Prevention of Medical Errors

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Wyndham Grand Jupiter

Disclosures

- Voluntarily come here
- No disclosures
- Do not ask me for legal advice
- Do not represent The Florida Board of Osteopathic Medicine nor any other organization I am affiliated with.

64B15-13.001 The following areas have been determined as the five most mis-diagnosed conditions:

- 1. Inappropriate prescribing of controlled substances;
- 2. Failure to monitor the safety of prescribed medications;
- 3. Retained foreign objects in surgery and wrong site/patient surgery;
- 4. Surgical complications/errors and pre-operative evaluations, including obtaining informed consent; and
- 5. Failure to timely diagnose sepsis.

Quality of care violations

Florida BOM 64 B8-13.005 (1)(C)

In addition to wrong site surgery surgery related complications

Cancer related conditions (example 92% breast cancer malpractice claims are attributed to a failure to diagnosis or a delay in diagnosis)

Respiratory related conditions

Ob/gyn conditions

Cardiology conditions

64B15-13.001 Prevention of Medical Errors

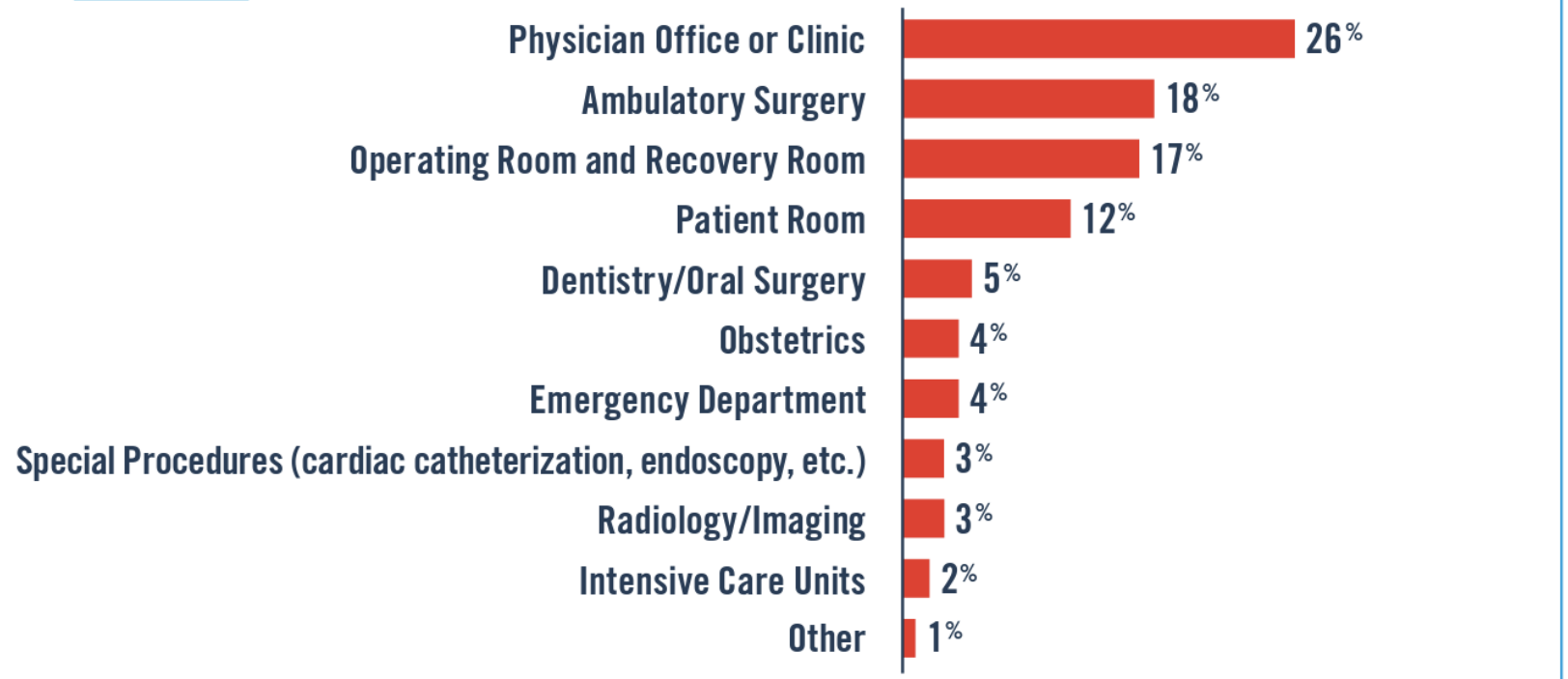
Study of root cause analysis, error reduction & prevention, & patient safety.

address medication errors, surgical errors, diagnostic inaccuracies, system failures, &provide recommendations for creating safety systems in health care organizations.

Most frequent locations where alleged harm occurred

FIGURE 2

Most frequent locations where alleged harm occurred



Source: The Doctors Company Closed Claims 2008–2017

Where adverse outcomes/injuries occur

Where Adverse Outcomes/Injuries Occur

We analyzed 17,964 claims against our members that closed from 2008–2017. As shown in **FIGURE 1**, we found that 44 percent of alleged harm occurred in inpatient hospital settings, followed by 28 percent in physicians' offices. Other sites where alleged harm occurred included ambulatory surgery facilities, diagnostic and treatment areas in clinics, skilled nursing facilities, psychiatric facilities, dialysis centers, substance abuse treatment centers, laboratories, and residential care facilities.

FIGURE 1

Source: The Doctors Company Closed Claims 2008–2017

"To Err is Human" report from the Institute of Medicine 1999

Generated significant publicity regarding the severe consequences of medical errors.

The authors of this reports estimated that medical errors in US might cause up to 98000 deaths annually

Medical errors

Medical errors are the third-leading cause of death after heart disease and cancer according to Makary & Daniel BMJ 5/3/2016

A recent Johns Hopkins study claims more than 250,000 people in the U.S. die every year from medical errors.

Other reports claim the numbers to be as high as 440,000 (discrepancy data from death certificates)

10% of medical errors are reported or planned action

Not all errors are intentional

Not all errors result in harm to patients

Report emergency care research institute Top 10 Patient Safety Concerns for 2019

1. Diagnostic errors & improper management of test results in electronic health record. The diagnosis, treatment plan and follow up plan must be clearly communicated in the electronic health record and must be written in a way that other clinicians and patients can understand.

2. Antimicrobial stewardship in physician practices. Noted 30% of antibiotic use is unnecessary & contributes to antimicrobial resistance. Give a rx for symptoms, for what to do, what to watch for. Follow up with them.

Report emergency care research institute Top 10 Patient Safety Concerns for 2019

3. Burnout & its effect on patient safety. Burnout has a consistent negative relationship with safety & quality. Beyond EHR, healthcare is evolving rapidly & keeping up with the changes can be a challenge. Increase number of patients with complex medical conditions, drawing on limited resources. Shift towards a culture that recognizes a job well done.

4. Mobile health patient safety. Remote monitoring devises that communicate thru smartphones or computers. Inadequate government regulation, barriers to ensuring accurate receive data, & possibility that patient not using the tech correctly or at all. Items are released without FDA testing. Cybersecurity threats .

Report emergency care research institute Top 10 Patient Safety Concerns for 2019

5. Reduce discomfort with behavioral health needs, behavior health destigmatized and incorporated into the overall goal of whole-person care. Know the community resources.

6. Detecting changes in a patient's condition and recognizing sepsis early in ambulatory care and aging services settings

Report emergency care research institute Top 10 Patient Safety Concerns 2019

7. Maintaining & developing new skills. Patient harm can occur if staff are uncomfortable using medical equipment or performing a procedure or are unaccustomed to an organization or care area's processes. Stimulation training with diabetic meters, infusion pumps or Foley catheter insertion

8. Detecting sepsis early in treatment. Develop protocols or algorithms to support the response.

Report emergency care research institute Top 10 Patient Safety Concerns for 2019

9. Infections from peripherally inserted intravenous lines. Sepsis should be recognized as early as possible, even prior to ER. Develop protocols.

10. Standardizing safety efforts across the health systems.

Malpractice 456.50 2(g)

- Medical practice means the failure to practice medicine in accordance with the level of care, skill & treatment recognized in general law related to health care licensure.
- The failure to exercise that degree of care used by a reasonable prudent physician in the same situation

Adverse event

- An injury to a patient as a result of medical management by either failure to dx, failure to treat, delays in dx or treatment. Considered preventable. Signals the need to ask why error occurred?
- Near Miss events-any potentially harmful event that could have an adverse events but thru chance or intervention in which harm was prevented
- Sentinel events - unexpected occurrences involving death or series physical or psychological injury. Requests immediate response & investigation. Sentinel events is not synonymous with error.
- Latent error -occurrence which failure is removed from the direct control of the frontline caregivers. Ex. Equipment failure, inadequate staff, inordinate time pressures
- Active error- occurrence in which an act or omission is committed by a caregiver in direct contact. Ex., administrates the wrong med, experiencing cognitive failure.. Example patient is discharge from emergency room prior to final reports on all x-rays (subtle fracture) and no follow up contact by treating ER PA, ARNP or doctor (lawsuit for civil for delay in treatment - however not on radiologist interpreting films- who is responsible to follow up?

459.026 Reports of adverse incidents in office practice settings

- Reported 15 days to DOH after the date of occurrence in writing via certified mail.

- “Adverse incident” means an event over which the physician or licensee could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries:

Adverse events 459.026

- (a) The death of a patient.
- (b) Brain or spinal damage to a patient.
- (c) The performance of a surgical procedure on the wrong patient.
- (d) 1. The performance of a wrong-site surgical procedure;
  2. The performance of a wrong surgical procedure; or

Adverse events 459.026

- (d) 3. The surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed-consent process if it results in: death; brain or spinal damage; if it results in brain or spinal damage, permanent disfigurement not to include the incision scar; fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory function; or any condition that required the transfer of the patient

Adverse events 459.026

- (e) A procedure to remove unplanned foreign objects remaining from a surgical procedure.
- (f) Any condition that required the transfer of a patient to a hospital licensed under chapter 395 from an ambulatory surgical center licensed under chapter 395 or any facility or any office maintained by a physician for the practice of medicine which is not licensed under chapter 395.

Adverse events 459.026

- 5) The department shall review each incident and determine whether it potentially involved conduct by a health care professional who is subject to disciplinary action, in which case s. 456.073 applies. Disciplinary action, if any, shall be taken by the board under which the health care professional is licensed.
- (6)(a) The board shall adopt rules establishing a standard informed consent form that sets forth the recognized specific risks related to cataract surgery. The board must propose such rules within 90 days after the effective date of this subsection.

