THE HONORABLE MAE A. D'AGOSTINO

KEYNOTE PRESENTATION

ASSOCIATION FOR HEALTHCARE RISK MANAGEMENT OF NEW YORK

FALL EDUCATIONAL CONFERENCE
10/30/23



MEDICAL MALPRACTICE IN FEDERAL COURT

TWO MAIN WAYS A FEDERAL COURT WILL HAVE JURISDICTION OVER MEDICAL MALPRACTICE CLAIMS:

1. Diversity Jurisdiction
2. Federal Tort Claims Act

DIVERSITY JURISDICTION:

1. The amount in controversy must exceed $75,000.
2. No plaintiff can be a citizen of the same state as any defendant.

DIVERSITY JURISDICTION:

- Diversity of citizenship is assessed at the time an action is filed.
- The general rule for diversity cases is that state substantive law and federal procedural law will apply.

FEDERAL TORT CLAIMS ACT

The Federal Tort Claim Act allows a plaintiff to sue the United States “for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment.”

ELEMENTS OF THE FEDERAL TORTS CLAIM ACT:

1. The claim must allege injury or loss of property, or personal injury or death.
2. The damage must have been caused by a negligent or wrongful act or omission.
3. The wrongful actor must have been an employee of the federal government.
4. The employee must have been acting within the scope of her employment.
5. The circumstances must be such that the United States if a private person would be liable to the claimant in accordance with the law of the place where the act or omission occurred.
6. The plaintiff must first have exhausted her administrative remedies by presenting the claim in writing to the appropriate federal agency.
7. The claim must demand an amount in money damages that does not exceed the amount set forth in the administrative claim.

ELEMENTS OF THE FEDERAL TORTS CLAIM ACT: EXHAUSTION

Before a FTCA claim can be brought, the claimant must first:

- Present the claim in writing to the appropriate federal agency
- Within two years after the claim accrues

If the claimant fails to do this, then the claim will be forever barred.

The claimant must plead and prove that she satisfied this requirement in order to bring an FTCA claim.

ELEMENTS OF THE FEDERAL TORTS CLAIM ACT:
EXAUSTION: WHEN DOES A CLAIM ACCRUE?

- At the time of the injury

OR

- At the time when the plaintiff discovers **or with reasonable diligence should have discovered** the critical facts of both his injury and its cause

ELEMENTS OF THE FEDERAL TORTS CLAIM ACT: EXHAUSTION AND THE STATUTE OF LIMITATIONS

- **If the agency denies the claim**, the claimant must bring her FTCA suit within six months after the date of mailing of the agency's notice of denial.

- **If the agency fails to make a final disposition of a claim within six months of the claim's filing**, then the claimant at any time after can deem the inaction a final denial of the claim.
  - Most courts have held that when an agency fails to act on a claim, the claimant's time for filing an FTCA claim is indefinitely extended.

ELEMENTS OF THE FEDERAL TORTS CLAIM ACT:
SUM CERTAIN:

- **The statute states that an FTCA claim cannot be "instituted for any sum in excess of the amount of the claim presented to the federal agency,"**
  - **"except where the increased amount is based upon newly discovered evidence not reasonably discoverable at the time of presenting the claim to the federal agency, or upon allegation and proof of intervening facts, relating to the amount of the claim."**

- **It then follows that if the plaintiff's claim to the agency does not demand a specified sum, then any FTCA claim seeking damages will be seeking a "sum in excess of the amount of the claim presented to the federal agency" and will be improper.**

- **Therefore, the administrative claim must set forth a specific demand for damages in a sum certain.**

FEDERAL TORTS CLAIM ACT:
BRINGING A MEDICAL MALPRACTICE CLAIM IN NEW YORK

- To bring an FTCA claim, the circumstances must be such that the United States if a private person would be liable to the claimant in accordance with the law of the place where the act or omission occurred.
- To bring a medical malpractice action in New York, the plaintiff must allege "a deviation or departure from accepted community standards of medical practice, and evidence that such deviation or departure was a proximate cause of injury or damage."

FEDERAL TORTS CLAIM ACT:
DEFENSES TO AN FTCA CLAIM

- Exhaustion not met.
  - The FTCA claim is filed before any administrative claim is made.

- The plaintiff failed to file an administrative claim with the appropriate agency within two years of the claim accruing.

- The plaintiff filed an administrative claim with the appropriate agency within the proper time period, but failed to file an FTCA claim within six months of the date of mailing of the agency's notice of denial.

- The administrative complaint does not include a specific demand for damages in a sum certain.

FEDERAL TORTS CLAIM ACT:
DEFENSES TO AN FTCA CLAIM

- Claimant asks for more in damages in FTCA claim than she requested in administrative complaint.

- The defendant was performing a discretionary function:
  - The discretionary function exception states that the FTCA does not apply to "[a]ny claim based upon . . . the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused."

WHAT TO EXPECT AT TRIAL

ARBITRATION OR FEDERAL COURT?

Are mandatory arbitration clauses in healthcare contracts wise from an insurer's perspective?

ARGUMENTS IN FAVOR OF MANDATORY ARBITRATION CLAUSES

- Defense costs are lower in arbitration.
- There is less uncertainty in arbitration then in litigation and the quality and accuracy of the decision-maker is increased.
- “Repeat players” theory
- Speed of resolution
- Eliminates the possibility of a class action lawsuit.

ARGUMENTS AGAINST MANDATORY ARBITRATION CLAUSES

- The decreased cost of arbitration may cause an increase in the number of potential plaintiffs who enforce their claims.
- Litigation outcomes tend to favor physicians.
- The absence of judicial review in arbitration eliminates a check on bias and error that is available in litigation.
- Some believe that arbitration unnecessarily induces compromise and might contend that a physician with a very strong case would have better success in a courtroom.

IMPORTANCE OF CIVILITY IN FEDERAL COURT

CIVILITY IN FEDERAL COURT

- 85% of U.S. residents believe civility in today's society is worse than it was ten years ago.

CIVILITY IN FEDERAL COURT

- “A lawyer's conduct should be characterized at all times by **personal courtesy and professional integrity** in the fullest sense of those terms. In fulfilling our duty to represent a client vigorously as lawyers, we will be mindful of our obligations to the administration of justice, which is a truth-seeking process designed to resolve human and societal problems in a **rational, peaceful, and efficient manner**.”

ABA - Preamble to the Guidelines for Litigation Conduct

CIVILITY IN FEDERAL COURT

- Civility is a cornerstone of our adversarial legal system.
  - Advocating zealously for opposing positions while maintaining respect at all times is required in order to resolve legal disputes in a “rational, peaceful, and efficient manner.”

- A lack of civility hurts a party’s reputation and credibility.

CIVILITY IN FEDERAL COURT (OR LACK THEREOF) –

N.D.N.Y - 2021

- Jury returned a verdict in favor of the defendants.
- After the jury left the courtroom, the defendants' lead attorney approached plaintiff and his attorneys and told them to "choke on their manufactured evidence."
- "[T]he remarks were completely a hundred percent inappropriate and right in this courtroom and will not be tolerated. I am going to recommend that [defendants' lead attorney] be disciplined and I hope that the discipline is firm. Unbelievable, [name of defendants' lead attorney]."
- The attorney was formally sanctioned for an "inappropriate, taunting comment."
  - He was ordered to pay a fine of $3,000 to opposing counsel.
  - He was barred from working on the case in any capacity.

CIVILITY IN FEDERAL COURT (OR LACK THEREOF) –

N.D. Ill. – 2021

- There was a "breakdown of civility and professionalism among counsel during the discovery phase of this case."
- Plaintiff's counsel engaged in "interruptions" and "extraneous conversations" during a deposition of the Plaintiff.
- "One interruption involved [Plaintiff's counsel] asking Plaintiff if he wanted some water while defense counsel was in the middle of asking a question. This led to a heated exchange between counsel about [Plaintiff's counsel] interruptions and [Plaintiff's counsel] yelling to his assistant in another room to bring water."

CIVILITY IN FEDERAL COURT (OR LACK THEREOF) –

N.D. Ill. – 2021

- Defendant's response to a motion to compel by Plaintiff was "insult-laden" according to the Court:
  - "Plaintiff . . . brings this meritless action out of spite."
  - "Plaintiff takes positions that fly in the face of reality."
  - Described Plaintiff's litigation strategy as "obnoxious[]."
  - "Plaintiff is completely unreasonable at every turn."
  - "There has not been one task at hand that has been properly handled by Plaintiff."

CIVILITY IN FEDERAL COURT (OR LACK THEREOF) –

N.D. Ill. – 2021

- “Counsel's dislike for each other, combined with a level of unprofessionalism, has resulted in any dispute in this case going from an intensity level of zero to ten in a moment's notice.”

- “Moreover, both counsel disregarded the Court's warning to decrease the animosity and work cooperatively together at Plaintiff's deposition. The Court wishes to emphasize this point, if not already clear: the Court will not tolerate incivility and lack of professionalism among counsel.”

CIVILITY IN FEDERAL COURT (OR LACK THEREOF) –

N.D. Ill. – 2021

- "There is a clear pattern of uncivil conduct here, and counsel's personal animus reflects a lack of professionalism. It is cases like these that leave the Court to wonder why the practice is called "civil litigation" – the attorneys' conduct here has been anything but civil. The breakdown in professionalism among counsel during the course of discovery caused the mistrust and inability to work cooperatively together at Plaintiff's deposition and to subsequently resolve the deposition issues without involving the Court."

- The Court did not issue sanctions, but stated that "the Court expects better from counsel moving forward and trusts that publication of this opinion will be sufficient to deter similar discovery conduct by counsel in this case or by lawyers in other cases before this Court."

THANK YOU!

Nuclear Verdicts, Reptiles & Anchors Impact on Litigation Trends

AHRMNY Presentation, Saratoga Springs, 10/30/23

Jeffrey C. Gerson, Esq.
Vice President of Claims
MedPro Group

Katherine A. Buckley, Esq.
Partner
Gale Gale & Hunt LLC

MedPro Group
a Berkshire Hathaway company









What is a Nuclear Verdict?

1. Nuclear Verdict (aka Shock Verdict) is defined as **any jury verdict of $10M or greater.**

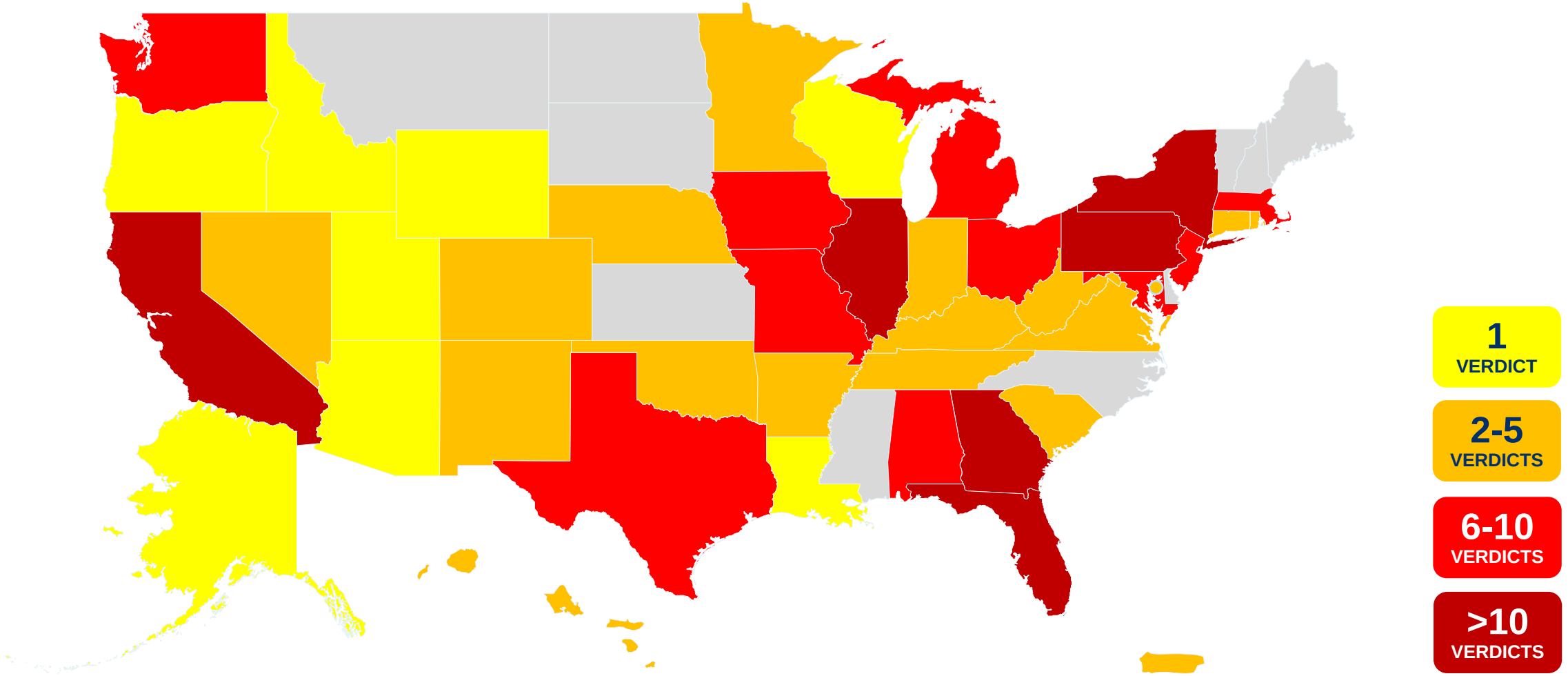
2. Nuclear Verdicts are on the rise across the country with concerning post-pandemic trends.

