Never Events:
A Claims Perspective

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Never Events

Clear and preventable medical errors that should never occur

“Never Event”

“Serious reportable events”

“Sentinel events”

“Hospital acquired conditions

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Disclaimer on Never Events

THE SKY IS NOT FALLING!

Never Events

Never Events remain rare overall

Why discuss?

- Patient safety
- Degree of injury
- Difficult/impossible to defend

Medical Negligence – Key Concepts

- Standard of Care – The health care provider must exercise that degree of care, skill and learning expected of a reasonable, prudent health care provider in the same profession as they belong acting in the same or similar circumstances
- Expert witnesses in the same specialty typically establish standard of care
- Res Ipsa Loquitur – Latin for “the thing speaks for itself”; No expert testimony required in res ipsa cases, shifts burden of proof

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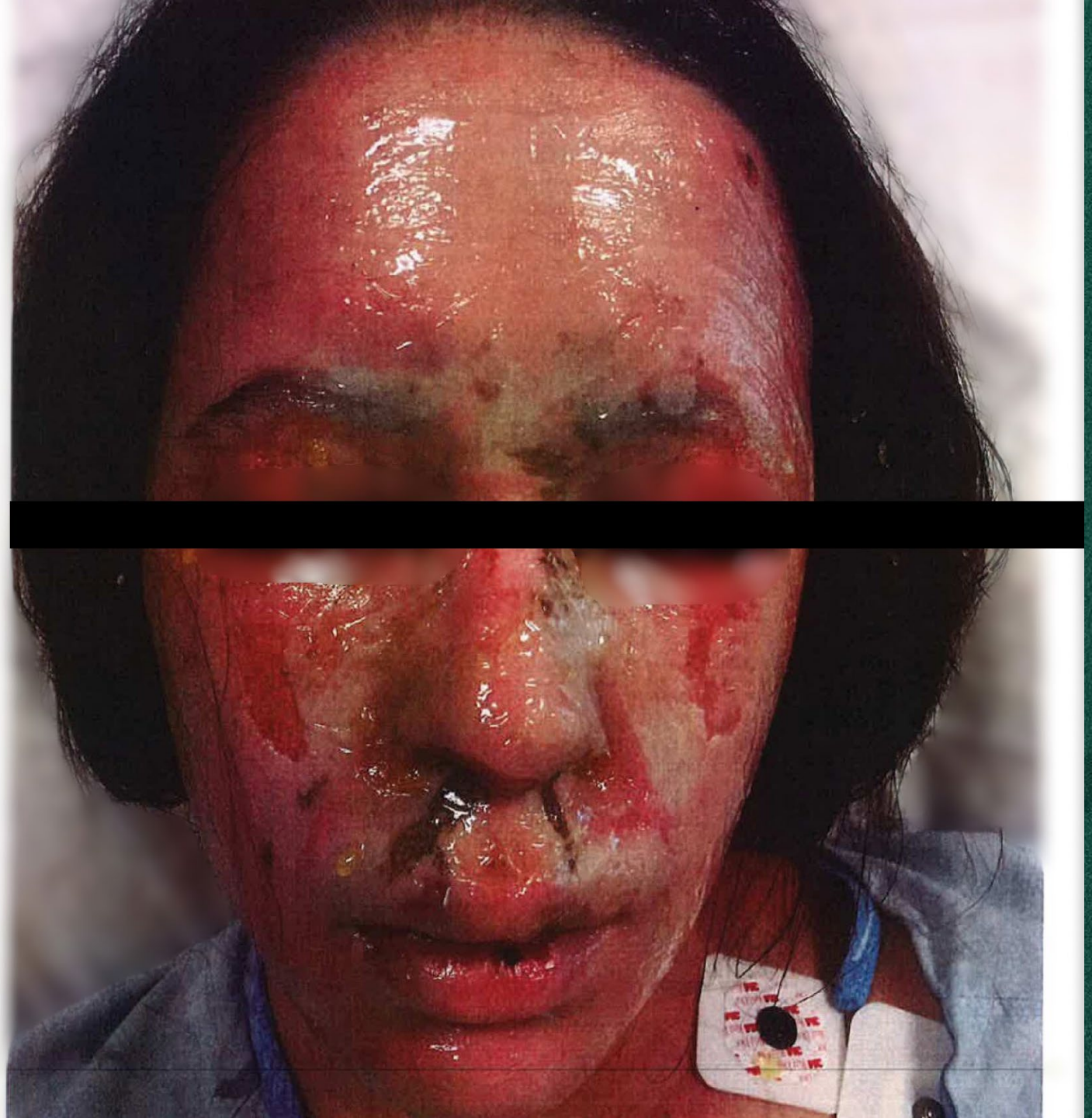
O.R. Fire – Case Study

- 32 y/o female presented for excisional biopsy of right posterior cervical lymph node
- Chloraprep used, dry time ~9min
- Drapes placed with focused on reduced O2 accumulation
- Less than 10 minutes into the procedure Anesthesiologist noted the patient began abruptly moving.