Adverse events 459.026

- b) Before formally proposing the rule, the board must consider information from physicians licensed under chapter 458 or this chapter regarding recognized specific risks related to cataract surgery and the standard informed consent forms adopted for use in the medical field by other states.
- (c) A patient's informed consent is not executed until the patient, or a person authorized by the patient to give consent, and a competent witness sign the form adopted by the board.
- (d) An incident resulting from recognized specific risks described in the signed consent form is not considered an adverse incident for purposes of s. 395.0197 and this section.
- (e) In a civil action or administrative proceeding against a physician based on his or her alleged failure to properly disclose the risks of cataract surgery, a patient's informed consent executed as provided in paragraph (c) on the form adopted by the board is admissible as evidence and creates a rebuttable presumption that the physician properly disclosed the risks.

Duty to notify patients 456.0575

- **456.0575 Duty to notify patients.**
- (1) Every licensed health care practitioner shall inform each patient, or an individual identified pursuant to s. 765.401(1), in person about adverse incidents that result in serious harm to the patient. Notification of outcomes of care that result in harm to the patient under this section does not constitute an acknowledgment of admission of liability, nor can such notifications be introduced as evidence

Disclosing medical errors

"Doctor's insurance" in their recommendations:

- Spikes

- S — setting up interview
- P — assess patient perception
- i — obtain patient invitation
- K — give knowledge & information to patient
- E — address patient emotion & empathize response
- S — strategy & summary

Protected apology considerations

Malpractice insurer, hospital counsel, surgeon own legal counsel, healthcare team

Disclosures & apologies delivered sincerity

Difficult to avoid self-incrimination

Candor

CANDOR Toolkit

AHRQ has developed the Communication and Optimal Resolution (CANDOR) Toolkit. CANDOR calls for a prompt response and specific actions after an adverse event. Within one hour, specially trained hospital staff should:

CANDOR

1. Explain the facts, and what might still be unknown, to patients and family members.

2. Contact the clinicians involved and offer assistance, because the stress and grief of the healthcare professionals can easily be overlooked in these incidents.

3. Immediately freeze the billing process to avoid further stressing the patient with a bill for the services that may have caused harm.

Evaluation process/safety systems in healthcare

- Step back, analyze and use resources
- Checklist, huddles, hand off

Teamwork & communication

- Common purpose
- Clear roles
- Accepted leadership
- Effective processes
- Solid relationship
- Excellent communication

Swiss cheese theory

- Accidents result form a chain of events not a single cause
- Professional communication
- Training
- Quality management
- Expect the unexpected
- Inform
- Credentialing
- Peer review
- Protections

etiology

- The person etiology individual blame game name, blame, shame
- Joint Commission adopted Root Cause Approach
- Discuss identify event
- Watch, repair the damages, look for underlying mechanism, find root cause in system
- Retrain redesign

etiology

- Systems approach
- Humans are fallible, errors are expected
- Find the root cause, basic reason, latent, failed, vulnerable patient
- Good root cause, fixable

RCA

- Emphasizes prevention
- Standardizes process
- Improve way to investigate medical errors, adverse events and near misses.
- Process looks at both active & latent errors & avoids the tendency to design individual blame
- Describes methodology

Root cause

- Surveillance tools
- Risk event reporting
- Patient complaints/press ganey scores
- Co worker observations
- Hand hygiene performance
- Look at data within the organization

“Competency”

Defined wisdom, judgement, compassion care, not just intelligence

Complaints about practitioners are rarely due to “an honest mistake”

What do patients want?

Accessibility	Affability (easy to talk to , civil, courteous)	Acknowledge

Competence interpersonal communication

- Safety of the public
- Transparent to members
- Accountability
- Consistency
- Fairness
- Serve to protect

Competency operation efficiency

- SOP. Standard operating procedure facilitate standardizations
- Data, workload
- Measurement
- Competency=interchangeable with widget

Literature competency

- Attendance of CME does not translate into practice change
- Competency drift why do practitioners allow their skills to deteriorate
- Goal is not to create competent practitioners, but someone engaged.
- Ones who are interested in their profession, their patients and their practice.

Creating engagement

- Consistently says positive things about the organizations
- Feels social connections to their workplace
- Positive feedback and supportive constructive

Failure mode effect analysis

- Proactive risk approach – allows analysis before they happen
- RCA structured in a way to address problems after they occur
- FMEA identifies and eliminates process failures for the purpose of preventing the events. Identifies unintended consequences prior to implementation
- Anticipates what might go wrong and do what we can to prevent this from happening
- Examples listening to traffic updates or Waze (real time) to avoid traffic jams or airline travel planning routes to avoid potential delays, fire drills, hurricane preparation, mass casualty drills

Failure to monitor the safety of prescribed medications

Updated beers criteria for potentially inappropriate medication use in older adults

Avoid concurrent use of opioids with either benzodiazepines or gabapentin due to increase risk of OD, & sedation – related adverse events such as respiratory depression & death.

Exercise caution in the use of aspirin for primary prevention of CVD or colorectal cancer in patients > 70 years old (previous 80 YO)

Use caution when px trimethoprim-sulfamethoxazole in patients taking ace inhibitor or ARB and who have decreased creatinine clearance to avoid hyperkalemia

OTC check

Medication related

- 20 % FDA safety changes
- 20% cause ADE
- 20% prescriptions are never filled
- 50-90% do not take meds as directed

prescriptions 39%

transcriptions 11%

dispensing 12%

Adverse drug event

- Refers to harm that occurs during medical care and is directly caused by the drug. It included medication errors, adverse drug reactions and overdose but not allergic reactions.
- Patient education & adherence were top factors in Doctor Company analysis of patient harms involving medication errors

Adverse drug event

- ADE major contributors' hospital related complications
- Narcotic issue
- Doctors company reviewed 1770 claims
- Closed 2007-2015 in which patient harm involved medication factors

  58% improper meds administration

  235 claims 17% narcotics

Location adverse drug events

- Outpatient setting 66%
- Physician offices & hospital clinics 87%
- Ambulatory day surgery 6%
- Emergency room 6%
- Patient home 6%

Outpatient setting

- Narcotic analgesic related causes 66%
- Classified as high severity
- Death was most common result of injury
- ADE are among the major contributors to hospital related complications account for more than 3.5M physician ov each year

Outpatient office setting

• Improper management	61%
• Ordering	18%
• Dispensing	14% 1

72%.	ADR
24%	death
13%	organ damage

LASA

- Institute safe medication practices
- ISMP high alert med
- Use both brand and generic names
- Include purpose

LASA-look alike sound alike

FIGURE 20

Source: Copyright Institute for Safe Medication Practices. Used with permission.

ISMP

The ISMP recommends the following safeguards to reduce the risk of errors related to LASA medications:

- Use both brand and generic names on prescriptions and labels.
- Include the purpose of the medication on prescriptions.
- Configure computer selection menus to prevent look-alike product names from appearing consecutively.
- Avoid alphabetical storage of medications; instead store them by category.
- Draw attention to products that look and sound similar. For example, affix a small, brightly colored sticker to medication containers to alert the user of a potential for error.

ISMP

Abbreviations are often used in documentation and charting. When used, abbreviations should be standardized to ensure that all personnel use the same format. Adhere to the recommendations of the ISMP (**ismp.org**) and The Joint Commission (**jointcommission.org/facts_about_do_not_use_list**). Improper or incorrect use of abbreviations is another root cause of ADEs. Using a "U" to indicate "units" may be misinterpreted as a "0" or "4." This simple misinterpretation may have catastrophic results.

Inappropriately using a zero with a decimal point has also contributed to medication incidents. Using a zero following a decimal point in a whole numeral, such as 2.0 mg, is contraindicated and may result in a patient receiving 20 mg—10 times the intended dose—because of a failure to notice the decimal point.

CPOE

- The stance of the CMS is therefore aligned with that of the Joint Commission.
- Secure text messaging platforms can be used in healthcare, just not for texting orders.
- Even though secure text messaging meet HIPAA requirements for privacy and security, the ban remains in place over concerns about inputting orders sent by text messages into the EHR.
- CPOE is still the preferred method of entry to ensure accuracy.

https://www.hipaajournal.com/cms-text-messages-in-healthcare/

Inappropriate prescribing of controlled substances

FS 456.42

Florida Statute 456.42, "Written prescriptions for medicinal drugs," requires that all written prescriptions be legibly printed or typed and be signed by the prescribing practitioner on the date issued. The prescription *must* contain all of the following information:[2]

- The name of the prescribing practitioner.
- The name and strength of the drug being prescribed.
- The quantity of the drug being prescribed.
- The directions for use.
- The date of the prescription.

If the written prescription is for a controlled substance it should contain the above with the following addition requirements:[3]

- The quantity in both text and numeric format.
- Additional clarification of the date prescribed.

Example

Dr. John Smith
1234 Main Street
Anytown, Florida

Date: February 11, 2013

Patient Name: Jane Doe DOB:05/29/1986

Address: 1111 Center Lane, Anytown, Florida 33312

Percocet (2.5/325)

Disp. # 60 Sixty

Sig: Take one tab every 6 hours PRN pain

No Refills

DEA # _____. Signature Line

64B8-9.013 and 64B15-14.005

Florida physicians who prescribe controlled substances for chronic nonmalignant pain management must indicate this information on their Department of Health Medical Quality Assurance practitioner profile. Florida Statute Chapter 893, Florida Administrative Code 64B8-9.013, and 64B15-14.005 set forth significant requirements for physicians involved in controlled substance prescribing for chronic pain management. Requirements include:

- Conducting and documenting a complete history and physical examination.
- Documenting the medical rationale for the use of controlled substances.
- Establishing treatment goals with the patient.
- Prescribing no more than a 30-day prescription of controlled substances.
- Monitoring medication use of patients receiving narcotics for chronic pain management, using the Prescription Drug Monitoring Program, known as E-FORCSE® (Electronic-Florida Online Reporting of Controlled Substances Evaluation Program).
- Negotiating and enforcing a controlled substance agreement with patients.
- Using tamper-proof prescription paper.
- Assessing risk for addiction or abuse.
- Performing random drug screening and monitoring to ensure compliance with the patient's prescribed drug regimen.

Who is at risk?

- Medically related causes has declined US
- All patients, older, frail, polypharmacy
  - Common error in ambulatory setting is medication related
- All providers, especially training institutions
- All doctors make mistakes

National Center for Education Statistics

- 40-44 M Americans functionally illiterate
- 50 M Americans are moderately illiterate
- Given the difficulty many patients have reading and comprehending health information

Ask me 3 program

When talking to patients

Main problem?

What do I need to do?

Why is it important for me to do this?