3. The leading personal injury categories of nuclear verdicts are:
   - Product Liability – 23.6%
   - Auto Accident – 22.8%
   - **Medical Malpractice – 20.6%**
   - Premises Liability – 15.4%
   - Misc. Others – 17.6%

Figures provided by US Chamber of Commerce Institute for Legal Reform article on Nuclear Verdicts [Sept. 2022]

$10M+ verdicts increasing in frequency

… and expanding beyond traditional "Judicial Hellholes"



Source: Trans Re and various internet articles with publication dates between **1/1/2016 and 9/8/2023**

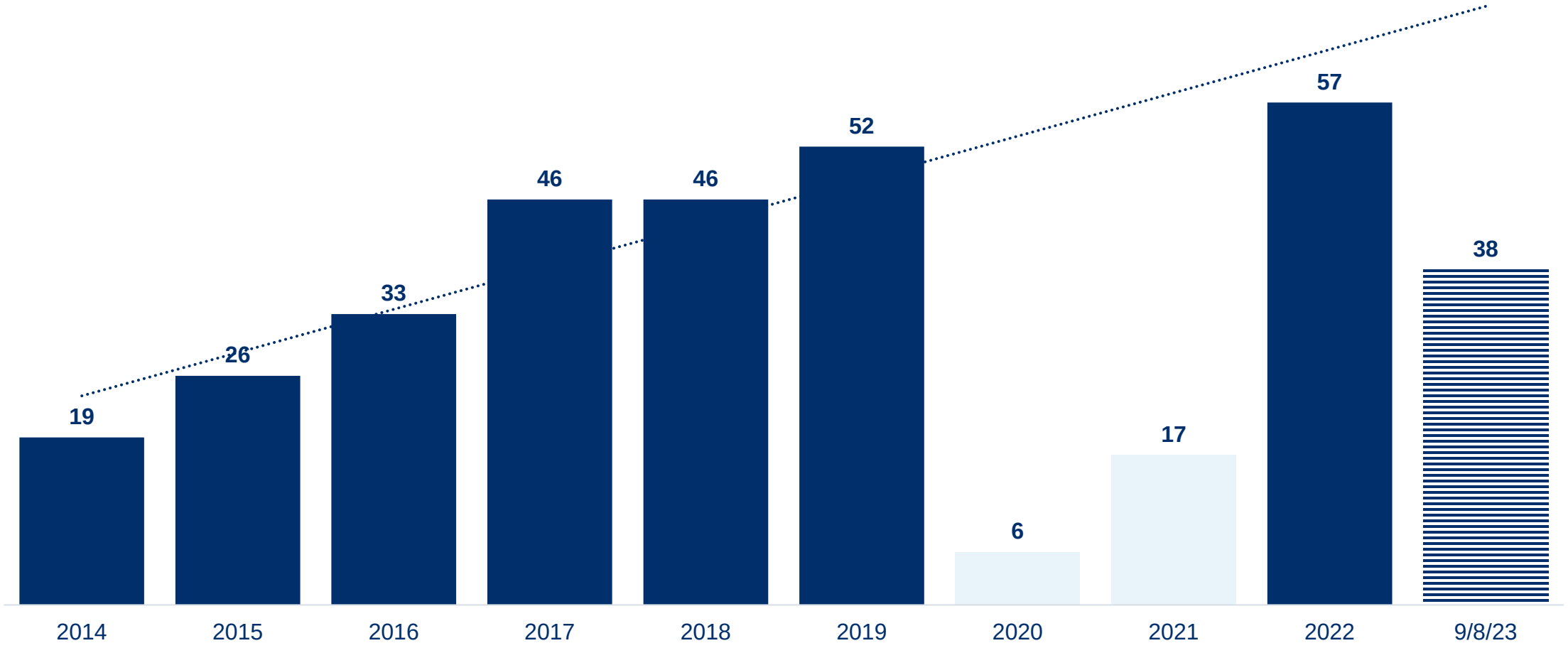
Nuclear Verdict Trends

- According to the US Chamber of Commerce, the average nuclear verdict has steadily increased from 2015 – 2019. New York Business Litigation Journal (2022) has calculated recent average nuclear verdict stats for 2022:

  - 2015 - $17.5M
  - 2016 - $19.5M
  - 2017 - $20.5M
  - 2018 - $23.0M
  - 2019 - $25.0M
  - 2022 - $41.1M (20 verdicts nationwide over $100.0M)

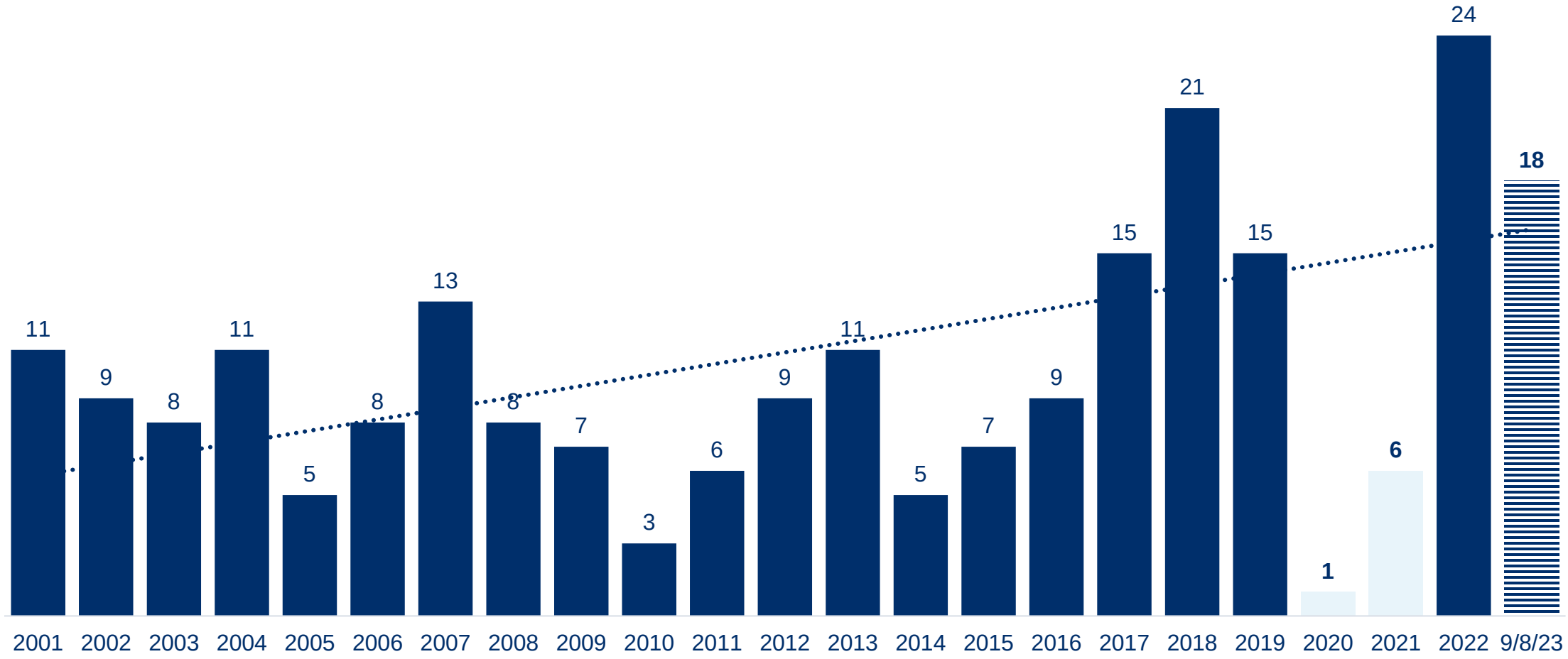
$10M+ verdicts increasing in frequency nationally

… returning to pre-pandemic trajectory as courts reopen countrywide



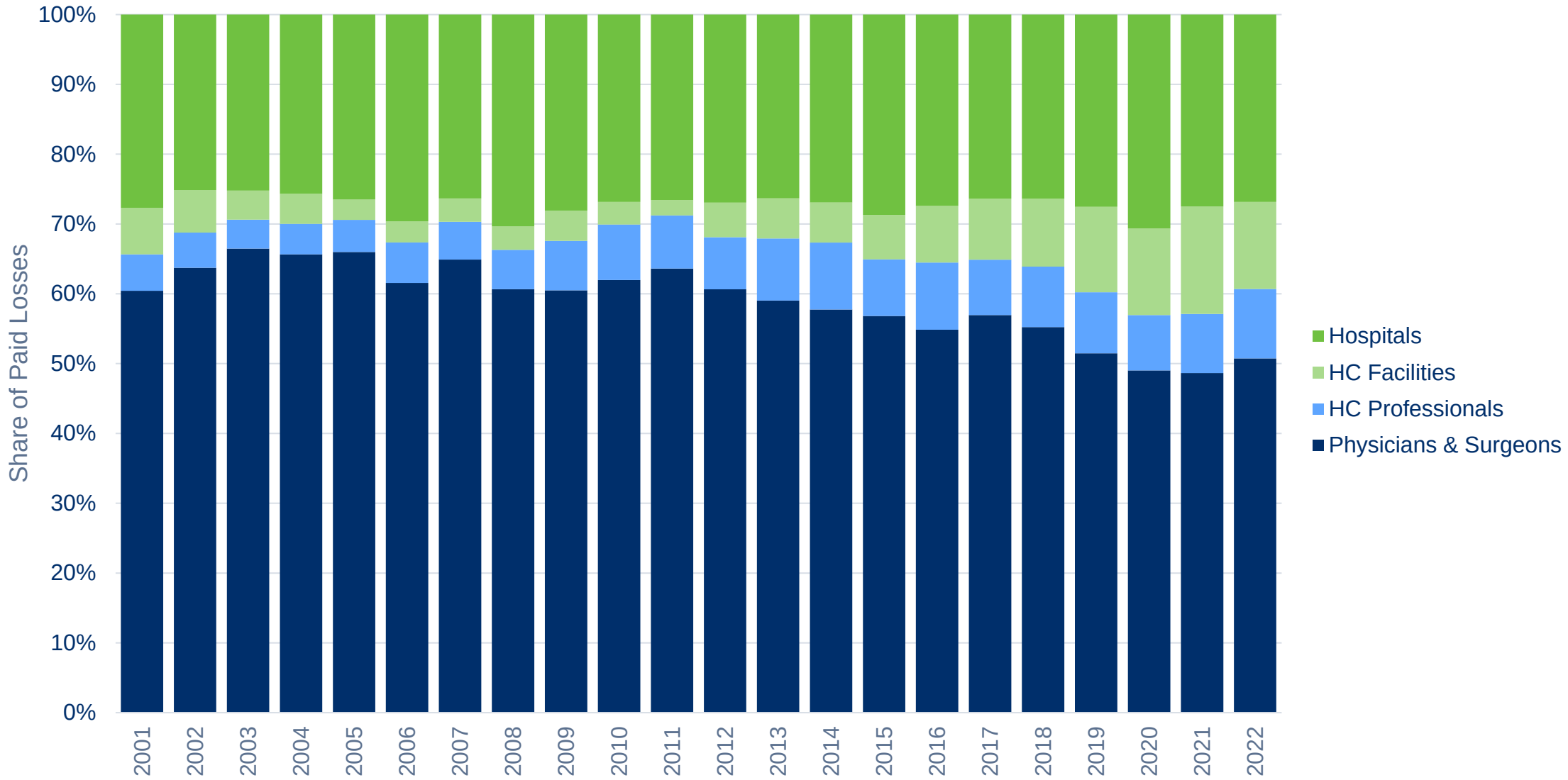
Source: Trans Re and various internet articles with publication dates between 1/1/2016 and 9/8/2023

$25M+ Aberration ("Super Nuclear") Verdicts Increasing Nationally



Source: Trans Re and various internet articles with publication dates between 1/1/2016 and 9/8/2023