O.R. Fire Case Study Continued

- Fire was noted around the patient's face
- Drapes were removed
- Nasal cannula on fire
- Fire extinguished with sterile towels and saline
- Procedure completed and the patient was transferred to a burn center
- Surgeon and facility settled for $350,000 jointly; anesthesiologist settled later for an undisclosed amount



O.R. Fire

Expert Criticisms

No fire risk assessment or time-out

Alcohol-based prep solution not allowed to dry

No communication between surgeon and anesthesia provider before electrocautery use

Surgeon’s use of monopolar cautery

Oxygen was not turned down or off before electrocautery use

No plan in place to manage O.R. fire

O.R. Fire

Risk Management Strategies

- Utilize a fire risk assessment
- Ensure communication exists between providers
- Place ignition sources in designated areas away from the patient and not on the patient or the drapes
- Allow adequate dry time of alcohol-based preps and avoid pooling
- Use a non-alcohol-based prep if possible
- Plan and practice how to manage a surgical fire.
- Minimize or avoid an O2 enriched atmosphere near surgical site (consider ETT or LMA, turn down/off O2 before ignition source use, <30% O2)
- Configure drapes to minimize accumulation of O2
- Moisten sponges and gauze when used in proximity to ignition sources
- Choice of cautery

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Falls from O.R. or Procedure Table – Case Study

- An obese 39 y/o male presented for an appendectomy.
- Nursing staff placed the patient on the bed with one arm tucked and the other on an arm board. Safety straps were placed across his hips. No safety straps were used on his upper body.
- Bed was rotated in the leftward direction for surgical access.
- 30 minutes into the procedure the patient slid off the table, hitting shoulder first.
- The case settled for $300,000 before litigation was filed.

Falls from O.R. or Procedure Table

Litigation Challenges

Juries will not accept that these types of injuries occur absent someone's negligence

- Injuries can include brain injures and even death.

Res Ipsa Loquitur – shifts burden of proof to defendants, no expert testimony required, all involved are liable

"Shared responsibility" and every member of perioperative team has a duty to prevent these adverse incidents and injuries

Punitive damages

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Falls from O.R. or Procedure Table

Risk factors

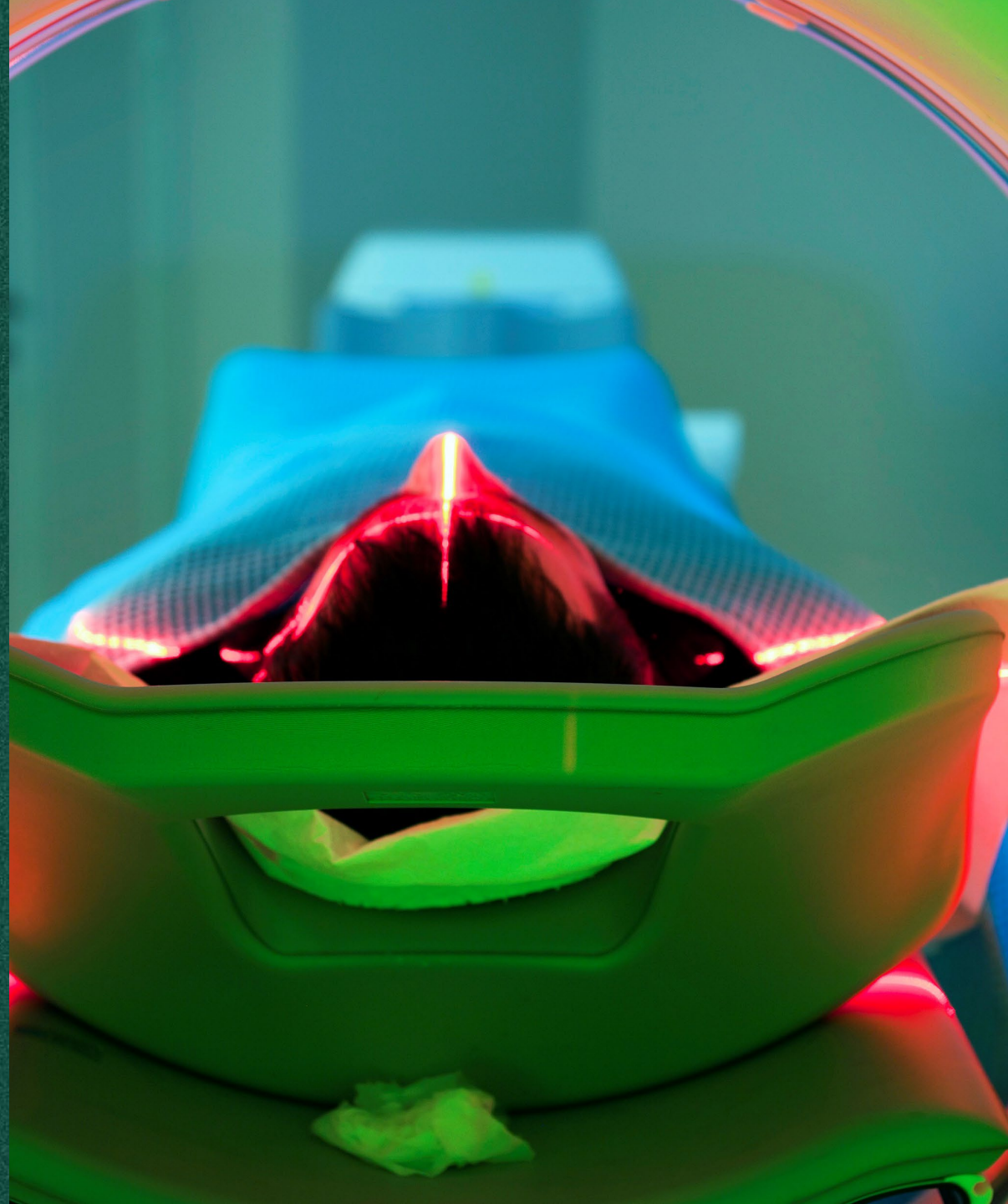
Patient Attributes – Obesity, age, lateral positioning, sedated or altered consciousness, and agitation during induction or emergence