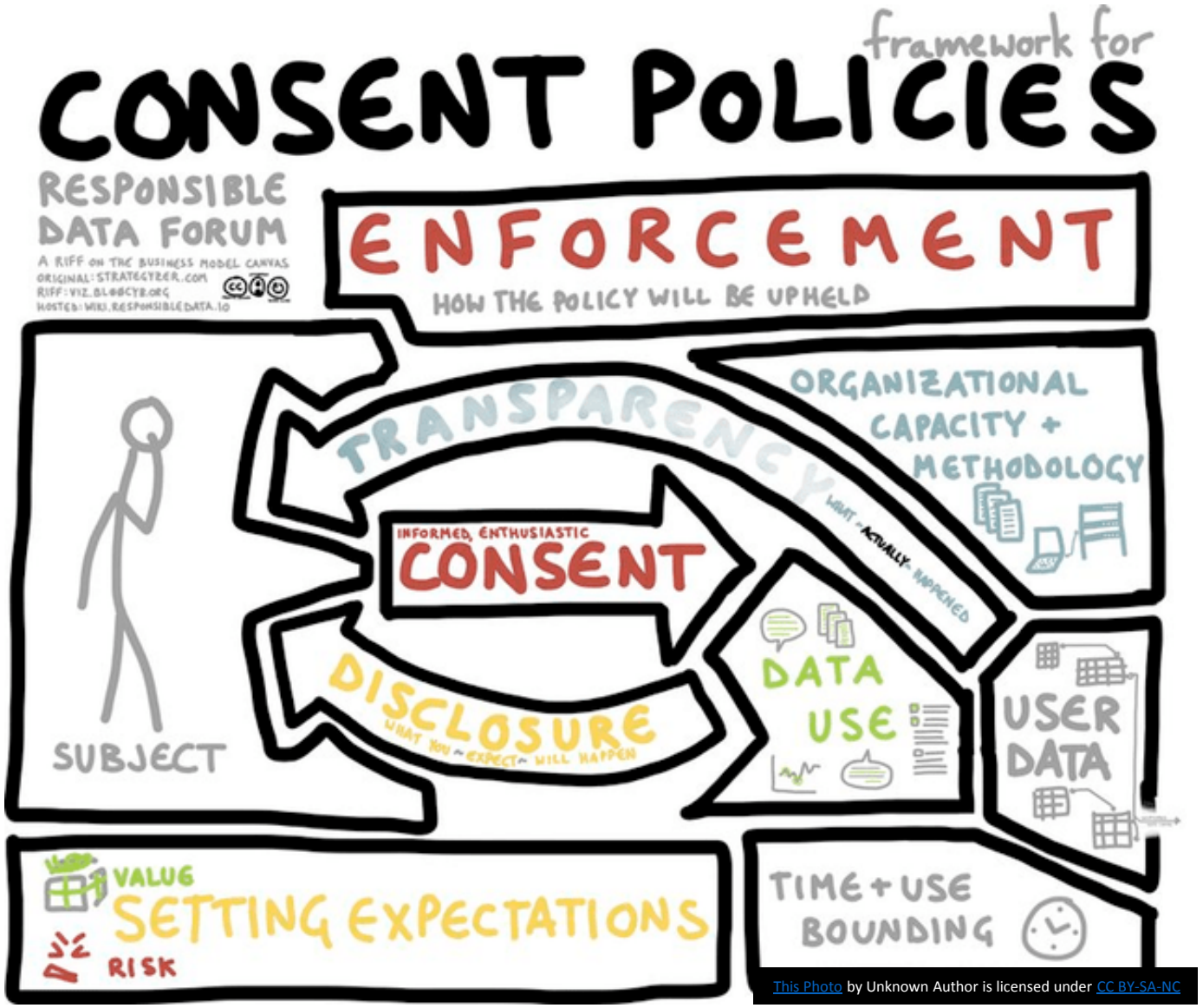
Accessing care of vulnerable elders how to improve prescribing practices

- Document the indication for a new drug therapy
- Educate patients on the benefits & risk associated with the use of new therapy
- Maintain a current medication list
- Document response to therapy
- Periodically review the ongoing need for a drug therapy

ADR related hospitalizations

- Data reviewed between 2007-2009 99,628 ADR related >65YO
- 2/3 due to unintentional overdoses
- Four meds implicated in 67% hospitalizations
  1. warfarin
  2. insulins
  3. oral antiplatelet agents
  4. oral hypoglycemic agents

Surgical complications/errors and pre-operative evaluations, including obtaining informed consent



BEST PRACTICES TO AVOID SURGICAL COMPLIANTS

- 1. LOOK AT THE COMPLAINT. THIS MAY BE THE FIRST INDICATION THAT A PATIENT IS SUFFERING.
- 2. POST OP PAIN. IS THE ANALGESIA ADQUATE? SELECTION OF A SETTING IN WHICH SURGERY CAN BE PERFORMED? A PATIENT WITH SIGNIFICANT COMORDIBITIES MAY NOT BE APPROPRIATE FOR OUTPATIENT SURGERY?
- 3. UNDERLYNG DISCUSSION ABOUT COMPLICATIONS IS LINKED TO THE INFORMED CONSENT.

FIGURE 10 outlines the most common types of complications that affect postoperative patients. All of the rates have decreased since 2015.

FIGURE 10

Top surgical complications affecting postoperative patients

INDICATOR	OBSERVED RATE (per 1,000 discharges)
Respiratory Failure	9.13
Hemorrhage/Hematoma	4.52
Sepsis	4.26
Pulmonary Embolism/Deep Vein Thrombosis	3.72
Wound Dehiscence	1.71

Source: AHRQ Patient Safety Provider-Level Quality Indicators for Overall Population, July 2017

DOH data

- The cases analyzed are from 2004, when the Joint Commission implemented the Universal Protocol, to 2015.
- All cases in this presentation are Final Orders where the physicians have been disciplined for Wrong Site/Procedure/Patient/Implant Surgery.
- It does not include PCP cases. Information was gathered from the Departments Licensee Database, research articles, and old reports given to the Board

Surgical cases

2004-2015 BOM 446 disciplined cases

Florida “pause rule”

Completed immediately prior to surgery & repeated if there is any delay or distraction

Correct patient (2 identifiers)

Correct procedure consent has been signed

Correct site and side of the procedure

Correct patient position, the site marked is & visible

Wrong side surgery, wrong patient, wrong procedure 456.072(1)(bb)

- Section- 456.072(1)(bb) Florida Statutes Performing or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition. For the purposes of this paragraph, performing or *attempting* to perform health care services includes the preparation of the patient.
- In Florida WSS may also trigger a civil litigation for negligence.

FS 64B8-9.087 STANDARD OF PRACTICE

- (2) THIS RULE IS INTENDED TO PREVENT WRONG SIDE, WRONG PATIENT , WRONG SURGERIES/PROCEDURES BY REQUIRING THE TEAM TO PAUSE PRIOR TO THE INITIATION OF THE SURGERY/PROCEDURE TO CONFIRM THE SIDE, SITE, PATIENT IDENTITY AND SURGERY PROCEDURE
- THE MR SHALL SPECIFICALLY REFLECT WHEN THE CONFIRMATION PROCEDURE WAS COMPLETED AND WHICH PERSONNEL ON THE TEAM CONFIRMED

Time Out Surgery

Despite “time out” surgery cases still come before the board.

If surgeon has more than one hospital privileges “time out procedure” vary from institution to institution.

Potential factors associated WSS

1.Human factors such as staff or physician fatigue, multiple team members, diffusion or lack of accountability, poor team communication, change of personnel, haste, heavy workload, staff inexperience, turnover, incompetence, cognitive factors

2.Patient factors pt. sedated confusion, inability to engage pt., patient illiteracy, pt. has a common name or same name as another pt.,

3.Procedure factors- wrong side draped/prepped

Similar or same procedures back to back, not observed marking, cross checking consent forms,

Surgical errors

- Misreading radiographic images
- Unknown human error
- Strange vertebral anatomy, miscounting vertebra
- Operating on the side closest to the physician after other side verified as correct side
- Correct site, wrong surgery
- Removed unintended tissue during procedure

Florida Dept of Health Data

2004	31
2005	32
2006	59
2007	52
2008	57
2009	41
2010	40
2011	20
2012	22
2013	31
2014	29
2015	20

Fig. 1.1 shows the downward trend of WSS over the last 11 years. 2006 was the highest year while 2011 and 2015 are the lowest years yet.

CLAIMS DATA

- DOCTOR INSURANCE REPORT THAT ORTHOPEDICS HAD MOST CLAIMS HOWEVER MOST COMMON WRONG SIDE SURGERY INVOLVED DENTAL BOARD (TEETH 17%) CASES.

WRONG SIDE SURGERY/ NO OPTH

It was asked at the last board meeting to see if the trendline would change if Ophthalmology cases were taken out of the data set.

Slope with Ophthalmology~ -2.1
Slope w/o Ophthalmology~ -1.9

It appears that the change in slope is not very significant without Ophthalmology cases.

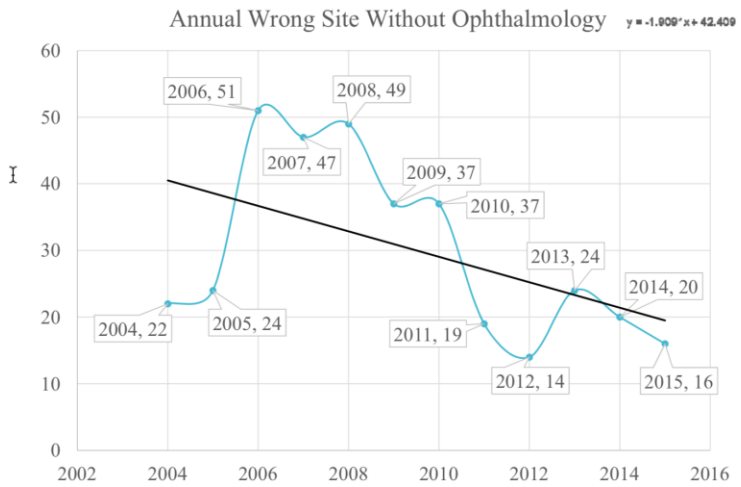


Fig 1.2 Without Ophthalmology cases the slope of the trendline does not change significantly. This indicates that Ophthalmology is not responsible for the decline in WSS over the last 11 years.

WRONG SIDE SURGERY PAUSE VS NO PAUSE

Whether or not a pause was done did not seem to have an affect on the occurrence of a wrong site surgery (WSS). This was due to the fact that in most cases at least 1 step of the Universal Protocol was done incorrectly.