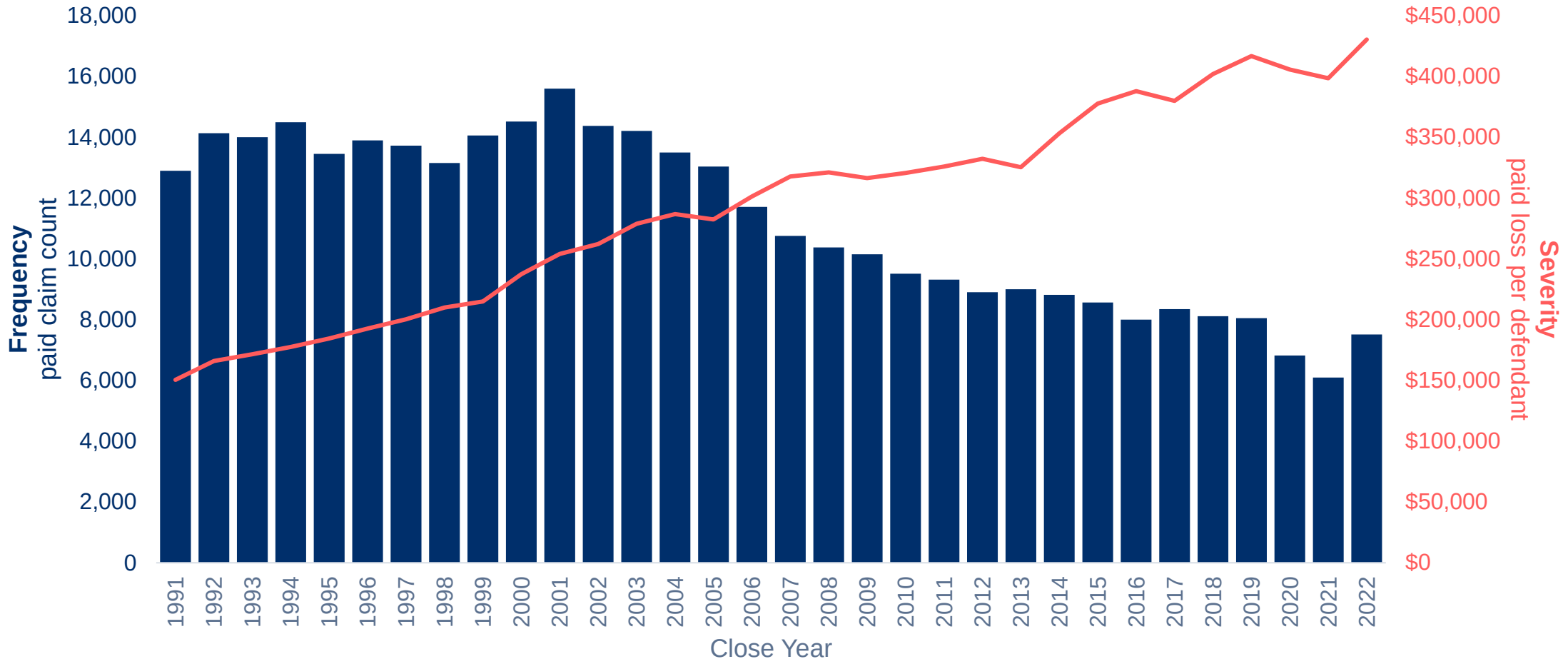
Industry losses shifting from HC Providers to HC Entities



Source: S&P Global Market Intelligence

Frequency & Severity Trends Nationally

Frequency trending flat from 2016 & Severity trending up from 2017 … until COVID-19 disruption



Source: National Practitioner Data Bank Public Use Data File, December 2022, Physicians & Surgeons Countrywide

New York medical malpractice nuclear verdicts (2013-2023)

- [redacted] verdict in **Rockland County** involving a cervical laminectomy that resulted in quadriplegia to a woman in her 60's. P developed post-op complications from a hematoma and P alleges a delay in re-operating and interpreting post-op imaging caused the permanent damages. P limited to w/c, has had aspiration pneumonia, ulcers and needs 24 hour ADL assistance. (2023)
- [redacted] verdict in **New York County** for New York Giants running back Michael Cox who suffered a fractured leg, damaged cartilage, and an injured ankle after a tackle. He alleged defendant physician failed to properly repair an ankle bone during surgery and then failed to recognize and treat his condition as he continued to deteriorate during post-operative visits. P alleged he would no long be able to play football. (2022)
- [redacted] verdict in **Jefferson County** for alleged misdiagnosis of tendonitis in a 50 y.o. male Fort Drum soldier resulting in a right above the knee amputation due to clots. P allegedly required a wheelchair and had to retire from the Army. (2021)
- [redacted] verdict in **Bronx County** for a Rikers' Island inmate who allegedly received no care or monitoring while in solitary despite suffering from tuberculosis. P alleged he was seen only once during 55 days in solitary and died two days after his release from complications of hepatic failure. He was survived by one daughter. (2020)

New York medical malpractice nuclear verdicts (cont'd) …

- [redacted] verdict in **Bronx County** for a neurological insult resulting from alleged improper treatment of asthma. P allegedly suffered a brain injury resulting in delayed cognition, nystagmus, ataxia, discoordination, weakness, and dysarthria. She required use of a wheelchair, speech therapy for risk of choking, assistance with ADLs, and 24-hour care. She suffered from depression. (2019)
- [redacted] verdict in **Bronx County** for a 12-year-old patient who was rendered paralyzed and mute, requiring a feeding tube, but still fully aware. P alleged the patient went into anaphylactic shock and her heart stopped after receiving a steroid shot. The ambulance that responded did not have the required equipment. Resuscitation was started but a new ambulance took twenty minutes to arrive. (2014)
- [redacted] verdict in **Suffolk County** for an allegedly improperly managed delivery resulting in a hypoxic event that caused brain damage and cerebral palsy. P alleged the infant plaintiff could not walk independently or speak. She was incontinent, dependent on others for ADLs, and was unable to comprehend or understand her surroundings. (2013)

What Factors Are Contributing to the Increase in Nuclear Verdicts

1. **Social Inflation** – refers to increase in claim severity above what could be anticipated under the usual scope of economic inflation and claim trends. (Exacerbation of already increasing inflation figures.)

2. Post-pandemic anger and anti-corporate environment.

3. Heavy advertising by Plaintiff's attorneys on TV, radio, newspapers and internet regarding recent nuclear verdicts.

4. Third-Party litigation funding.

5. Courtroom tactics by Plaintiff's attorneys:
    1. **REPTILIAN TACTICS!**
    2. **Anchoring!**

What is the Reptilian Theory?

1. The Reptilian Theory gained prominence through a book written by a prominent trial lawyer and jury consultant in 2009 entitled, "Reptile: The 2009 Manual of the Plaintiff's Revolution". The alleged science underlying this theory is to get jurors to use their "reptile brains" to instill a sense of being threatened and danger causing them to react in a way to render a verdict that punishes the defendant in order to protect themselves and their community.

2. Although the alleged "science" underlying the Reptilian Theory has been largely debunked, the tactic at trial can be extremely persuasive because it serves to divert jurors' attention away from the evidence by making them feel angered and empowered to protect the public at large from an uncaring corporation, a bad doctor or a bad hospital. It persuades jurors to put themselves in an injured plaintiff's position, inflame their sense of outrage, and award a nuclear verdict to not only punish the defendant, but protect the community and "send a message".

How to address Reptilian Theory tactics

- Many courts refused to consider motions in limine to preclude reptile theory arguments as premature and advised attorneys to make objections when such arguments are raised at trial, indicating such motions are too vague or broad to warrant prophylactic relief ("Federal courts have hissed at motions based on this theory that seek a broad prospective order untethered to any specific statement the other side will make." *Aidini v. Costco*, 2017 WL 10775082, at *1 (D. Nev. April 12, 2017))
- No New York caselaw exists directly precluding reptile theory arguments, but Golden Rule arguments—attempts to appeal to jury sympathy and put them in the place of the victim to determine an award or verdict—have long been precluded. *See People v. Fogarty,* 86 AD2d 617 (2d Dep't 1982); *Loisi v. Vaccaro*, 35 AD2d 790, 790 (1st Dep't 1970); *Boshnakov v. Bd of Ed. of Town of Eden*, 277 AD2d 996, 996 (4th Dep't 2000). Federal Courts in New York also specifically prohibit such arguments. *Okraynets v. Metropolitan Transp. Authority*, 555 F.Supp. 2d 420, 431 (SDNY 2008); *Marcoux v. Farm Svc and Supplies, Inc.*, 290 F.Supp. 2d 457, 463 (SDNY 2003).
- If you have reason to believe Reptile Theory tactics will be used and can provide clear information about what evidence or arguments will be presented, it is worth making a motion in limine. The most successful positions in cases throughout the country are arguments that reptile theory references imply a higher standard of care or are new attempts to present impermissible "Golden Rule" arguments, encouraging jurors to exercise personal bias.

What is Anchoring?

1. Anchoring is another technique used by plaintiffs' attorneys to encourage jurors to award grossly inflated and sometimes nuclear verdicts. In New York, attorneys are permitted to suggest a damages amount in summation or a method of calculating damages like lost wages, life care plans, etc., that can result in grossly excessive numbers that go beyond the bounds of evidence, fair and just compensation, or reasonableness. The amount demanded by the plaintiff's attorney may be based on nothing more than arbitrary and/or inflammatory numbers that establish an unsupported baseline ("anchor") of damages that jurors then have to struggle with to come up with an award.

2. Through an anchor, plaintiff's attorneys provide a number that jurors can either accept to back up their acceptance of the "reptilian theory" or use as their baseline through which they come up with a "compromise" verdict that may be less than the anchoring amount, but still far in excess of reasonable and fair compensation supported by the evidence.

Addressing Anchoring

- In New York, the CPLR permits the P to request specific dollar amounts in closing for appropriate compensation for any element of damages. This makes it more challenging to argue anchoring is improper. Indeed, a New York court has declined to address this issue because it was unpreserved for appeal. *Perez v. Live Nation,* 793 AD3d 517 (1st Dep't 2021). The Judge will subsequently instruct the jury that the amount requested by the P is not evidence, but a suggestion and the jury is free to consider it or disregard it. PJI Sect. 4016(b).
- A recent case out of Texas declared "unsubstantiated anchoring" as improper. The court described the tactic as suggesting damages amounts by reference to objects or values with no rational connection to reasonable compensation based on the facts of the case. It referenced analogies to the costs of fighter jets or famous paintings. *Gregory v. Chohan,* 670 S.W. 3d 546 (Sup Ct TX 2023).
- Although no case law reflects such arguments, it may work in New York State courts as well. P's are allowed to request only "appropriate" compensation. Damage amounts analogizing to unrelated values should not be considered appropriate.

Impact of Nuclear Verdicts: 1. creates an earthquake



Impact of Nuclear Verdicts, cont'd

2. Causes After Shocks



- Shock Settlements
- Change in Future Case Assessments
- Change in Approach to Decision-making on Defending or Settling cases.
- Increases public perception (JURORS!) on what cases are worth and types of damages that should be awarded.

What Do We Do Going Forward?

1. Recognition of the problem.

2. Establish a plan to fight back in the Legislatures and the Courts.

1. Challenge the legality of "Reptilian Theory" litigation.

2. Challenge the legality of "anchoring." Alternatively, consider **"reverse anchoring," but this is controversial in the defense Bar.**

3. Fight back in the public media through our health care organizations by exposing the damaging implications of the earthquakes caused by nuclear verdicts and limit the damage of their after shocks. **

4. Develop a responsive and coordinated plan with Insurance Companies, Risk Managers, Corporate Leadership, Underwriting, Marketing, Risk, Business and Legal Departments to control "after shock" response to an earthquake caused by a nuclear verdict.

**(Credit reference: the concept of "earthquakes" and "after shocks" was developed by attorneys Stratton Horres and Karen Bashor of the national defense firm Wilson Elser, et al.)

Thank you!

Jeffrey C. Gerson, Esq.
Vice President of Claims
MedPro Group

Katherine A. Buckley, Esq.
Partner
Gale Gale & Hunt LLC

Let's Get Ready for the Wearable Revolution!



Judy L. Klein, PA, CPHRM, FASHRM
MedPro Group
judy.klein@medpro.com

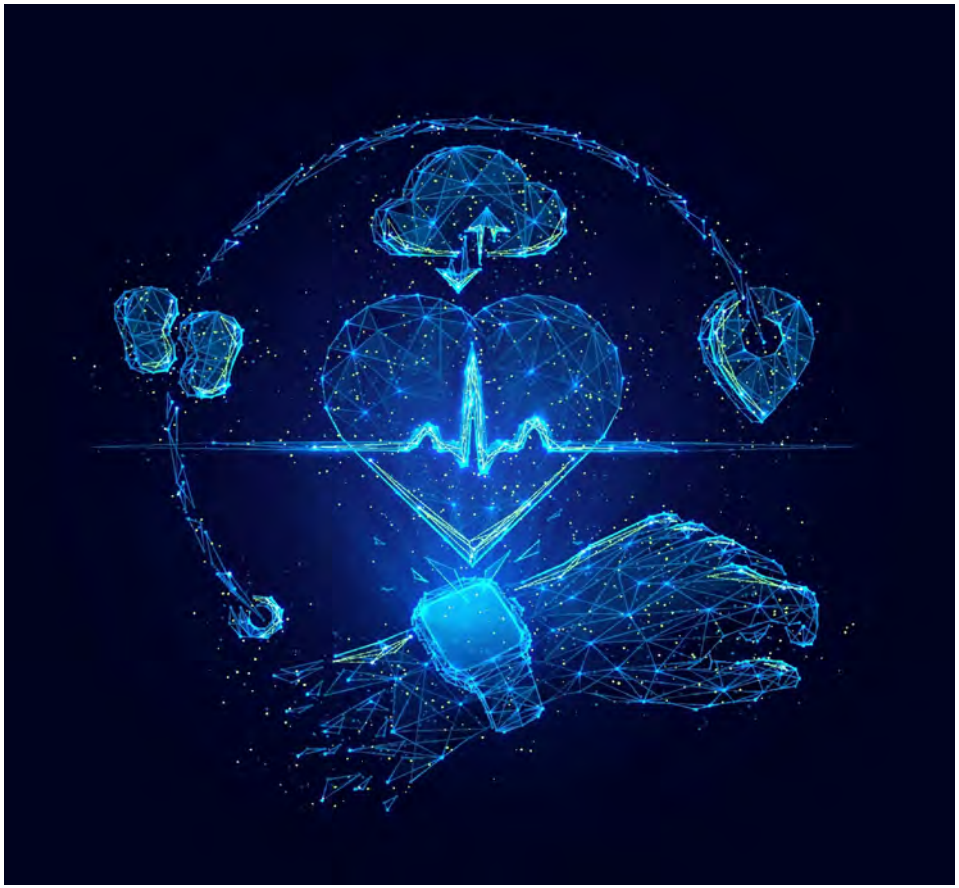
Learning Objectives

This presentation will enable participants to:

- Discuss definition, types and uses of Remote Patient Monitoring/Wearables
- Identify potential risks and liability exposures regarding Remote Patient Monitoring/Wearables
- Incorporate risk mitigation strategies and best practices to minimize and/or eliminate the risks/liability associated with Remote Patient Monitoring/Wearables

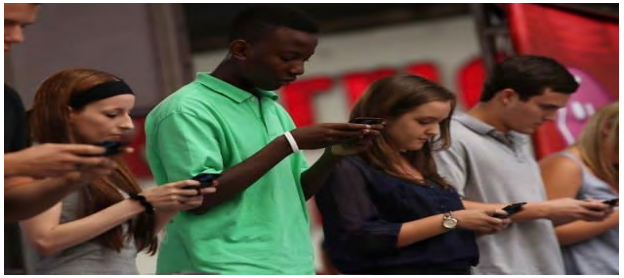


- By 2025 wearables will be ubiquitous
- By 2027 the global medical wearables market is estimated to be worth $34.89 billion

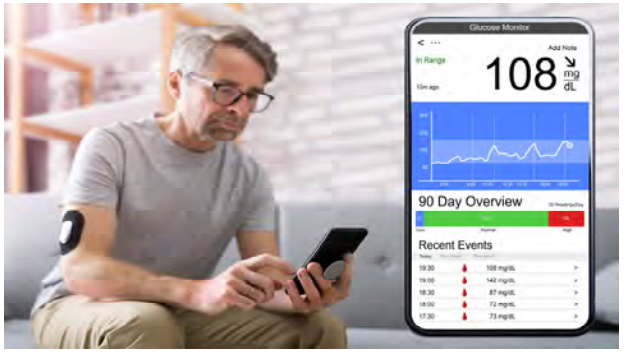


What's Driving the Revolution?

- Pandemic
- Migration to Hybrid Models of Care/Virtual Care/Telemedicine
- Continued Innovative Technology
- Consumerism
  - Customer Demand/Meet Customer Expectations
  - Aging Population
  - Chronic Disease Management
  - Home Health Demand
- Efficient Means to Deliver Care for Certain Conditions
- Patient Engagement
- Incentivizes Patients
- Improved Outcomes
- Decrease in Readmissions
- Cost Savings for Patients
- Reimbursement

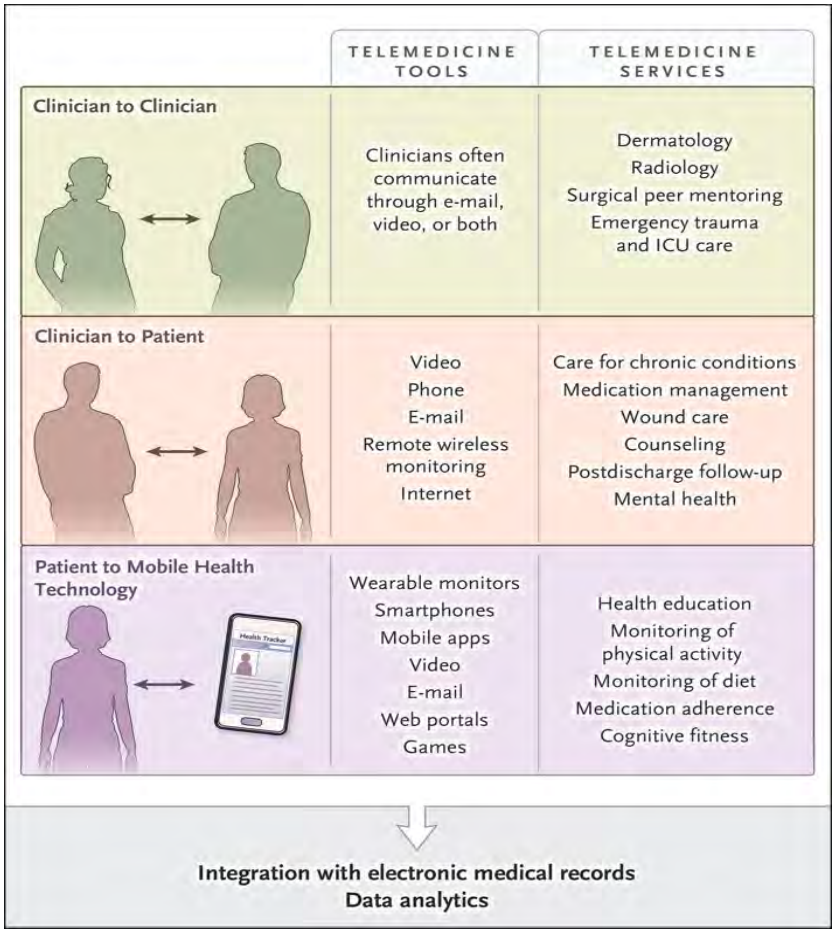






Hybrid Models of Care

- Technologies, tools, and services are becoming an important component of virtual health care interactions among:
  - Clinicians and support staff
  - Clinicians and patients
  - Patients/providers and RPM/wearable/mobile devices



Consumer Sentiment: Digital Technology



26% of consumers own a wearable health device or use a smartphone to track wellness



50% of patients would allow information to be sent directly from their device to the physician's office



57% believe the data is useful and want it to be collected by their doctor

What is RPM and Wearables?



- Remote patient monitoring (RPM)
  - Using a device that meets FDA standards to collect and transmit patient physiological data wirelessly to a HCP who uses the data to remotely engage a patient in managing an acute or chronic condition either directly or via delegates who may be under direct or general supervision of the HCP. (Wein et al, 2020).
  - Well suited for:
    - chronic disease management
    - management immediately after discharge
    - hospital-at-home environment



What is RPM and Wearables?

- Wearables
  - Electronic devices worn on the body that sense, analyze, and transmit biological data that can be used to manage diseases or improve health (Fotiadis DI et al, 2006; Chandrasekaran R et al, 2020)
  - Data collected may include: heart rate, blood pressure, temperature, blood oxygen saturation, blood glucose levels, sleep patterns, activity (i.e. steps, running distance and speed), sleep, etc.
    - Types: medical or consumer grade
    - Examples:
      - CGMs
      - Smartwatches-collect physiological data
      - Socks-monitor foot temperature to detect ulceration
      - Smart clothes-yoga pants that monitor posture
      - Fitness socks-monitor walking or running technique
      - Swimsuits-alert to high UV levels
      - Glasses



All Wearables are not Created Equal

FDA Approved vs Consumer Grade

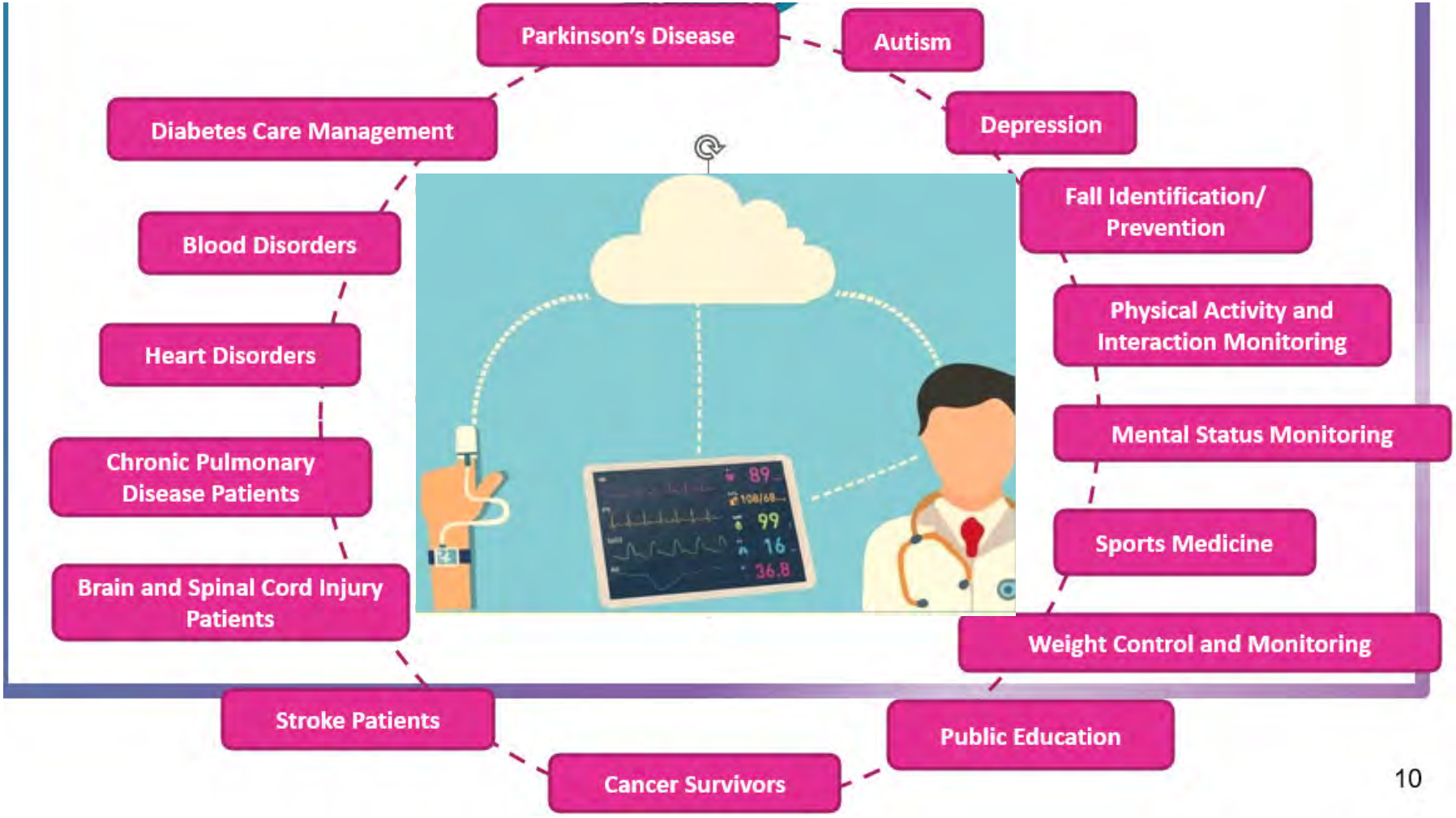
- Medical-grade devices
  - Comparable to other medical devices
  - FDA approved or cleared
  - They have undergone testing and validation, the results of which were submitted to the FDA for review
  - More accurate and reliable than consumer-grade devices
  - For disease management and available by prescription only (a few exceptions e.g. FDA cleared heart monitors are available on smart devices)

- Consumer-grade devices
  - Not approved or cleared by FDA
  - Over-the-counter
  - More variability (of accuracy and reliability) in the data, either over or underestimating compared to a medical device
  - Primarily motivational aids for fitness and wellness
  - Intended to promote wellness or healthy lifestyle
  - Available to consumers without a Rx

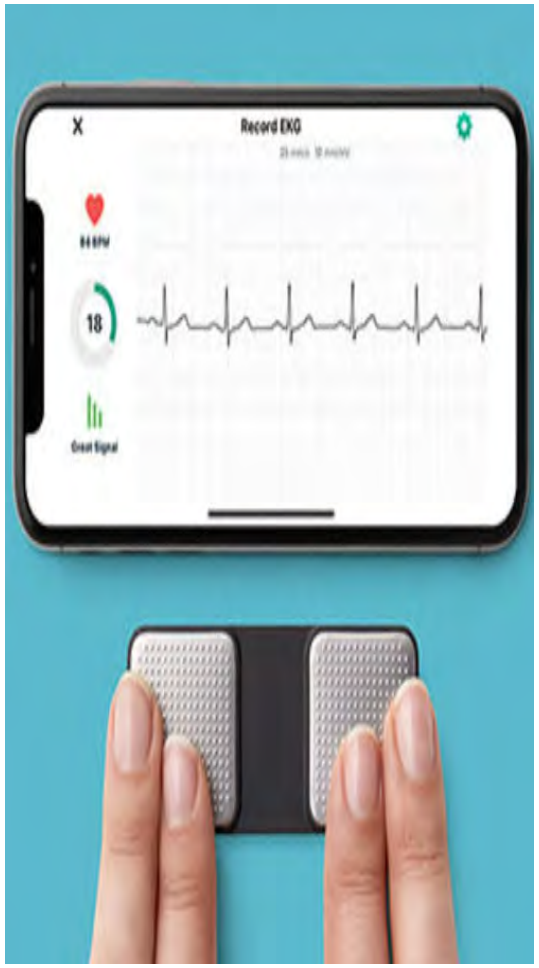
- **Be aware of the limitations of the data when using for clinical decision-making; this must be explained to the patient**



Examples of RPM/Wearable Use in Health Care



How Does RPM/Wearables Monitoring Work?







