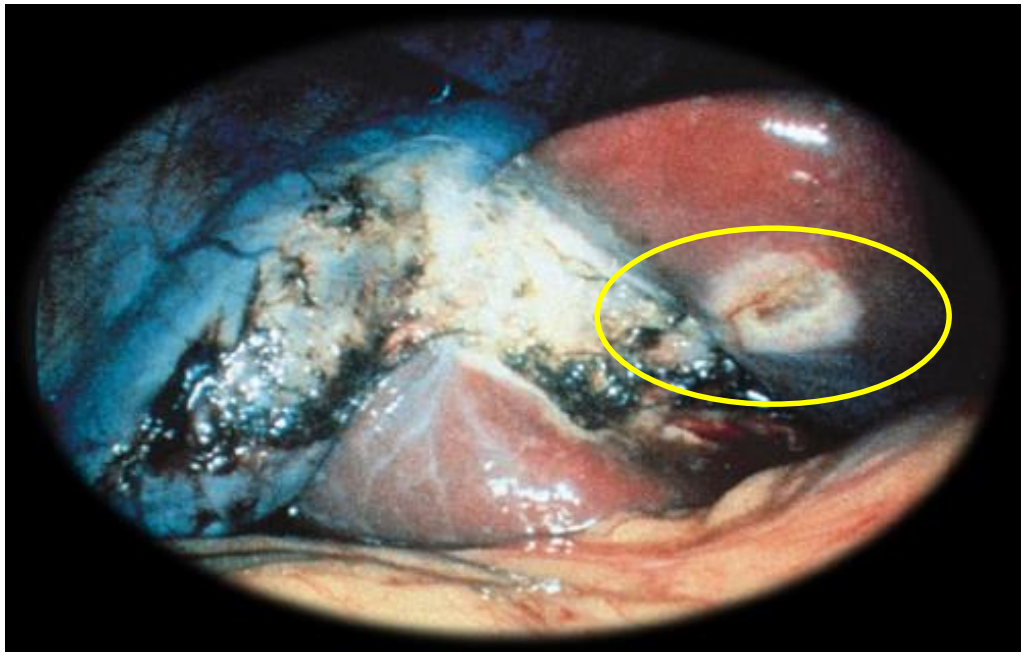
A hospital with annual $5 billion in revenue could lose $20 million per year in funding due to HAC reduction program penalties

- **$5,000,000 total revenue x 40% revenue from CMS x 1% HAC reduction =**
  $20,000,000 CMS penalty

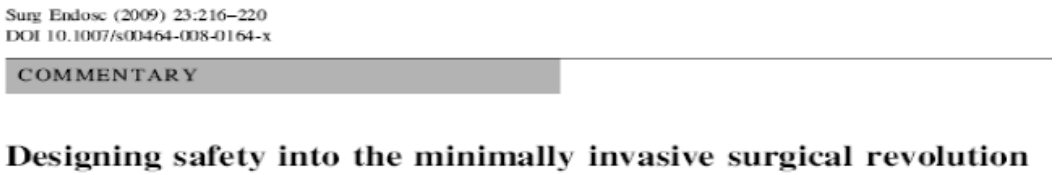
CMS, 2014

New – CMS Final Rule to Improve Quality of Care

The National Quality Forum (NQF) recently highlighted errant electrosurgical energy in accidental lacerations and punctures



Risk Reduction Strategies Education



Surg Endosc (2009) 23:216–220
DOI 10.1007/s00464-008-0164-x

COMMENTARY

Designing safety into the minimally invasive surgical revolution

- Most thermal injuries involving MIS result from electrosurgery
- Complications from electrosurgery are from bad habits or lack of awareness
- The necessity of electrosurgery makes education on best practices important

Clarke, 2009

Implement Competency Validation Program

Provide training to surgical staff and perioperative nursing staff

- Didactic learning experiences with lectures by electrosurgery experts such as manufacturer representatives
- Self-study modules
- Internet learning

Staff Competency

- The competence of all staff members is assessed, maintained, demonstrated and improved
- On-going in-service and other education and training to maintain and improve staff competence
- The hospital regularly collects aggregate data on competence patterns and trends to identify and respond to the staff's learning needs
- The hospital assesses each staff member's ability to meet the performance expectation stated in his or her job description

The Joint Commission

Risk Reduction Strategies Competency

Outcome 5 The patient is free from evidence of injury related to the application of electrosurgery.

Diagnosis	Risk Factors	Outcomes Indicators
Risk for Injury related to electrosurgery	☐ Excessive hair at the patient return electrode site ☐ Scar tissue at the patient return electrode site ☐ Internal or external prosthetic device at the patient return electrode site ☐ Impaired skin or tissue integrity at the patient return electrode site ☐ Presence of a pacemaker or an automatic implantable cardioverter-defibrillator (ACID) ☐ Obesity ☐ Emaciation ☐ Use of a ground reference generator ☐ Use of an isolated generator *not* equipped with a contact quality monitoring system ☐ Procedure done in the presences of an oxygen-enriched environment ☐ Use of a flammable prepping agent ☐ Coiling, clamping, or twisting of active and patient return electrode cords ☐ Failure to use a non-conductive safety holster ☐ Contact of a electrode shaft (suction coagulator, electrode extensive) with adjacent tissue during activation	☐ Is there evidence of impaired skin integrity at the patient return electrode site? Is the skin discolored? Does the skin appear to have an allergic reaction to the patient return electrode conductive adhesive? ☐ Does the patient show evidence of postprocedure skin and tissue disruption/ destruction at the patient return electrode site or at alternate pathway sites? ☐ Was there an ignition incident during the operative or invasive procedure? ☐ Does the patient fail to make reasonable progress after a laparoscopic procedure? Are there signs of fever? ☐ Does the patient complain of abdominal pain?