Yes, Pause done	243
No Pause done	190
Unknown	2

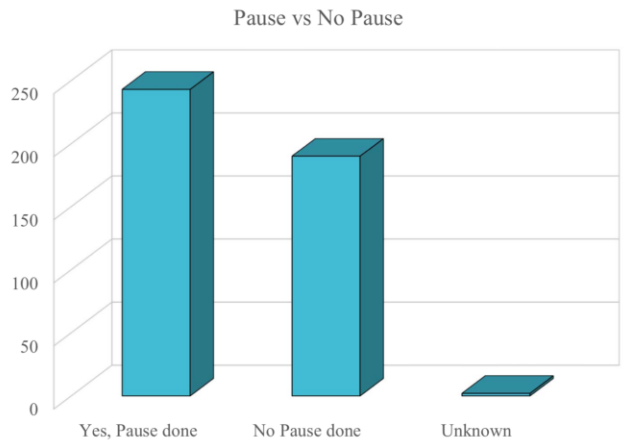


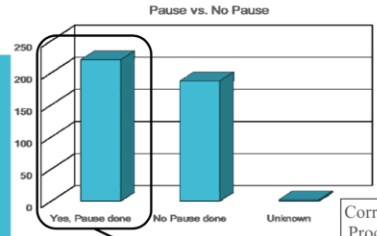
Fig 1.5 is an absolute representation of whether a pause was done or not. I will be breaking this down further in the presentation to give more information about this graph.

UNIVERSAL PROTOCAL MISTAKE/PAUSE

This is a breakdown of the "Yes, pause done" column on the previous slide. As you can see, in the majority of cases with a pause, some part of the Universal Protocol was done incorrectly.

Errors include-

- Incorrect Patient Verification
- Incorrect Procedure Verification
- Incorrect/no site marking
- Incorrect Consent
- Incorrect Pause procedure



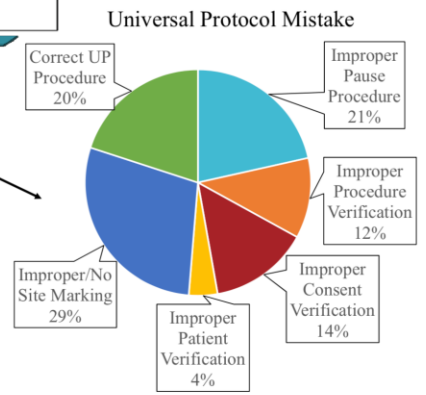


Fig 1.6 shows what caused the WSS when a pause was done.

PROPER/IMPROPER/NO PAUSE BY FACILITY TYPE

The Universal Protocol mistakes can be generalized to Proper, Improper, and No Pause categories. Here are those numbers as they relate to Facility type.

	Hospital	ASC	Office	Total
Proper	39	11	1	51
Improper	92	89	8	189
No	97	83	15	195

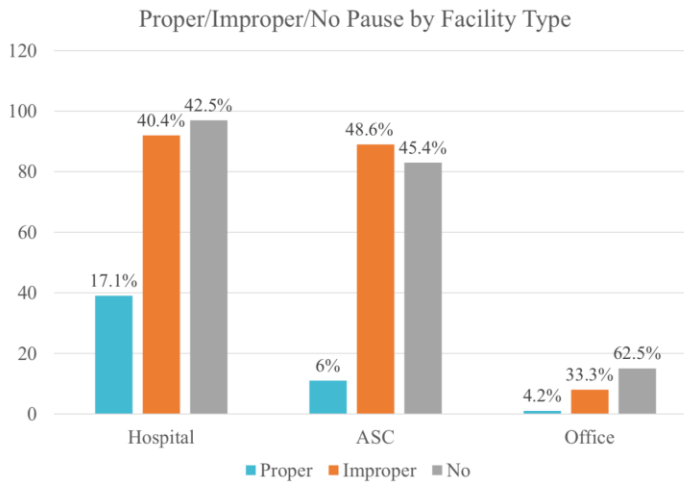


Fig 1.7 shows what percentage of proper/improper/no pause was done within each facility and shows the relative amounts of proper/improper/no pause done between facility types.

WRONG SIDE SURGERY BY FACILITY TYPE

The number of estimated annual procedures are generated from an past report to the board coupled with a report from the CDC regarding Ambulatory Surgery.

It appears that a wrong site surgery is most likely to happen at an ambulatory surgery center (ASC) and least likely to happen at a Hospital.

Occurrence of a Wrong Site/Procedure/Patient/Implant Surgery Organized by Facility Type

Facility Type	Estimated Procedures 2004-2015	% that are WSS
Hospitals	77,573,320	0.000294
ASC	29,236,680	0.000623
Office	7,590,000	0.000316

Fig 1.8 shows the percentage occurrence of WSS at each facility type.

TYPES OF ERRORS

WRONG SITE	317
WRONG IMPLANTATION	37
WRONG PATIENT	31
WRONG PROCEDURE	50

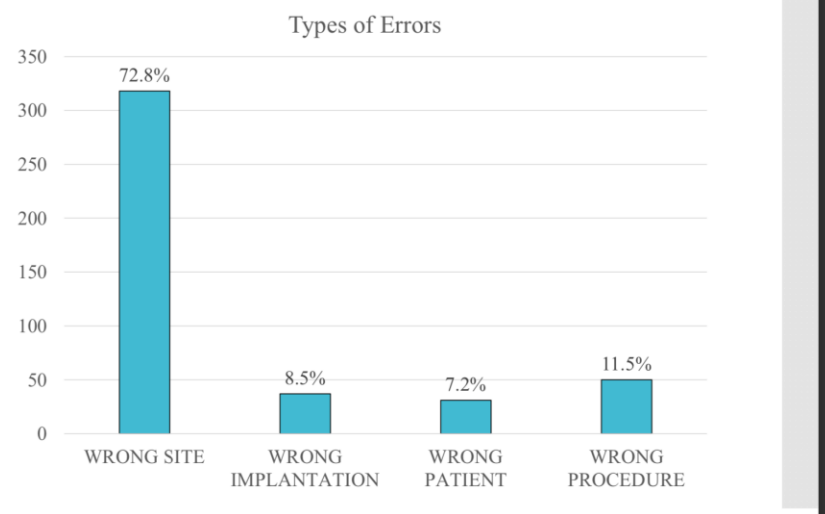


Fig 1.9 shows which types of errors are most common within the description of a WSS.

DOH data By Specialty

This chart indicates which specialties committed the most wrong site/procedure/patient/ or implant surgeries. "Other" category contains specialties with fewer than 3 cases.

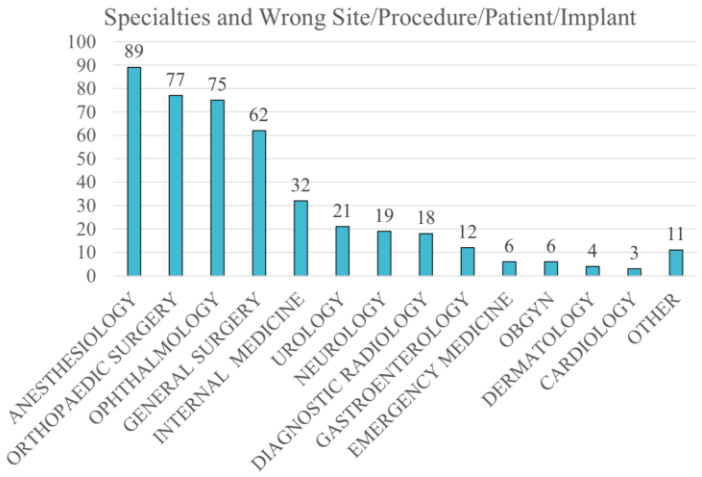
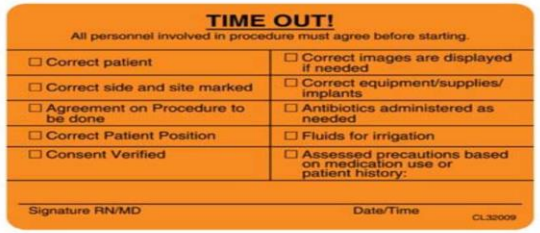


Fig 1.10 shows the top specialties with WSS mistakes in the last 11 years.

Possible solutions

Possible Solutions

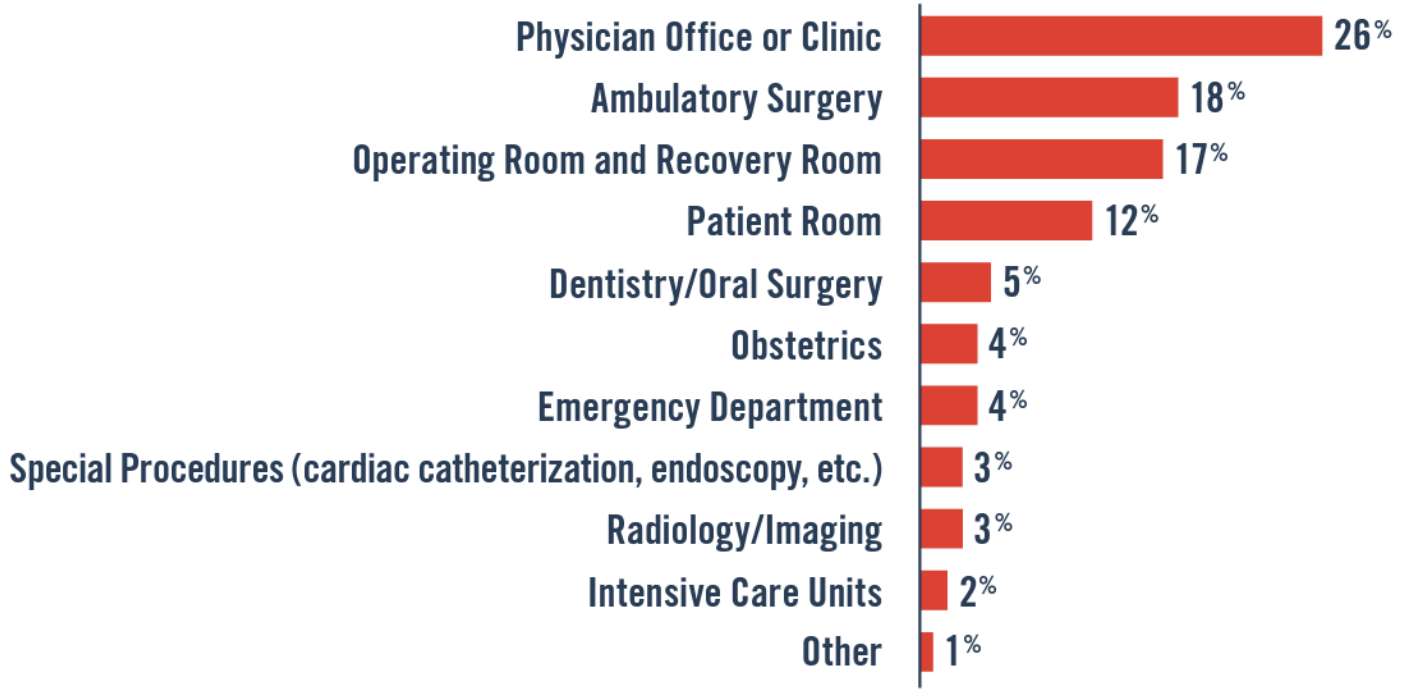
- Strict Adherence to the entire Universal Protocol including correct marking of the surgical site and mindful and intentional time-outs.
- Active participation is needed. Just "going through the motions" of the steps of the protocol can also lead to wrong site surgeries.