What's Out There ?
RPM/ Wearables Claims



RPM/Wearables Allegations

- Failure to educate/train patient in use of device/technology
- Failure to educate/train staff on device/technology, data interpretation, etc.
- Failure to monitor/treat/detect/respond to incoming data resulting in missed/delayed diagnosis
- Failure to assure adequacy/accuracy of technology being recommended
  - Failure to function as intended
  - Failure to assure safety/reliability of device
  - Device malfunction
- Communication breakdowns
  - Lack of informed consent
  - Lack of follow-up on incoming data
  - Documentation related
- Failure to Protect Data



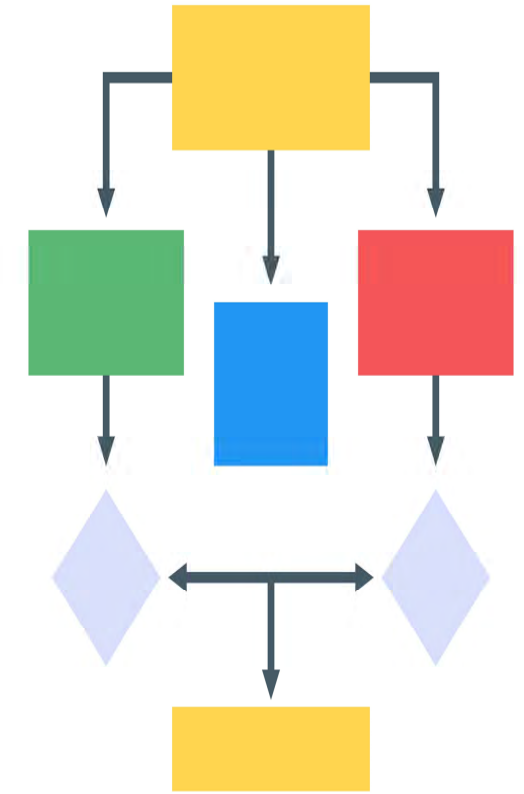
Little Guidance in Case Law

- Does monitoring via a wearable create an MD-pt relationship that brings a duty of care?
- Does it matter if the MD provided the device, recommended it or was merely made aware of the data by the pt?
- Once a wearable device is known to the MD, when and how often must the data be reviewed?
- When does an MD's knowledge of data from a wearable obligate the inclusion of the information in treatment decisions?
- When does the failure to obtain or use the data constitute a breach of the duty of care?



Workflows are Key

- Establish a Patient Base
  - Determine conditions to be managed
- Who Will Supply and Set Up Devices?
  - Your organization, vendor, etc.
  - Distinguishing between data from medical vs. consumer grade
- Managing Patient Data
  - Who Will Review Patient Data?
  - What happens if the pt has not been using their device?
  - Who will inform the HCP of pt's condition change/need for medical attention?
  - And, who will follow-up with pt?
  - How will pt data be integrated into the EMR?
  - Which actions should be documented?
  - Who will train clinical staff?
- Debrief with staff
  - What is/isn't working
  - Identify opportunities for improvement



RPM/Wearables Risks Can Be Managed

- Considerations
  - Patient Selection
  - Education/Training
  - Informed Consent
  - Documentation
  - Interoperability with EMR/Systems Integration
  - Data Protection, Data Breaches and Cybersecurity
  - Device Considerations
  - Data Quality



Patient Selection Considerations

- Will patient be able to operate the device?
- Will patient's lifestyle support proper use of the device?
- Will patient be able to afford the device and accessories?
- Does patient have a smartphone (if required)?
- Does patient have a reliable internet (if required)?
- Is there a measurable metric that can be improved by changes in patient behavior?
- Will the wearable improve the patient's health/outcomes compared to the current plan?
- Is the patient likely to become more / less engaged in their care by using the device?
  - More than one parameter may need to be tracked



Staff Education/Training

- Expectations, roles and responsibilities
- Overview of device: set up, how to operate, FAQ about device
- Education/Training regarding:
  - Device use
  - Monitoring protocols and response
  - Hours of availability/describe operation of RPM services
  - Patient monitoring schedules/guidelines
  - Staff responsibility for receiving data from patients (when, how often, who reviews data)
  - Communicating and documenting results/follow-up (who)
  - Alerting appropriate clinician to a potential problem
  - Verifying device quality control
- Health care privacy and security training specific to RPM
- “Alert Fatigue” (can lead staff to ignore/override incoming alerts)
- Other:
  - Adequate Staffing
  - Competency testing specific to staff roles and responsibilities





Patient Education/Training



- Set expectations/clarify roles and responsibilities
- Communicate elements of treatment plan re: when and what data will be reviewed; how alerts will be handled
    - Data will be reviewed during office visit; data will not be reviewed unless pt calls with specific concern
    - How readings outside thresholds are to be communicated i.e. what you will do, what pt must do
    - What constitutes an emergency reading, and how to respond i.e. call 9-1-1, go to the emergency department, etc.
- How to use/maintain the device
    - If office provides device, determine process for educating pt on use, understanding of use and what to do if device malfunctions
- What device failure or malfunction looks like, and what the pt should do if that happens
    - Include risks of malware compromising the effectiveness of the device and pt privacy
- Inform about HCP “available hours” and the limitations of RPM
    - Consider having pt sign an acknowledgment, similar to emailing a practice with questions or issues
    - Patient must understand there are limitations for RPM, and that review of the data will occur during certain hours and within a certain timeframe
- Consider use of teach-back/show me to confirm pt understanding of information/proper use of device

Informed Consent



- Benefits, Risks, Alternatives
- How to use technology/device
- How technology/device will be used by organization
- How to properly maintain device
- Technological limitations
- Confidentiality and privacy provisions
- Physician /Patient right to discontinue
- Expectations, roles and responsibilities of patient
- Elements of treatment plan
  - What times the device will be monitored
  - How alerts will be handled by the healthcare team
- What device failure/malfunction looks like, and what patient should do if that happens
- Emergency procedures
  - What to do if patient feels sick/is having a medical emergency

Documentation



- Purpose and goals for use of device/wearable
- Technology/Device Used
- Informed Consent
- If wearable data was used in clinical decision and any modifications to care plan, changes in meds, etc.
- Education provided:
  - What constitutes an emergency reading, and how to respond (i.e., call 9-1-1, go to the ED, etc.)
  - Risks of a RPM/wearable device failing or malfunctioning
  - Risks of malware compromising the effectiveness of the device and patient privacy
  - Provider “available hours” and limitations of remote monitoring
    - Pt must understand there are limitations to RPM, and that review of the data will occur during certain hours and within a certain timeframe
- Documentation via written acknowledgment or documentation of discussion
  - A written acknowledgment should reference patient education about how RPM works, the limitations, and warnings
- If device was discontinued, reason why, action taken, any f/u communications

Interoperability with EMR/Systems Integration

- Receiving, Analyzing and Following-Up on Data can be Daunting
- Secure and reliable transmission of data using platforms that integrate data transmission and alert systems into workflows and the patient's EMR is key
  - Designating a qualified HCP and having a process to monitor and quickly respond to the incoming data is recommended
  - Educating healthcare team on "alert fatigue"



Protecting Data, Data Breaches and Cybersecurity



- Ensure compliance with HIPAA
  - Properly encrypted data transmission
- Ensure compliance with FDA
  - FDA guidance on cybersecurity risks for medical devices
  - Don't rely on manufacturer to ensure security
  - Organizations must safeguard patient information within their network
- Ensure all employees who participate in RPM services receive remote monitoring-specific health care privacy and security training
- Include RPM/Wearables equipment in your organization's Security Management Plan and annual Security Risk Assessment
- Incorporate reference to RPM technologies into your Notice of Privacy Practices
- Determine need for Business Associate Agreements
  - Evaluate all parties, including any vendors involved in the provision of services, for compliance with federal and state privacy and confidentiality regulations
  - Require the ability to provide proof of compliance if asked; and require vendors to hold their subcontractors accountable

Device Considerations

- Stay informed on latest device information
  - Manufacturer's warnings, device safety record, devices approved uses
  - Be aware of FDA alerts or recalls
- Read and consult with legal counsel on all contracts with medical device vendors
  - Does contract outline who is responsible in the event of a device malfunction or failure?



Quality Control Process for RPM/Wearables

- May be managed by vendor or home health agency
- Patient brings device to office visit to evaluate patient use and compare device results vs. office-based findings



Concluding Thoughts…

- RPM/Wearables Risks Can Be Managed
  - A new frontier to manage patient care, engage and improve quality of life for patients
  - New and rapidly evolving area with unclear or absent guidelines/standards/case law
  - Rules, roles, standards and uses are still evolving/being sorted out/they change as technology improves or new capabilities evolve
  - Stay informed by monitoring the literature and following FDA alerts, recalls and updates
  - Consult with your agent, insurance carrier(s) and legal counsel for guidance

RPM/Wearables Vendor Checklist

- Device Management
  - Types of devices, FDA approved?
  - Ease of Use
  - Physiological parameters measured
  - Connectivity medium (WiFi, Bluetooth, Cell, other)
  - Shipping and tracking
  - Returns and cleaning
  - Who buys the device?
- Patient Engagement
  - Onboarding onto the service
  - Verification and documentation of consent
  - Reminders to measure
  - Engagement recovery
  - Games/prizes to incentivize
  - Churn rate (% of patients lost each month)
- Clinical Support
  - •Is there a clinical monitoring service ?
  - •How are alerts responded to ?
  - •How are escalations communicated ?
  - •How is communication with patient done and documented?
- Workflow Integration
  - How are orders/referrals for RPM services generated?
  - Integration into EMR (ordering, receiving data)
- Compliance
  - Audit trail of work done
  - Recordings of communications
  - HIPAA
  - Audit of RPM services by legal counsel
- Billing/Coding
  - Is work timed automatically or manually
  - Report generation capability
  - Ability to export data
  - Ability to bill on behalf of provider

RPM/Wearables Resources

- US Food and Drug Administration (FDA): Information and fact sheet on regulation of medical devices and medical device cybersecurity www.fda.gov
- World Health Organization (WHO): Established a global multidiscipline technical group on mHealth www.who.int
- American Telemedicine Association: Information on a wide range of discipline specific telemedicine guidelines as well as core standards, assessment and outcome measures as well as information on RPM www.americantelemed.org
- American Medical Association: Digital Health Implementation Playbook and RPM Implementation Playbook www.ama-assn.org
- American Hospital Association: 2022 Environmental Scan data and trends regarding implications for the health care field for the coming year and beyond. www.aha.org
- Center for Connected Health Policy: Resource for laws and regulations https://www.cchpca.org/
- Centers for Medicare and Medicaid Services (CMS): Oversees many federal healthcare programs www.cms.gov



Thank you!

Judy Klein, PA, CPHRM, FASHRM
MedPro Group
Judy.klein@medpro.com



AHRMNY's Fall Upstate Educational Conference

October 30, 2023

Understanding Adverse Events: Source, Capture, Action!

Robert J. Panzer, MD

Chief Quality Officer & Associate CMO

Professor of Medicine and of Public Health Sciences

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David Feldman's ideas for this session

To ensure patient safety and quality, healthcare leaders need to understand the nature of adverse events that can lead to patient harm.

This presentation will highlight the importance of using multiple sources to capture adverse events, recognize the common types of adverse events seen in hospitals, and learning strategies to help reduce common adverse events.

Strong Memorial Hospital

University of Rochester Medical Center





UR MEDICINE | STRONG MEMORIAL HOSPITAL

University of Rochester

Central
(core operations)

College of
Arts, Sciences &
Engineering

Simon School

University General
(endowments)

Graduate School
EHD
(Warner school)

Eastman
School of Music

Memorial Art
Gallery

URMC research, teaching, patient care

Health Sciences
Division
(Administration)

School of Medicine
& Dentistry
(doctors, scientists)

School of
Nursing

Eastman
Institute for
Oral Health

UR Medicine patient health management & care network

Strong Memorial Hospital

Golisano Children's Hospital

Wilmot Cancer Center

Flaum Eye Institute

Strong West

Outpatient Clinics

Medical Faculty Group

Eastman Dental

UR Home Care

Highland Hospital

The Highlands Living Center

The Highlands at Brighton

The Highlands at Pittsford

Thompson Health

Noyes Memorial Hospital

Jones Memorial Hospital

St. James Hospital

Finger Lakes Health

Topics

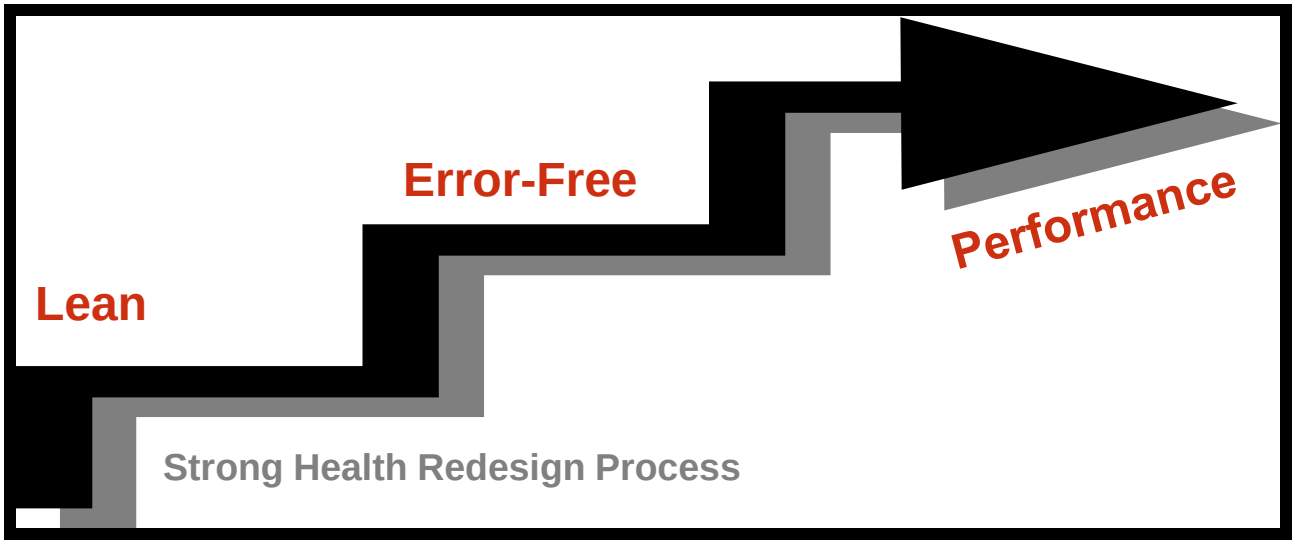
- Event Reporting Redesign
- Event Reporting at Strong Memorial Hospital today
- NYPORTS – Early History
- Root Cause Analysis +
- Looking to the Future

Event Reporting Redesign

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Strong Health Redesign Process



A team approach to improve healthcare systems striving for safe and efficient patient care through error reduction and waste elimination techniques.