Risk Reduction Strategies Skill Assessment

Name: _____ Title: _____ Unit: _____ Date of Validation: _____

Type of Validation: ☐ Initial ☐ Annual ☐ Bi-annual

Competency Statement: The nurse demonstrates competency to implement appropriate safety measures to prevent injury related to the use of electrosurgery.

	Performance Criteria	*Met*	*Not Met*
1.	Ascertains equipment is in good working condition prior to use.	☐	☐
2.	Selects correct adaptor, if necessary, and dispersive electrode for patient use.	☐	☐
3.	Assesses and documents the patient's skin condition at the dispersive electrode site prior to application.	☐	☐
4.	Applies dispersive electrode properly, on an appropriate site, according to manufacturer's recommendations.	☐	☐
5.	Uses appropriate generator for the planned procedure.	☐	☐
6.	Encases the foot switch in a clean, clear, impervious cover when there is a potential for fluid spills.	☐	☐
7.	Places the generator on a movable stand that will not tip.	☐	☐
8.	Positions cords in a manner to prevent tripping.	☐	☐
9.	Allows alcohol-based skin preparation solutions to dry prior to draping.	☐	☐
10.	Sets generator settings appropriately per manufacturer's recommendations and surgeon's oral instruction; verbalizes safe setting ranges.	☐	☐
11.	Monitors for loosening or displacement of the dispersive electrode during the procedure.	☐	☐
12.	Assesses and documents the patient's skin condition at the dispersive electrode site after electrosurgery use.	☐	☐
13.	Describes the alarm system and parameters being monitored.	☐	☐
14.	Verbalizes correct procedure to follow for equipment malfunctions.	☐	☐
15.	Verbalizes correct procedure to follow in the event of a patient injury.	☐	☐
16.	Verbalizes correct procedure to follow in the event of a fire.	☐	☐
17.	Demonstrates correct set-up and operation of smoke evacuation system.	☐	☐

_____ _____

Validator's Signature Employee's Signature

_____

Validator's Printed Name

Medical Staff Competency

- Individuals with delineated clinical privileges participate in continuing education
- Each individual's participation in continuing education is documented
- Appointment or reappointment to the medical staff and the initial granting and renewal or revision of clinical privileges are also based on information regarding the applicant's competence

The Joint Commission

Medical Staff Competency

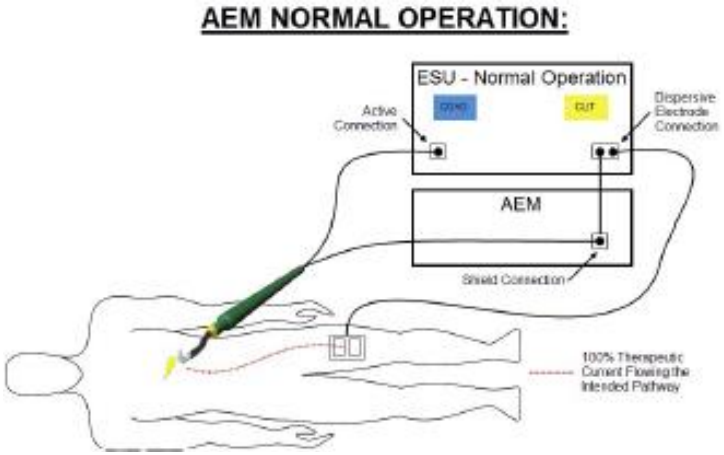
- Continuing surveillance of professional performance
- Determination of qualifications and competence of department or service personnel who are not licensed independent practitioners and who provide patient care services
- Orientation and continuing education of all persons in the department

The Joint Commission

Risk Reduction Strategies – Build Safety Into Technology

- Detects insulation failure
- Deactivates ESU preventing a patient burn
- Stray energy sensed through the primary insulation defect to the protective shield
- 100 percent of power delivered at intended site
- Capacitively coupled energy is continually drained safely back to the generator by the protective shield

Active Electrode Shielding



Options to Address Stray Electrosurgical Current

- Do nothing!
- Visual inspection
- Electrical testing before and after each use
- Active electrode shielding

Risk Reduction Strategies – Build Safety Into Technology

Active electrode monitoring addresses:

- Capacitive leakage
- Insulation failures
- Trocar insertion site injury

Risk Reduction Strategies – Build Safety Into Technology

BUT WAIT…

Risk Reduction Strategies – Build Safety Into Technology

Active electrode monitoring – the EASY way!

Connector / Cable / Instrument

As the Tools Improve…

So too will the procedures

Teamwork and use of evidence-based best practices can help to create a culture of safety during minimally invasive procedures:

- Assure equipment works and team is trained to use it
- Use checklists to reduce errors
- Standardize around best practices and equipment
- Improve electrosurgery safety
- Practice teamwork
- Critique and register problems
- Continue to improve improvement

Clarke, 2009

Not Merely Matching, but Enhancing Human Capacity

Standard of Care driven by:

The delivery of quality care and to minimize danger to the patient