Claims data

FIGURE 2

Most frequent locations where alleged harm occurred



Source: The Doctors Company Closed Claims 2008–2017

Retained foreign objects in surgery and wrong site/patient surgery

Section- 456.072(1)(cc) Florida Statues

- Leaving a foreign body in a patient, such as a sponge, clamp, forceps, surgical needle, or other paraphernalia commonly used in surgical, examination, or other diagnostic procedures.
- For the purposes of this paragraph, it shall be legally presumed that retention of a foreign body is not in the best interest of the patient and is not within the standard of care of the profession, regardless of the intent of the professional

Florida Dept of Health

- There were far fewer Retained Foreign Object (RFO) cases found so conclusions are harder to draw from such a small sample. Cases analyzed are from 2004 to 2015. All cases in this presentation are Final Orders where the physicians have been disciplined for a Retained Foreign Object, PCP cases are not included. Information was gathered from the Departments Licensee Database, research articles, and old reports given to the Board.

Retained foreign objects cases

2004	6
2005	7
2006	3
2007	6
2008	7
2009	6
2010	8
2011	3
2012	7
2013	2
2014	1
2015	3

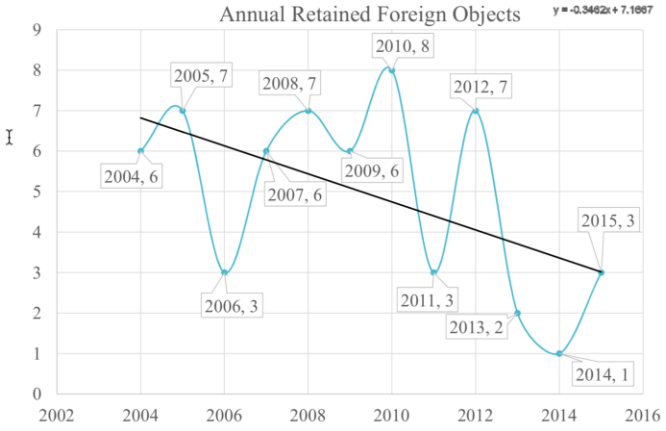


Fig 2.1 shows the downward trend of RFOs over the last 11 years. This result is subject to change as 24 unclosed cases between 2013-2015 get their final orders.

Count

The count was deemed correct in the majority of cases due to counting mistakes, the retained item not being included in the count, or the surgical item breaking off in the patient.

CORRECT COUNT	42
COUNT INCORRECT	3
NO COUNT	14

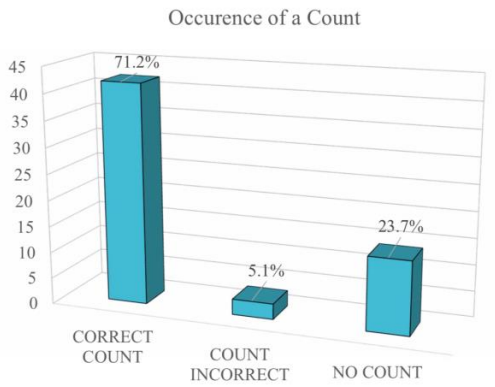


Fig. 2.2 shows whether or not a count was completed before and after a surgery. In most cases the count was completed and deemed correct before the occurrence of a RFO.

Conclusions

- Any conclusion is difficult to draw from a sample of 59. However, by looking at the collected data it appears that the count before and after a surgery is not adequate to eliminate retained foreign objects after surgery.

- It also appears the occurrence of these events is declining.

Retained foreign object

- This is a chart of what happened when the count was deemed correct and a RFO occurred. The most common occurrence was a counting mistake tied with a broke item being retained.
- The next most common occurrence was the item not being counted in the first place.

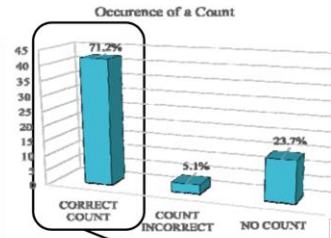


Fig. 2.2

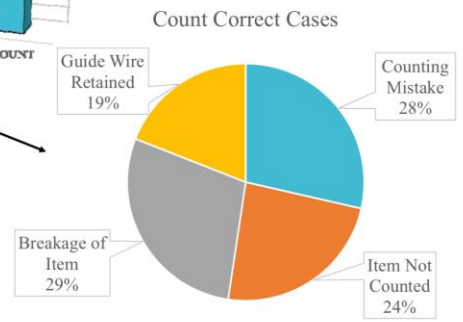


Fig. 2.3 shows what happened that lead to a RFO after the count was deemed correct. The most common instance was a broken item was left inside the patient.

Retained foreign object by facility type

As demonstrated by the previous graph, a RFO is most likely to happen at a Hospital and least likely to happen in an Office. This table shows the exact percentages of occurrence.

Occurrence of a Retained Foreign Object Organized by Facility Type

Facility Type	Estimated procedures 2004-2015	% that had a RFO
Hospital	77,573,320	0.000068
ASC	29,236,680	0.000017
Office	7,590,000	0.000013

Fig. 2.7 shows the exact percentages of occurrence of RFO by facility type

Occurrence of a count

The count was deemed correct in the majority of cases due to counting mistakes, the retained item not being included in the count, or the surgical item breaking off in the patient.

CORRECT COUNT	42
COUNT INCORRECT	3
NO COUNT	14

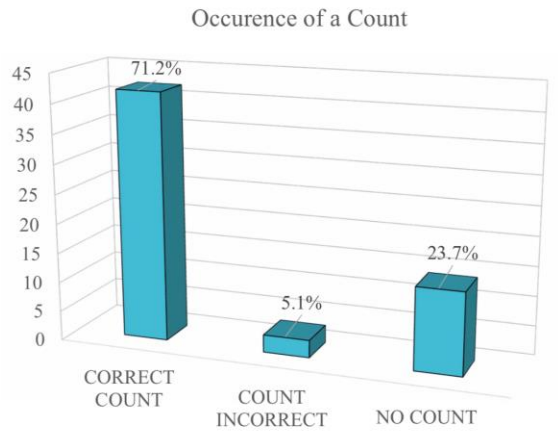
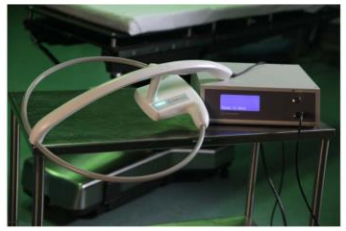


Fig. 2.2 shows whether or not a count was completed before and after a surgery. In most cases the count was completed and deemed correct before the occurrence of a RFO.

Possible solutions

Possible Solutions

Radiographic Screening intra and post operation, RFID infused sponges/towels with a smart bin, and barcoded sponges and towels accompanied by app or laptop are all technological ways to take human error out of surgical counts. Improper counts and correct counts can both lead to retained foreign objects, these technologies could prevent that.



Possible solutions

Policy regarding the inspection of all equipment, especially guide wires, to look for any breakage that might have occurred. This will initiate an investigation of the surgical site, in the event of a broken off piece, and hopefully lead to its discovery.

Making sure every item is counted will also help reduce RFOs

URFO (unintended retention of a foreign object) prevention

- 4 practices
- Verify “the sponge and needle count” were reported to be correct
- Perform procedure that follow universal protocols
- After every surgical procedure make sure the correct counts are performed and reported to the surgeon. Recount all items before they close the case
- If wound healing is complicated rule out “URFO”

Preventative measures

Surgeons should adopt four preventive measures:

1. Perform procedures only in facilities with established written protocols for counting sponges, sharps, and instruments that meet the Association of periOperative Registered Nurses (AORN) standards and/or that are accredited by a national accrediting body.

Preventative measures

2. Make certain that counts are performed and reported to surgeons as correct at the conclusion of every surgical procedure.

3. Include one phrase—without fail—in every operation report: "The sponge and needle counts were reported to be correct."

4. Maintain a healthy level of suspicion that complicated wound healing might be caused by a retained foreign body.

News

From 2011 to 2016, there were 25 BBL deaths among members of the American Society for Aesthetic Plastic Surgery.

In 2017, a plastic surgery task force astonishingly reported that 3 percent of plastic surgeons who performed the procedure had a patient die.

From 2013 to 2018, just one Florida clinic had at least eight patients died.

https://www.usatoday.com/story/opinion/voices/2019/01/31/plastic-surgery-brazilian-butt-lifts-florida-death-column/2374585002/

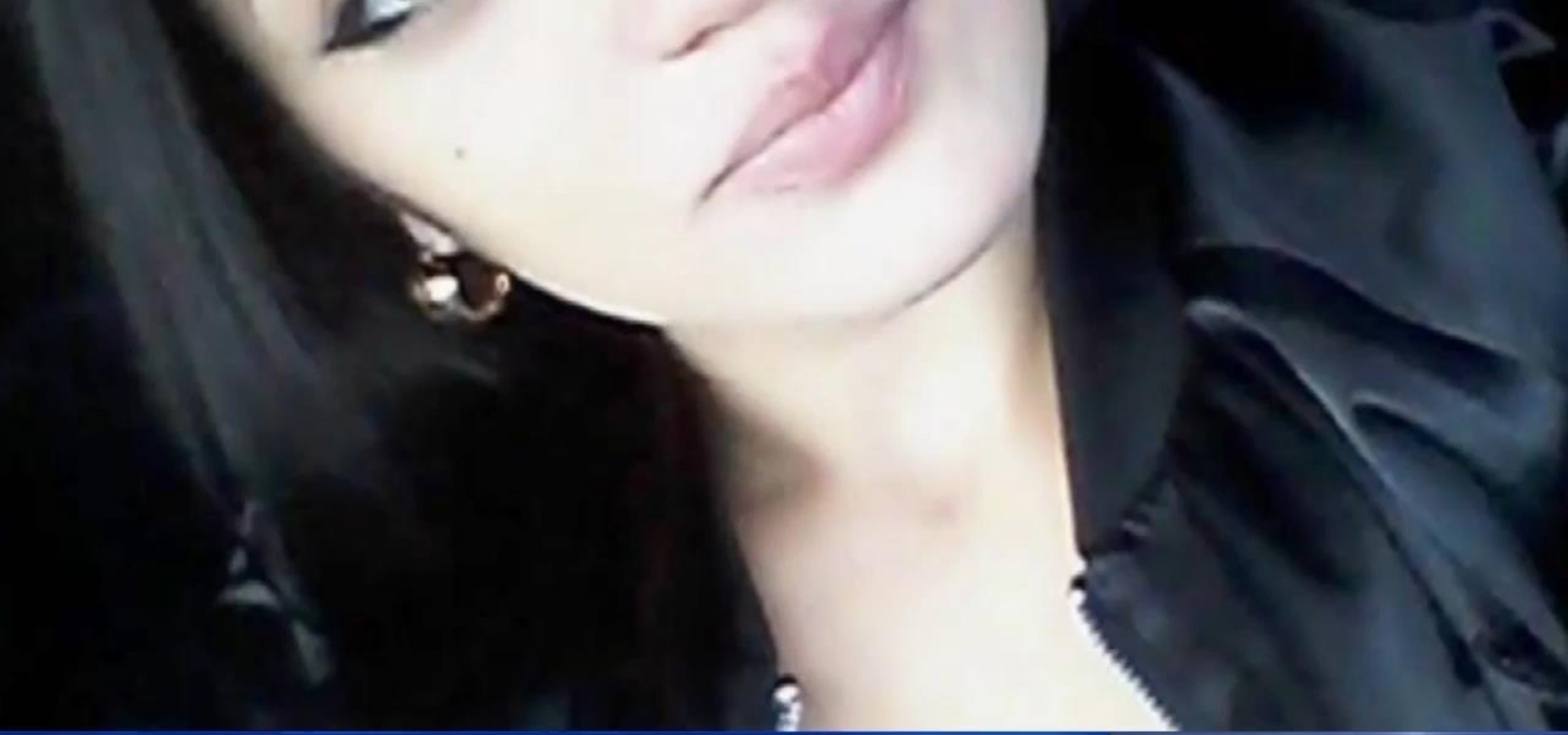
Office surgery incidents: what seven years of Florida data show us.