Events Central Redesign Workshop

Workshop Participant	Position
Robert Panzer, MD (Team Leader)	Chief Quality Officer
	Office of Clinical Practice Evaluation
	Quality Improvement/Quality Assurance
	Office of Counsel to the Medical Center
	Quality Improvement/Quality Assurance
	QA Liaison, OB/GYN
	Quality Improvement/Quality Assurance
	QA Liaison, Surgery
	QA Liaison, Ambulatory
	QA Liaison, Medicine
	Nursing, Quality Improvement
	Office of Counsel to the Medical Center
	Patient Relations
	QA Liaison, Orthopedics
	Office of Counsel to the Medical Center
	Clinical Nursing Chief
	Nursing Practice Support Operations
	Quality Assurance
	Quality Assurance
	Office of Clinical Practice Evaluation
	Credentialing
	Associate Quality Officer, Redesign Facilitator
	Health Project Coordinator, Redesign

Events Central Redesign Workshop

Focus:

Events Central

Scope:

From: The first awareness of an actual or potential event, near miss or unsafe condition

To: Completion of investigation and follow-up intervention

Events Central Redesign Workshop

- Goals – 7
- Site visits - 15
  - Visit the process
  - Visit the information flow
- Brainstorming – 130 ideas
- Enablers - 7 categories with 31 items
- Waste and Errors - 10 items
- Actions - 2 immediate, 8 short-term, 2 long-term
- Benefits - 5 to employees, 5 to patients, 5 to organization
- Measures of success - 7 measures

Events Central Redesign Workshop

Events

1) Complaints
2) Incidents

   e.g., medication, falls, equipment failure
3) PRO referrals

   Quality, UR
4) Mortality review
5) State reportable events

   - short form & detailed reviews
6) Sentinel events
7) Infection Control referrals
8) Near misses

Events Central Redesign Workshop

Events (cont'd)

9) Payer referrals
10) OCMC referrals
11) Quality concerns from patients, staff, departmental generated QA reviews
12) Blood utilization reviews
13) NYSDOH referrals & deficiencies
    OHSM, OPMC
14) JCAHO referrals
15) Referrals from hospital collections
16) Surgical case review

Events Central Redesign Workshop

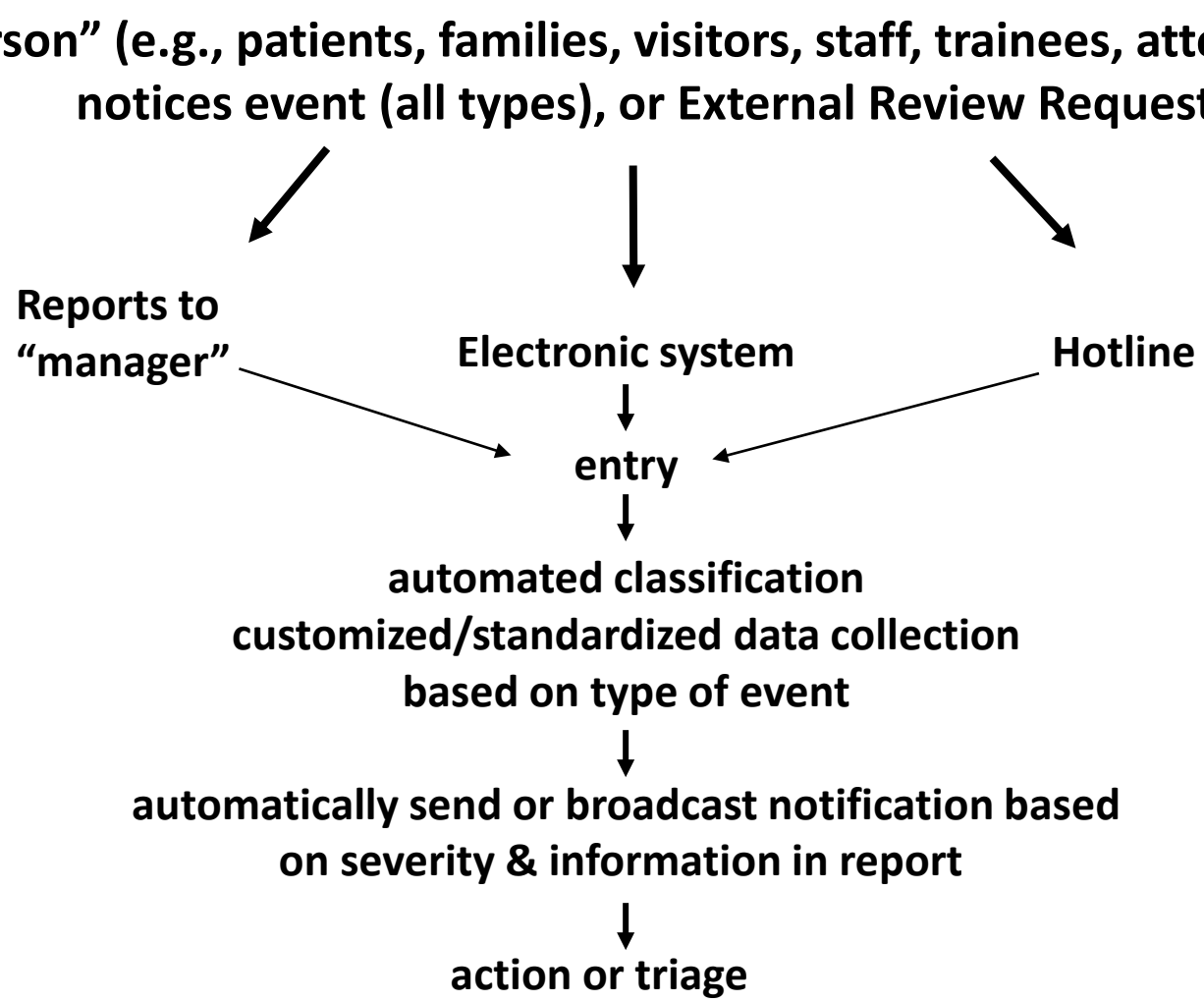
Events Central Redesign Workshop
Customer & Information Flow Analysis &
Failure Modes & Effects Analysis

Process:On 2 wk f/u visit to ortho surgeon, discovered pt. walked on cast should be NWB, called pt. relations to complain re: lack of d/c instructions when leaving ED

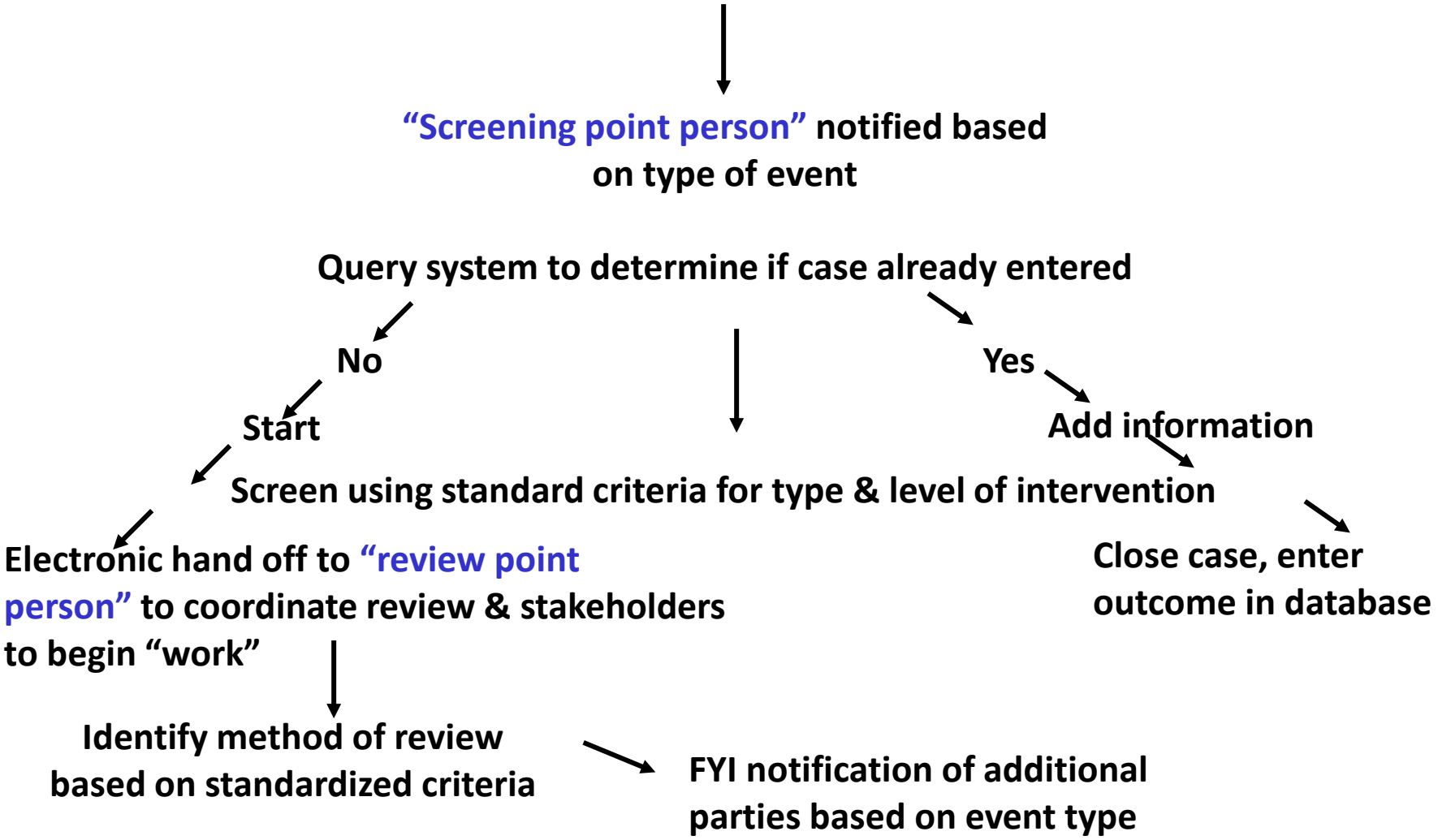
#	Step	VA	Time	Dist	Potential Failure/Error	Possible Causes	Like-lihood	Severity	RPN
1	Pt. relations receives phone call from pt. takes notes, discusses nature of complaints & specifics	X	30 min.	0					
2	Confirm demographics in OMEGA		5 min.	0	**unable to locate pt. in system**	OMEGA system down	1	2	2
3	Enters case in Pt. relations database		15 min.	0					
4	Deploy secretary to obtain ED record		15 min	300 steps	**Unable to locate record**	misfiled, not coded, record signed out to another party	2	3	6
5	E mail pt. accounts/CBO to hold bill	X	5 min.	0					
6 B	Briefly review record to determine care providers, determine who should do review		20 min.	0	**Necessary info. not in record; delay in reviewing record**	Illegible handwriting, incomplete documentation; Conflicting priorities interfere	2 3	3 3	6 9
7 B	Prepare request for review for ortho and ED		30 min.	0	**Misidentified appropriate reviewer; delay in review**	Documentation unclear Conflicting priorities	1 3	2 3	2 9
8	Secretary photocopies referral & ED record & mails cc copies		10 min.	50 steps					