Provider Actions and Inactions – Distractions, shifting attention from the patient to other unrelated O.R. tasks, assumption that other providers are securing patient, and vulnerability to production pressure

O.R. Table Factors – New or unfamiliar table and controls, improper function or use of locking mechanism of Jackson spinal table or other mechanical table failures, extremes of positioning (e.g. side tilt, steep or reverse Trendelenburg position), table tipping

Absence or inadequacy of safety restraints

Failure to lock wheels of O.R. table or gurney



Falls from O.R. or Procedure Table

Risk Management Strategies

Familiarity with the controls, operations and the safe weight limits of all O.R. tables in use; or have ready access to such information or to knowledgeable personnel

Coordination of *all* patient movements/transfers - sudden and unexpected transfers of obese patients may be difficult to stop once initiated

Entire perioperative team should understand their specific roles and proactively discuss patient observation responsibilities for all phases of intraoperative and near-perioperative periods

Follow manufacturer recommendations on maintenance

Remove equipment from service until it has been repaired

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Medication Errors: Case Study

- Patient presented for total hip replacement performed under spinal anesthesia
- Two CRNAs were setting up anesthesia tray
- Syringes were labeled with white and grey stickers for the bupivicaine and tranexamic acid, respectively
- After performance of the spinal block, it was determined patient received an intrathecal injection of tranexamic acid instead of bupivicaine

Medication Errors

Other Case Examples

Wrong doses

Patient history/drug interactions

Look-alike and sound-alike drug names

Incorrect labeling

Medication Errors

Risk Management Strategies

Specific to TXA intrathecal injection error:

Use barcode-assisted medication safety checks, if available, when preparing and prior to administering medications in surgical and obstetrical areas.

Develop protocols to use premixed intravenous (IV) bags of TXA or pharmacy-prepared infusion bags to prevent mix-ups.

Maintain a high level of vigilance when these two medications are given during a case.

Meet with key stakeholders to review their workflow when ordering and administering TXA to ensure safe practices.

Evaluate workload to ensure workload pressures will not result in unsafe workarounds and practices.

Report near misses and unsafe medication practices.

Conduct regular reviews and discussions of medication events and close calls reported in your institution.

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Medication Errors

Risk Management Strategies

General Medication handling recomendations:

Conduct regular reviews and discussions of medication events and close calls reported in your institution.

Standardization - Standardize organization of medication storage and keep similar-looking vials away from each other

Technology - Facilities should implement systems and processes including bar code scanning systems, computerized physician order entry systems and automated information systems

Pharmacy/Prefilled - Clinical pharmacists should be part of O.R. team, pre-prepared medication kits should be used whenever possible

Culture – Establish a culture for reporting errors (including near misses), education, and accountability

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Medication Errors – Final Risk Management Strategy

READ THE LABEL CAREFULLY!!!

Other Considerations

- PED use – what's your reputation?
- Civility – How well do you get along with others? How well do you "comply"?
  - Good working relationship with colleagues good for patient safety; valuable in event of complication > lawsuit
  - Foster culture where compliance with policies and protocols is the rule; be part of the solution, not the problem
- Patient Relations
  - Communication with patients – pre-op, post-op
  - To bill or not to bill in the event of adverse outcome
  - Contacting your insurance carrier

Questions?

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All caregivers, giving their all. Making sacrifices to make a difference, day and night.

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Sometimes, just to listen.

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Resources

- Anesthesia Patient Safety Foundation O.R. Fire Prevention Video and supporting commentary – http://www.apsf.org/resource_center/fire-safety.mspx
- Unraveling a Recurrent Wrong Drug-Wrong Route Error—Tranexamic Acid in Place of Bupivacaine: A Multistakeholder Approach to Addressing this Important Patient Safety Issue https://www.apsf.org/article/unraveling-a-recurrent-wrong-drug-wrong-route-error-tranexamic-acid-in-place-of-bupivacaine/
- FDA Alerts Healthcare Professionals About the Risk of Medication Errors with Tranexamic Acid Injection Resulting in Inadvertent Intrathecal (Spinal) Injection https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-healthcare-professionals-about-risk-medication-errors-tranexamic-acid-injection-resulting

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