- In 7 years there were 31 deaths and 143 procedure-related complications and hospital transfers.
- Liposuction and liposuction with abdominoplasty or another cosmetic procedure resulted in 24 complications and 8 deaths.
- Of the offices reporting adverse incidents, 38.5% were accredited by an independent accrediting agency, 92.5% of the physicians were board-certified, and 96.6% had hospital privileges.
- A total of 58% (18/31) of the deaths and 61% (87/143) of the complications were associated with nonmedically necessary (cosmetic) procedures.
- A total of 78% (14/18) of these deaths were in ASA Class 1 patients.
- Plastic surgeons were responsible for 48% of all deaths (83% of cosmetic surgery deaths) and for 52% of all hospital transfers (83% of cosmetic surgery complications and hospital transfers).

- https://www.ncbi.nlm.nih.gov/pubmed/18177404

Office surgery incidents: what seven years of Florida data show us.

- **CONCLUSION:**
- Plastic surgeons were responsible for an inordinate number of deaths and hospital transfers.
- Requiring physician board certification and physician hospital privileges would not seem to increase safety, because most physicians already have these credentials, and physicians without these credentials were not responsible for a disproportionate share of incidents.
- These data do not show an emergent hazard to patients from medically necessary office surgery.
- Liposuction under general anesthesia deserves continued scrutiny because deaths due to this procedure continue to occur and this procedure can be performed with dilute local anesthesia, with which no deaths were reported.
- Mandatory reporting of office incidents should be strongly supported, as well as reporting of incidents that occur after surgery in the hospital outpatient department and ambulatory surgery center.
- These data should be available for analysis after protecting patient confidentiality. A national debate needs to occur to determine how many deaths and injuries are acceptable from cosmetic procedures performed under general and intravenous anesthesia.



NEW DETAILS IN PLASTIC SURGERY DEATH

6:05 89°

SOUTH FLORIDA'S MUST SEE VIDEO: SUBSCRIBE TO NBC 6 ON YOUTUBE

Proposed rule change- standard of care for office surgery

64B8-9.009/64B15-14.007

- (f) Standard of Care for Gluteal Fat Grafting. When performing gluteal fat grafting procedures, fat may only be injected into the subcutaneous space and must never cross the ~~superficial~~ gluteal fascia. Intramuscular or submuscular fat injections are prohibited.

NEW OFFICE SURGERY RULE 459.328

459.0138 Office surgeries.—

(1) REGISTRATION.—

(a) An office in which a physician performs a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery must register with the department unless the office is licensed as a facility under chapter 390 or chapter 395.

(b) By January 1, 2020, each office registered under this section or s. 458.328 must designate a physician who is responsible for the office's compliance with the office health and safety requirements of this section and rules adopted hereunder. A designated physician must have a full, active, and unencumbered license under this chapter or chapter 458 and shall practice at the office for which he or she has assumed responsibility. Within 10 calendar days after the termination of a designated physician relationship, the office must notify the department of the designation of another physician to serve as the designated physician. The department may suspend a registration for an office if the office fails to comply with the requirements of this paragraph.

(c) As a condition of registration, each office must establish financial responsibility by demonstrating that it has met and continues to maintain, at a minimum, the same requirements applicable to physicians in ss. 458.320 and 459.0085. Each physician practicing at an office registered under this section or s. 458.328 must meet the financial responsibility requirements under s. 458.320 or s. 459.0085, as applicable.

JOINT COMMISSION

- 3 STEPS TO PREVENT WSS
- PATIENT ID
- SURGICAL SITE MARKING AND
- PERFORM A PAUSE IMMEDIATELY BEFORE PERFORMING A SURGICAL PROCEDURE AND MUST BE REPEATED IF THERE IS ANY DELAY OR DISTRACTION BETWEEN THE PAUSE AND THE INITIATION OF SURGERY

Joint commission patient safety goals

- Identify patient correctly – use 2 identifiers
- Improve staff communication/patient results
- Use medications safety/use alarms
- Prevent infections-handwashing, use proven guidelines
- Identify patient safety risk. Find out which patients are most likely to try to commit suicide

Joint commission

Prevent mistakes in surgery

Make sure the correct surgery is done, correct patient and at the correct place in the body

Mark the correct place in patient’s body, where the surgery is to be done

Pause before the surgery to make sure that a mistake is not being done

Safe surgery

to prevent URFO surgeon should adopt 4 practices & include in every post op note “the sponge and needle count were reported to be correct.”

Perform procedure only in facilities that follow AORN compliant written protocol for during surgery

After every surgical procedure make sure the correct counts are performed and reported to the surgeon

Recount all items before they leave the or

Be suspect that a complicated wound healing may be caused URFO

Complex matter

FRAGMENTATION OF HEALTH CARE

Safe surgeries tie into the personal health and wellness physicians

PHYSICIAN BURN OUT OVERDEMAND FOR SERVICES

ACOS RECOMMEND

Voluntary PHYSICAL EXAM

VISUAL SCREENING 65-70 yo

VOLUNTARY NEUROCOGNITIVE SCREENING

ACOS SUGGESTED ADDRESSING SCREENING APPLY TO ALL AGES

http://bulletin.facs.org/2016/01/statement-on-the-aging-surgeon

Over half of adverse surgical events due to human error, study finds

Over half of adverse surgical events are due to human error, meaning those events could have been prevented, according to a study published July 31 in *JAMA Network Open*.

Researchers collected data from three adult teaching hospitals over six months. The hospitals performed over 5,300 surgeries during this period, 188 of which resulted in adverse events, including death and major complications. Of the 188 adverse events, over 50 percent, or 106, were due to human error.

The researchers also organized the errors by type. They were surprised to find that errors related to communication, teamwork and systems were relatively low. In contrast, over half of the errors were cognitive, involving lack of attention, lack of recognition and cognitive bias.

"This means our efforts to optimize communication, teamwork and system-related safety in our work culture have succeeded," said James Suliburk, MD, associate professor of surgery at Baylor College of Medicine in Houston and the study's first author.

To further decrease preventable medical errors, the study suggests, healthcare organizations should shift their focus to cognitive training and teach medical staff to recognize their own mental pitfalls.

https://www.beckershospitalreview.com/quality/over-half-of-adverse-surgical-events-due-to-human-error-study-finds.html

Failure to timely diagnose sepsis

Sepsis

- Leading cause of death US Hospitals
- Mortality from sepsis is #1 cost of hospitalization in US consuming more than $24 Billion each year
- 11th leading cause of death US
- Difficulty to diagnosis S&S mimics other entities

sepsis

- Life threatening organ dysfunction caused by dysregulated host response to infection
- Septic shock subset of sepsis with circulatory and cellular metabolic dysfunction associated and higher risk of mortality
- Sepsis is a core measure
- CDC report that the 4 types of infection most often associated with sepsis are lung, urinary tract, skin and GI

SIRS criteria

Two or more system inflammatory response criteria are:

1. Temp> 100.9F or < 96.8F
2. Heart rate> 90
3. Respiratory rate > 20/min
4. Wbc > 12000 or < 4000or > 10% bands

Organ dysfunction

evidenced by any one of the following

- Sbp < 90 or MAP , 65 or drop SBP > 40
- Acute resp failure as evidence by a new need for invasive or non invasive mechanical ventilation including bi pap or c pap
- Creatinine > 2.0
- Urine output < 0.5mg/kg/hr for 2 consecutive hours
- Total bilirubin > 2 mg/dl
- Platelet ct < 100000
- Inr > 1.5 or PTT > 60 s
- Lactic acid > 2 mmol/l

SIRS consideration

- If SIRS criteria or sign of organ dysfunction is normal for that patient, is due to a chronic condition, is due to an acute condition , that is not an infection or is due to a medication, it should not be used as a criteria for SIRS

Septic shock criteria

- Severe sepsis (2 sirs, a source, end organ damage) and either

1. Lactic acid > 4 mmole/L
2. Hypotension (SBP < 90 or Map ,65 or SBP> 40) that persists after 30 ML/KG IVF bolus. One must have 2 documented BP within the hour after finishing the IVF bolus

BMI > 30 the fluid bolus maybe based IBW

SIRS

- Sepsis clock
- Develop nursing tool EHR
- Communication is key
- Fluids infused, lactic acid, reevaluate
- Transfer from out of the ER complete a sign out communication to the next attending, or hospitalist.