Events Central Redesign Workshop

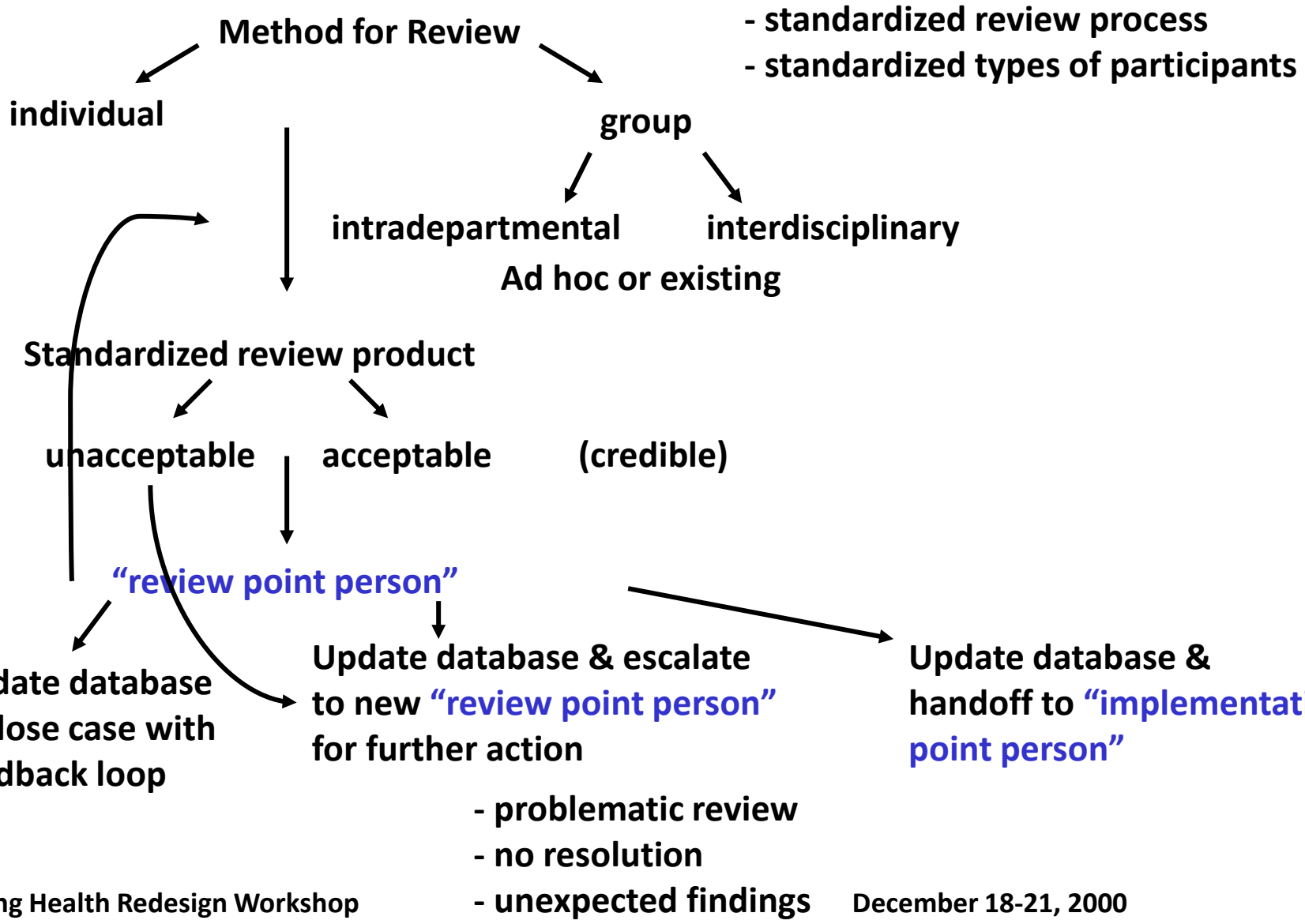
Event Central Process



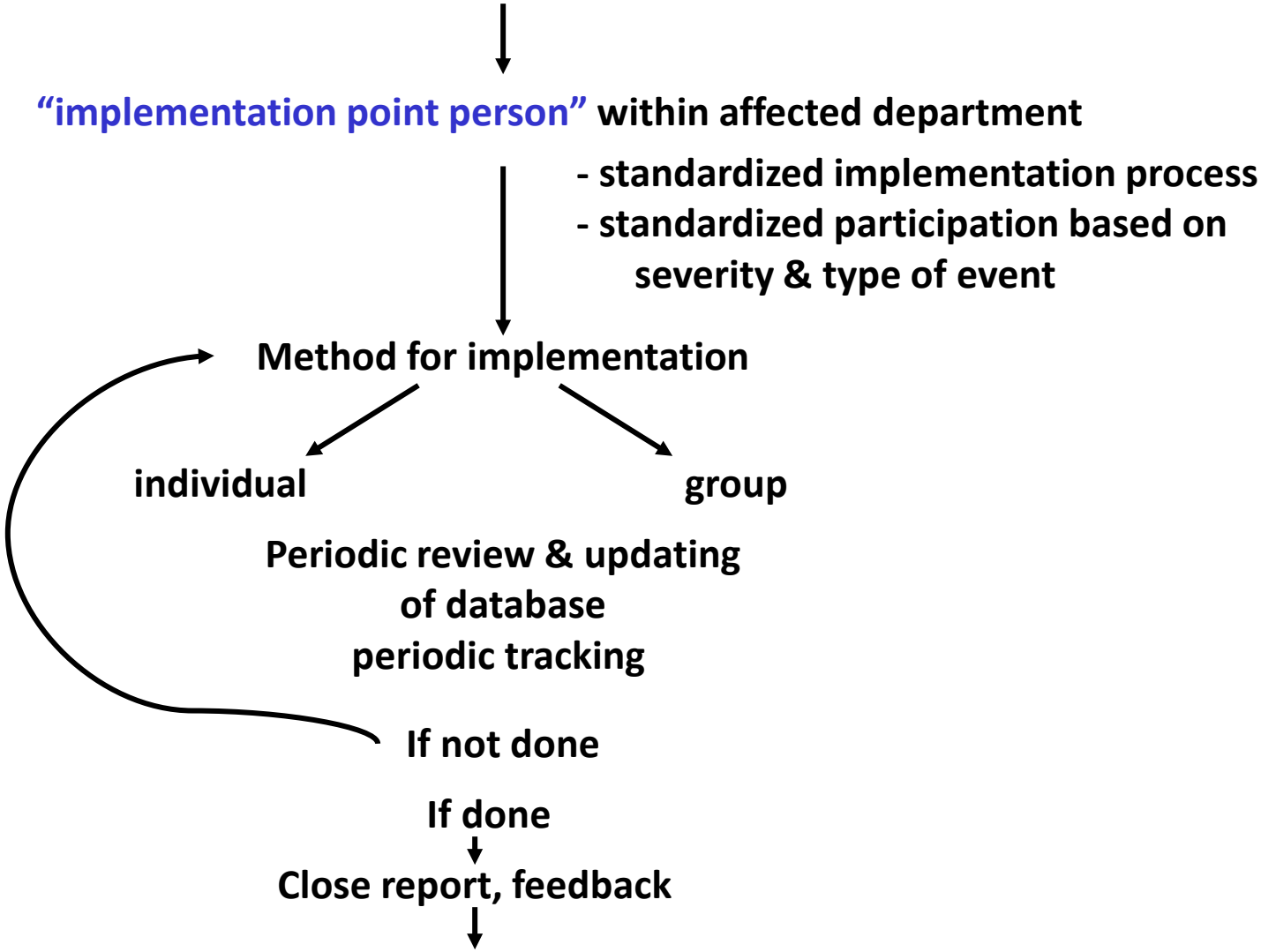
Events Central Redesign Workshop



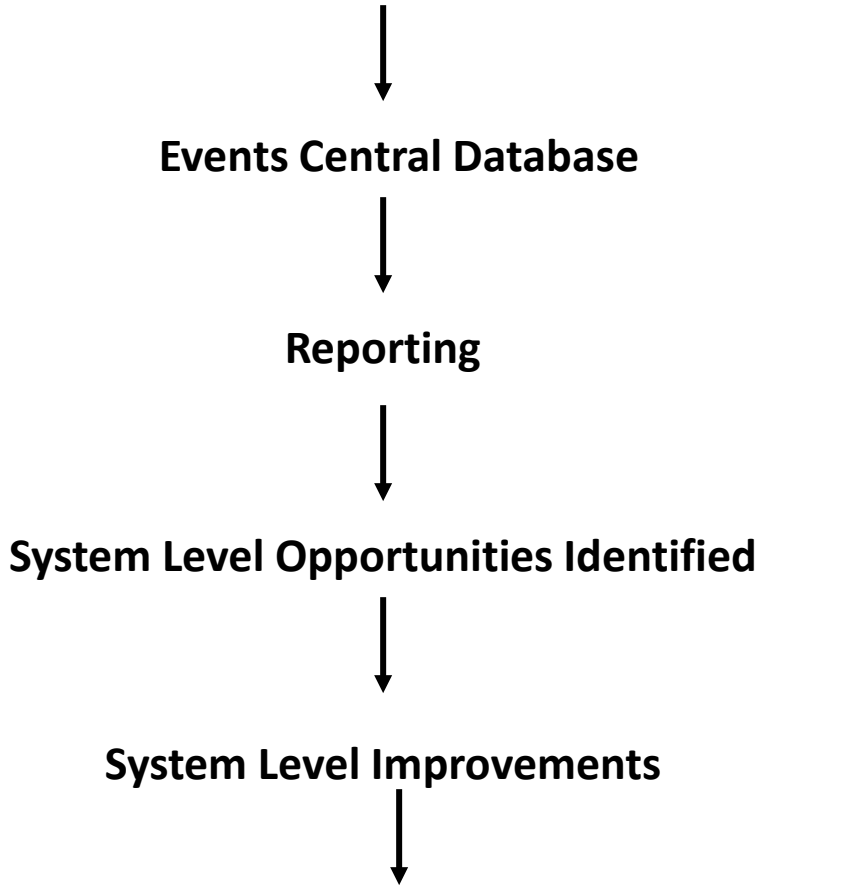
Events Central Redesign Workshop



Events Central Redesign Workshop



Events Central Redesign Workshop



Event Reporting at SMH

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Event Reporting at SMH

Systems

- Paper and email
- DoctorQuality
- Quantros
- RL Solutions
  - Risk module
    - Have added risk assessment to harm level
  - Feedback (complaints and grievances)
  - Include professional conduct and other special categories (e.g. DEI) rputed to limited leadership group
  - Mandatory annual resident reporting with extra confidentiality option

Event Reporting at SMH (cont.)

Continuing Challenges

- Predisposition to report varies by event type and profession
- Immediate feedback to reporter
- Routine review as appropriate and closure by accountable manager
- Actions that are strong when needed and not too local
- Feedback to reporter at closure
- Feedback to organization of important actions
- Ensuring non-punitive, just culture approach regardless of outcome

Event Report Tableau Dashboards

https://tabanalyticstest.urmc-sh.rochester.edu/#/site/TableauAnalyticsUAT/workbooks/3653?:origin=card_share_link

Event frequencies at Strong Memorial Hospital

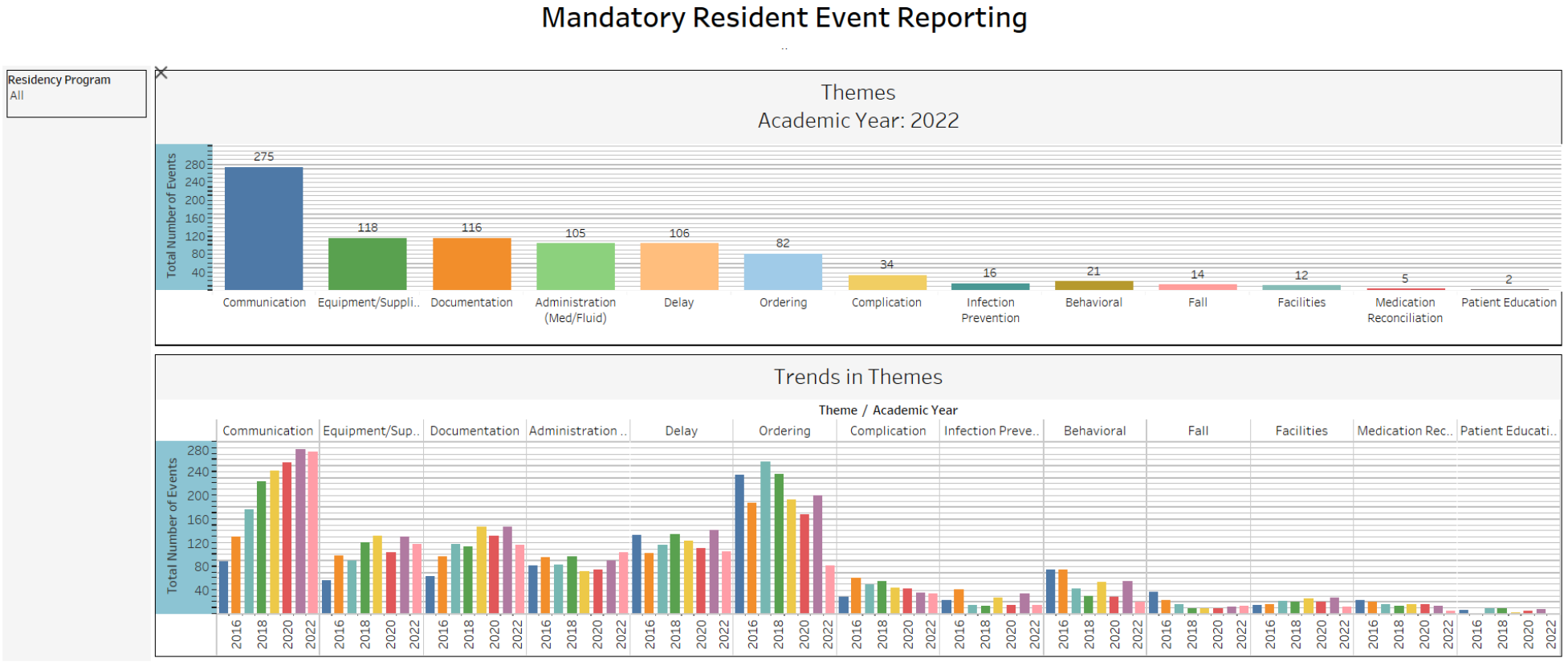
Our only interpretation of increased event reporting –