Quality of care

FLORIDA DATA 115/100000 INDIVIDUAL AT RISK FOR BREAST CANCER

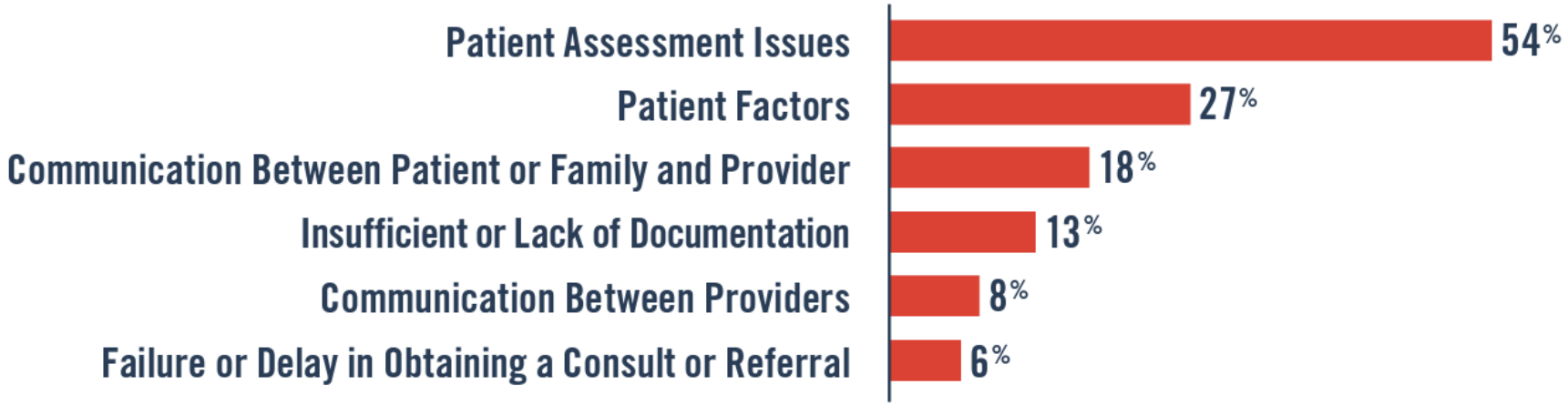
95% OF WOMEN WHO HAVE ABNORMAL MAMMOGRAM DO NOT HAVE CANCER

92% OF BREAST CANCER CLAIMS ARE CAUSED BY FAILURE TO DX OR DELAY IN DX

Quality of care issues breast cancer

FIGURE 7

Top factors contributing to misdiagnosis of breast cancer



Note: More than one factor may contribute to misdiagnosis, so the percentages total more than 100 percent.
Source: The Doctors Company Closed Claims 2008–2017

Self breast exam discovery

Lung cancer

Lung cancer is the leading cause of cancer deaths both women and men

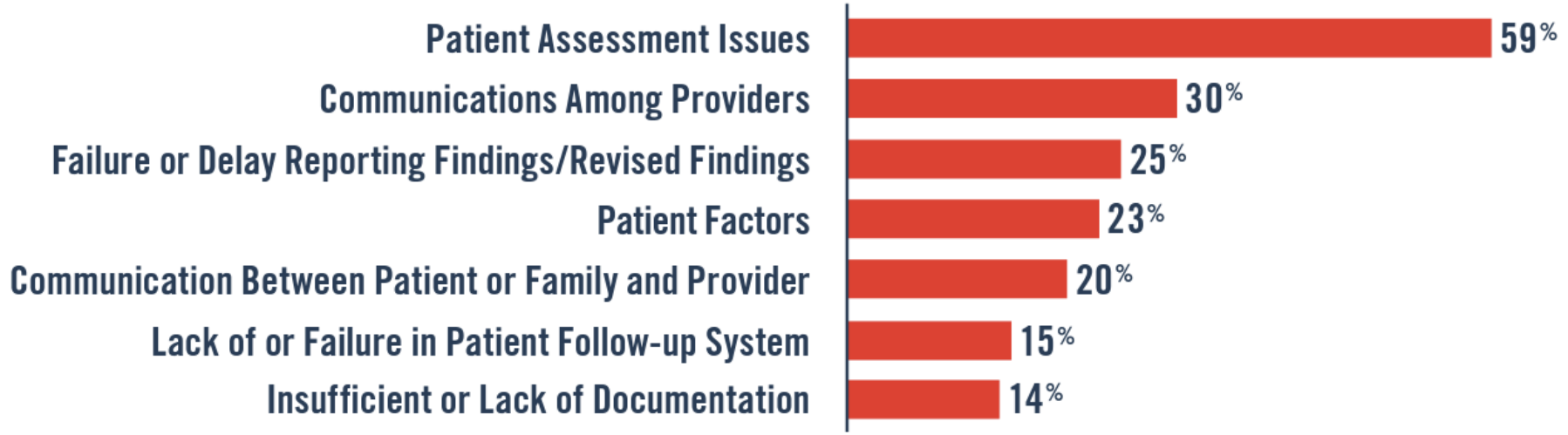
In addition ACS recommends smoking cessation counseling to current smokers

Should remain a high priority to ages 55-74 patients with > 30 pack years

Lung cancer

FIGURE 8

Top factors contributing to misdiagnosis of lung cancer



Note: More than one factor may contribute to misdiagnosis, so the percentages total more than 100 percent.
Source: The Doctors Closed Claims 2008–2017

Best practices

Best Practices for Reducing Cancer-Related Misdiagnosis

These best practices can help in reducing the misdiagnosis of cancer:

- Review and document the patient's histories, including a personal history (medical, surgical, and social) and a family history.
- Assess and document the patient's physical examination with specificity.
- Explore and document the patient's complaints.
- Provide information about risk factors, signs and symptoms, and continued monitoring and screening guidelines (including benefits and limitations).
- Offer patient education materials, such as those from the ACS and the CDC.
- Use shared decision-making tools to enhance patient compliance and understanding.
- Ask questions to ascertain the patient's understanding of the information provided.
- Provide copies of progress notes, diagnostic results, and other relevant findings when referring a patient.
- Document all care recommendations, including referrals, additional diagnostics, and procedures.
- Record details when patients refuse care, and consider using an informed refusal document.

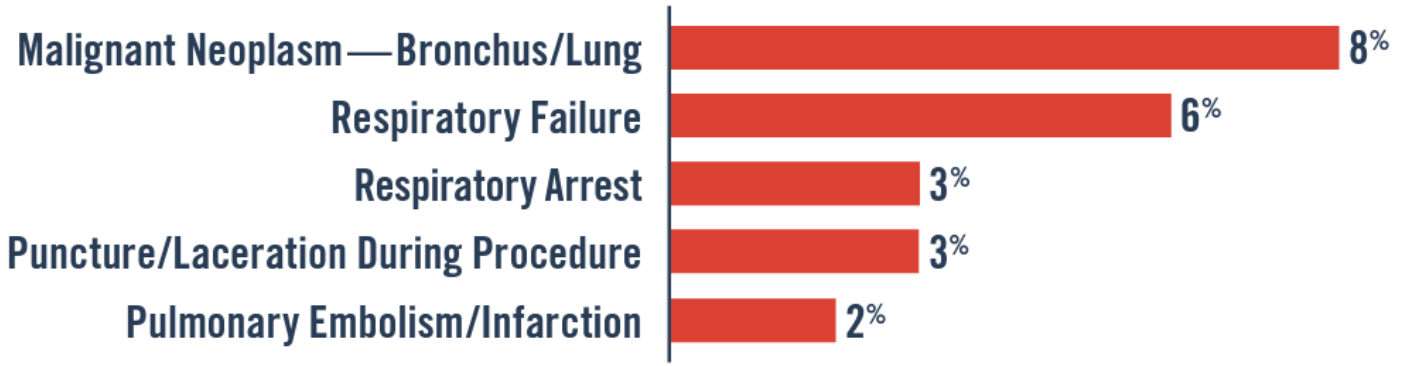
"Problems with the diagnosis and classification of cancer may lead to errors in treatment."

- Discuss screening, diagnostic, and referral results in lay terms that are easy to understand, and discuss the implications of findings.
- Employ a process to ensure that diagnostic results and referral reports have been reviewed by the practitioner and that the date of the review and the initials of the reviewer are noted on the report before filing.
- Review previous studies/film, diagnostic results, and referral findings, and compare those findings with the clinical picture.
- Implement fail-proof procedures to follow up on monitoring, track referral and consultation results, and review diagnostic results and treatment planning.

Respiratory related

Top final diagnoses for respiratory-related claims

FIGURE 14

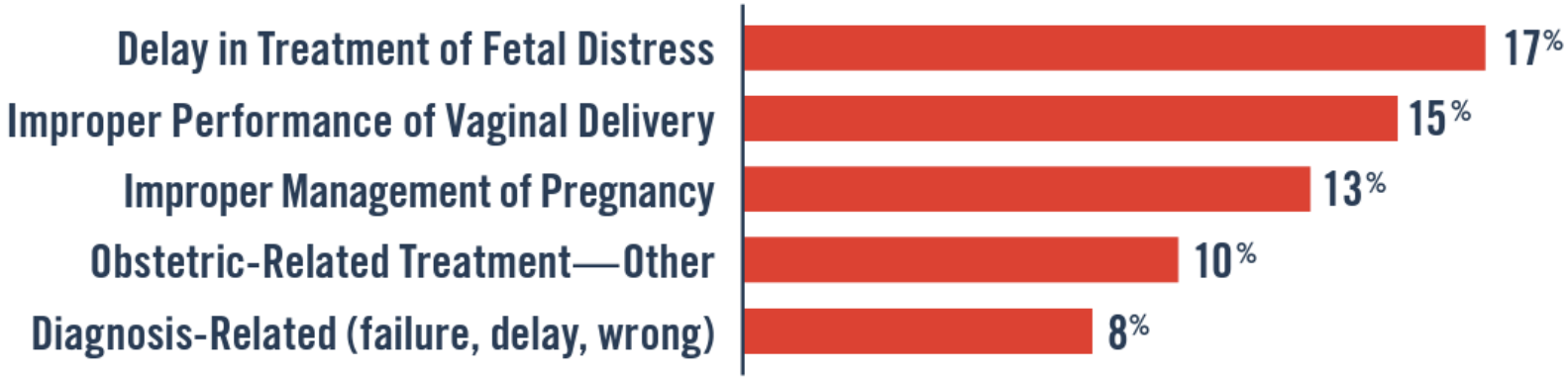


Source: The Doctors Company Closed Claims 2008–2017

Ob/gyn diagnosis related claims

Top allegations in ob/gyn diagnosis-related claims

FIGURE 16

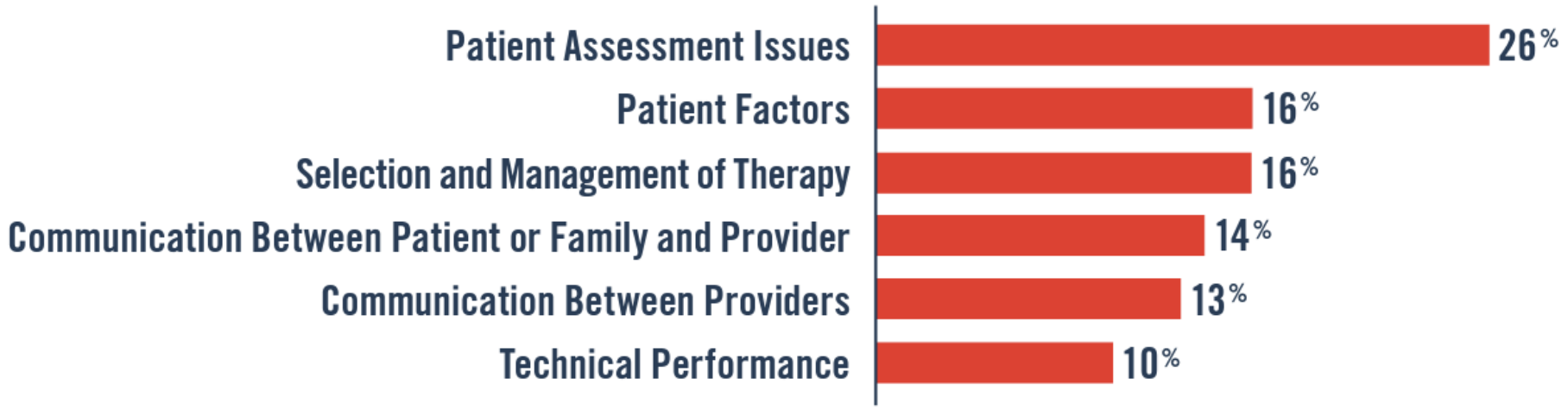


Source: The Doctors Company Closed Claims 2008–2017

Cardiac related claims

FIGURE 18

Top factors contributing to patient injury in cardiac claims

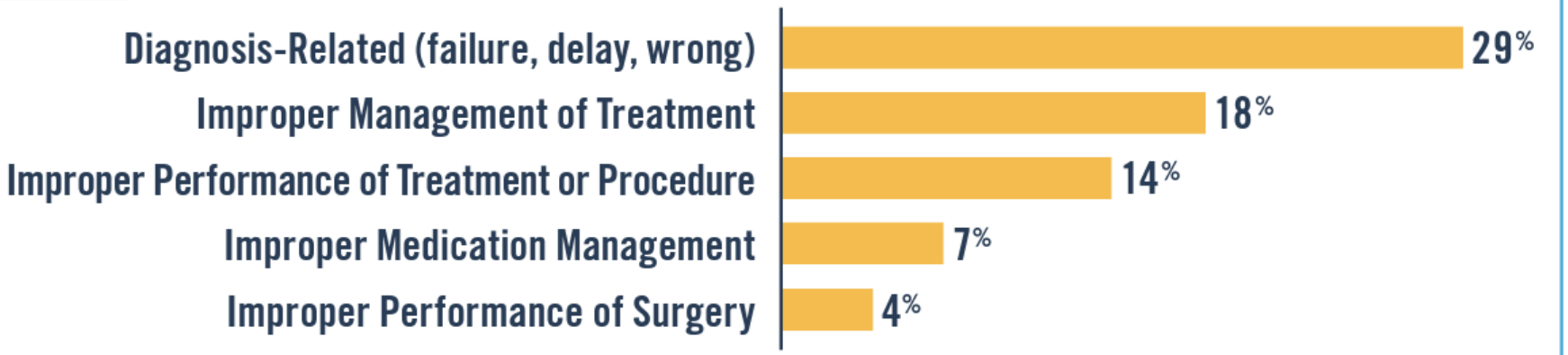


Source: The Doctors Company Closed Claims 2008–2017

Cardiac related claims

Top allegations in cardiac claims

FIGURE 17



Source: The Doctors Company Closed Claims 2008–2017

2020 emergency care research institute

- 1. Misuse of Surgical Staplers –malfunction & misuse can lead to harm
- 2. Adoption of Point-of-Care Ultrasound Is Outpacing Safeguards-speed of adoption has outpaced polices & practices that can prevent misuse

2020 emergency care research institute

- 3. Infection Risks from Sterile Processing Errors in Medical and Dental Offices- failure to consistently & effectively sterilize contaminated items can lead to patient infections.

- 4. Hemodialysis Risks with Central Venous Catheters—Will the Home Dialysis Push Increase the Dangers? - Can potentially lead to patient infections?

2020 emergency care research institute

- 5. Unproven Surgical Robotic Procedures May Put Patients at Risk. -early adoption sometimes before the risks have been fully accessed

- 6. Alarm, Alert, and Notification Overload – high # of notifications can be overwhelming

2020 emergency care research institute

- 7. Cybersecurity Risks in the Connected Home Healthcare Environment- connected home healthcare security

- 8. Missing Implant Data Can Delay or Add Danger to MRI Scans - being unaware of devices can put patient & staff in danger and create delays in the MRI suites

2020 emergency care research institute

- 9. Medication Errors from Dose Timing Discrepancies in EHRs- proper CPOE

- 10. Loose Nuts and Bolts Can Lead to Catastrophic Device Failures and Severe Injury- failure to maintain devices can lead to potential retained foreign bodies

©RICHTENNANT
5/26
Oh come on- how fatal can it be?
FATAL ERROR
www.the5thwave.com
© 2002 Rich Tennant/Dist. by Universal Press Syndicate

isements

2020 Hospital National Patient Safety Goals

Improve staff communication

Get important test results to the right staff person on time

2020 Hospital National Patient Safety Goals

Identify patients safely

Make sure that the correct patient gets the correct blood when they get a transfusion.

2020 Hospital National Patient Safety Goals

Use medicines safely

Before a procedure, label medicines that are not labeled

Take extra care with patient who take medicines that thin their blood

Record and pass along correct information about a patient's medicine. Remind bring their up to date list of medicines every time they visit.

2020 hospital national patient safety goals

Use alarms safety.

Make improvement to ensure that alarms on medical equipment are heard

2020 hospital national safety goals

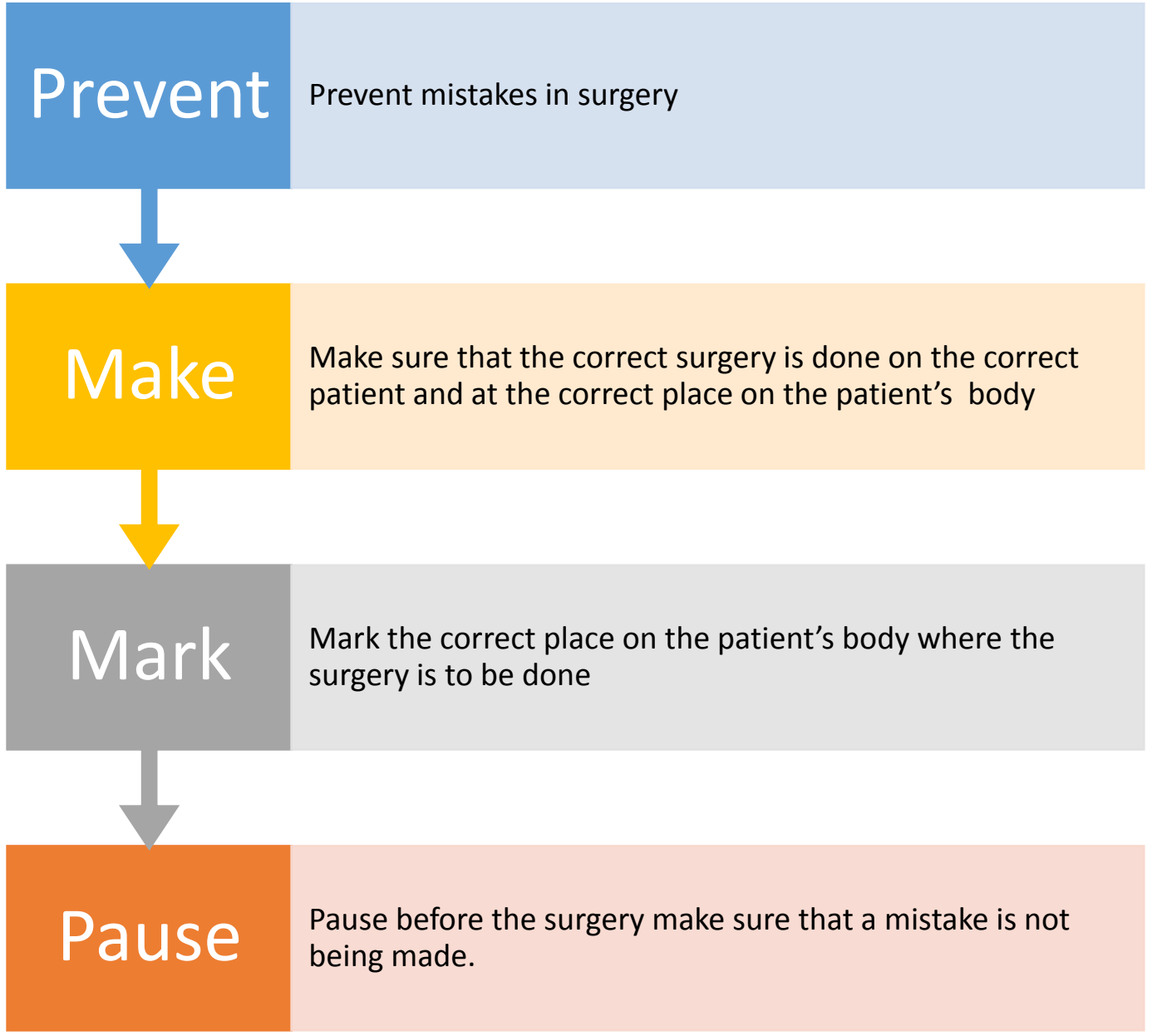
Prevent	Prevent infections
Use	Use hand cleaning guidelines from CDC
Use	Use proven guidelines to prevent infections that are difficult to treat
Use	Use proven guidelines to prevent infection of the blood from central lines
Use	Use proven guidelines to prevent infection after surgery
Use	Use proven guidelines to prevent infection of the urinary tract that are caused by catheter

2020 Hospital National Safety Goals

Identify patient safety risks

Reduce the risk for suicide

2020 Hospital National Safety Goals



2019 Bace data (board action content evaluation) FSMB data census 985,026 physicians USA

7617 actions for 3642 physicians
Most common controlled substance violations
Failure to maintain adequate medical records
Failure to conform to minimal standards of acceptable practice
Unable to practice with reasonable skill & safety standards
Sexual misconduct

OSTEOPATHIC PLEDGE OF COMMITTMENT

- Provide compassionate, quality care to my patients;
- Partner with them to promote health;
- Display integrity and professionalism throughout my career;
- Advance the philosophy, practice and science of osteopathic
- medicine;
- Continue life-long learning;
- Support my profession with loyalty in action, word and deed; and
- Live each day as an example of what an osteopathic physician should be

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FLORIDA BOARD OF OSTEOPATHIC MEDICINE CHAPTER 459, F.S., RULE CHAPTER 64B15, F.A.C. AND CHAPTER 456, F.S.

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2020-ahc-npsg-goals-final.pdf