- **Our patient volumes are increasing**
- **Our safety culture is promoting more reporting as the voice of staff**

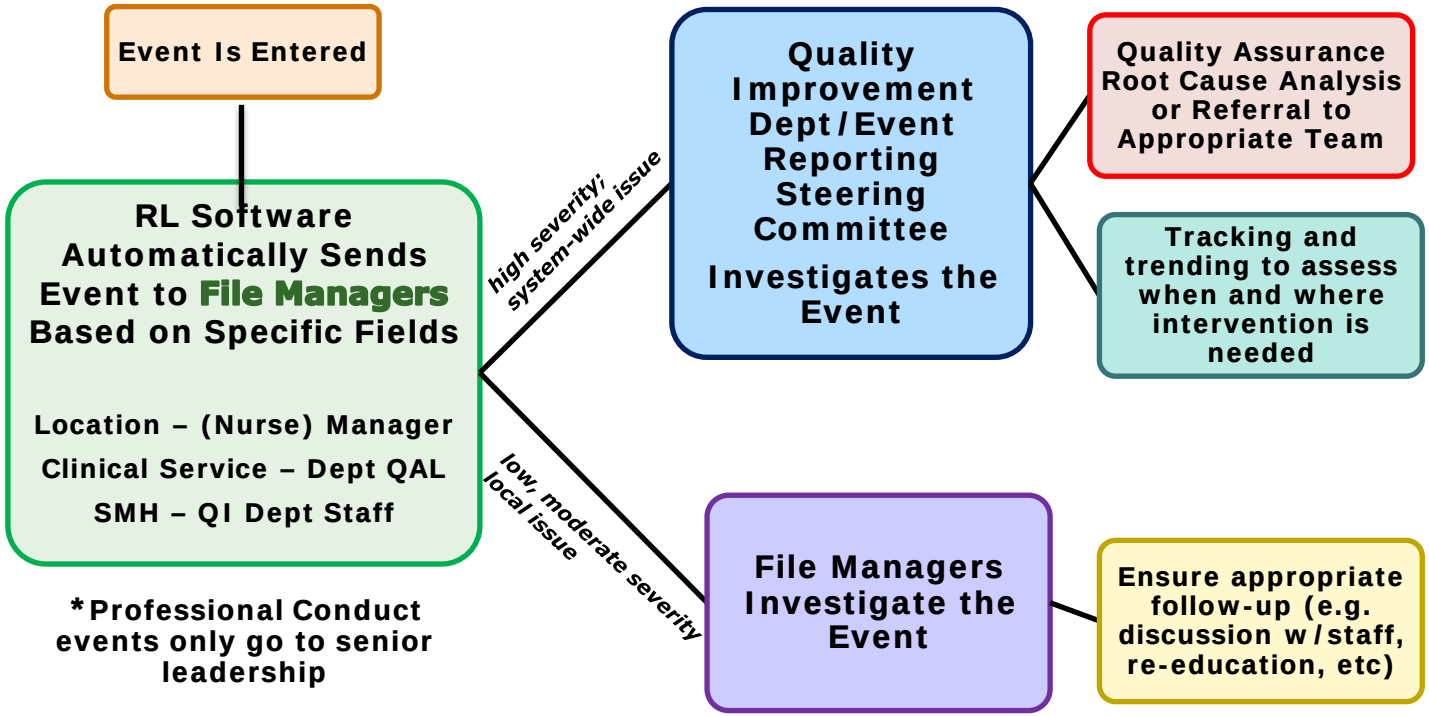
Transparent event summary reports

https://rl6app-2016.urmc-sh.rochester.edu/RL6_Prod/dashboardservices/dashboardviewer.aspx?id=1&type=INFOCENTER

Mandatory Resident Event Reporting



Triaging and Following Up on Events



Selected Committees Where Reports are Addressed

- Medical Error and Risk Management (weekly system level)
- Patient Safety and Risk Management (weekly system level)
  - New RCA's
  - 1 month, 3 month, 6 month, and 12 month implementation follow-up as needed
- Patient Safety Quality Improvement Coordinating Group (weekly)
- Medication Safety Quality Improvement Coordinating Group (weekly)
- Hand-off Team (monthly or less often)
- Infection Prevention Committee (monthly)
- Department Level and Nursing Quality Councils

Sharing events, follow-up, and harm report stories

https://sites.urmc.rochester.edu/urmc-operations/quality-institute/healthcare-safety/

The Joint Commission Journal on Quality and Patient Safety 2021; 47:755–758

EDITORIAL

Incident Reporting Systems: What Will It Take to Make Them Less Frustrating and Achieve Anything Useful?

Kaveh G. Shojania, MD

https://pubmed.ncbi.nlm.nih.gov/34716115/

Healthcare Event Reporting Collaborative

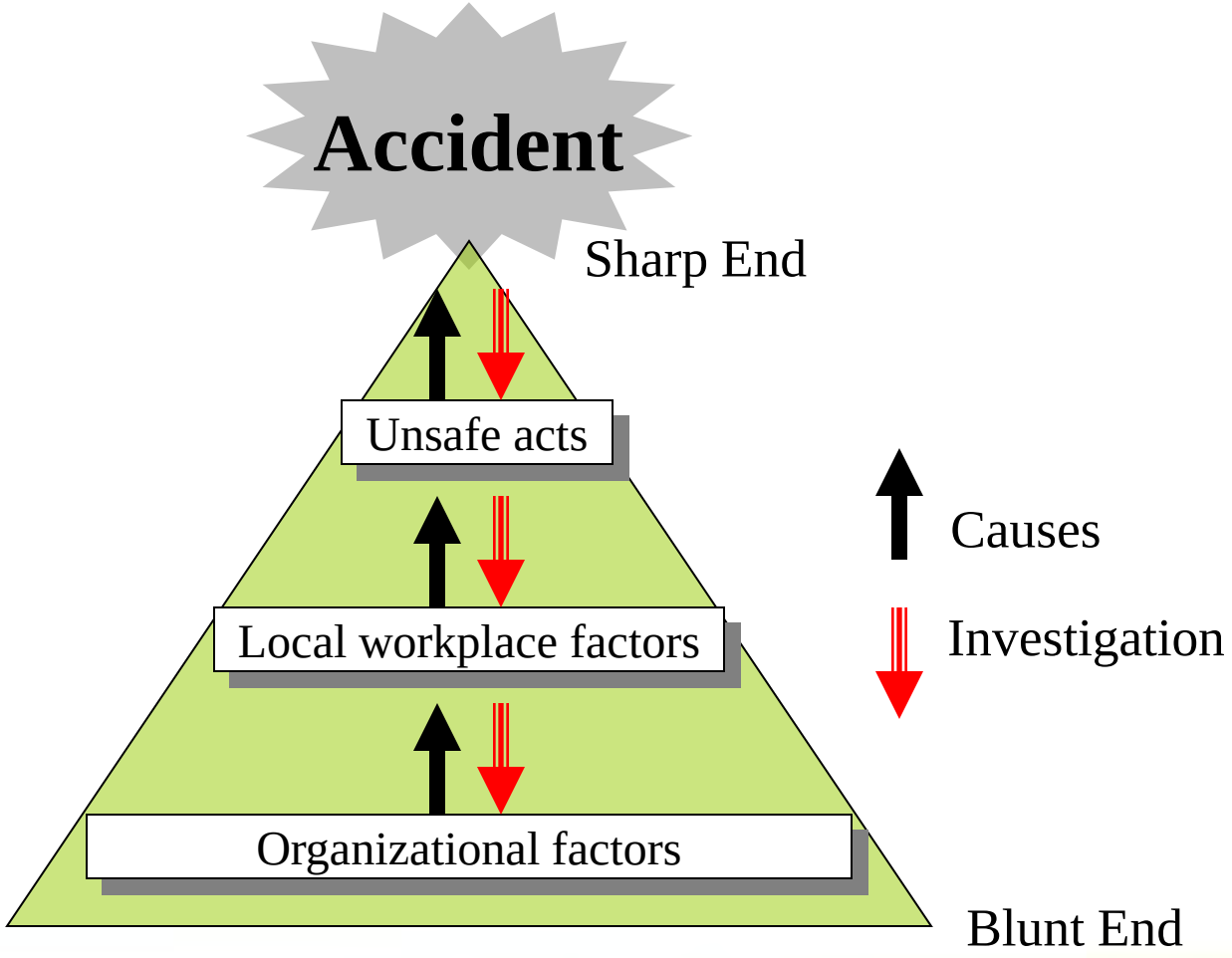
Coordinated by Johns Hopkins Armstrong Institute

Christine Robson cbosman1@jhmi.edu

Development of Reason model in healthcare

- Focus on identifying chain of events
- Identification of `care management problems' - often a series of `unsafe acts'
- Development of framework of factors that provide the conditions for safe/unsafe practice

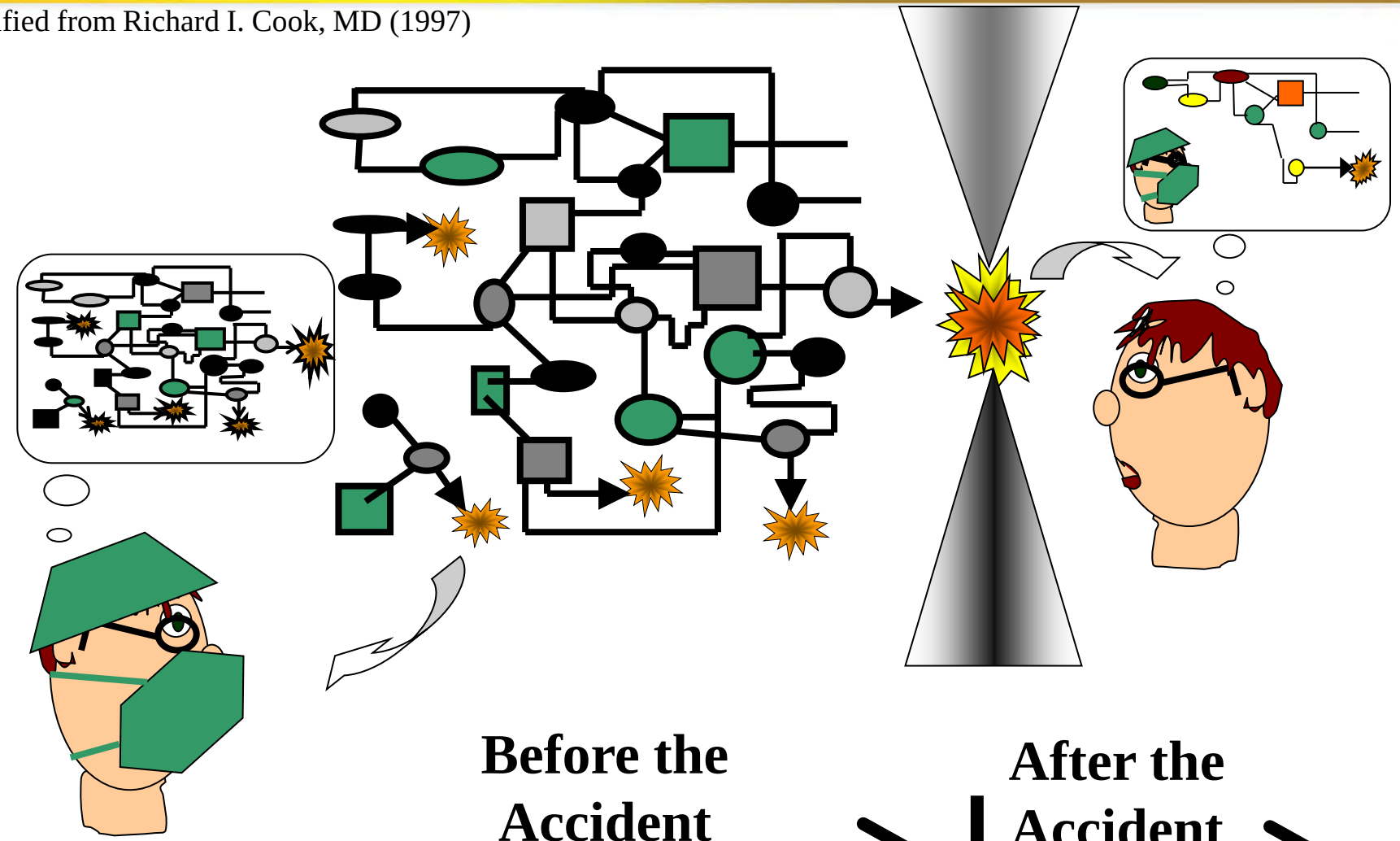
Errors Development and Investigation

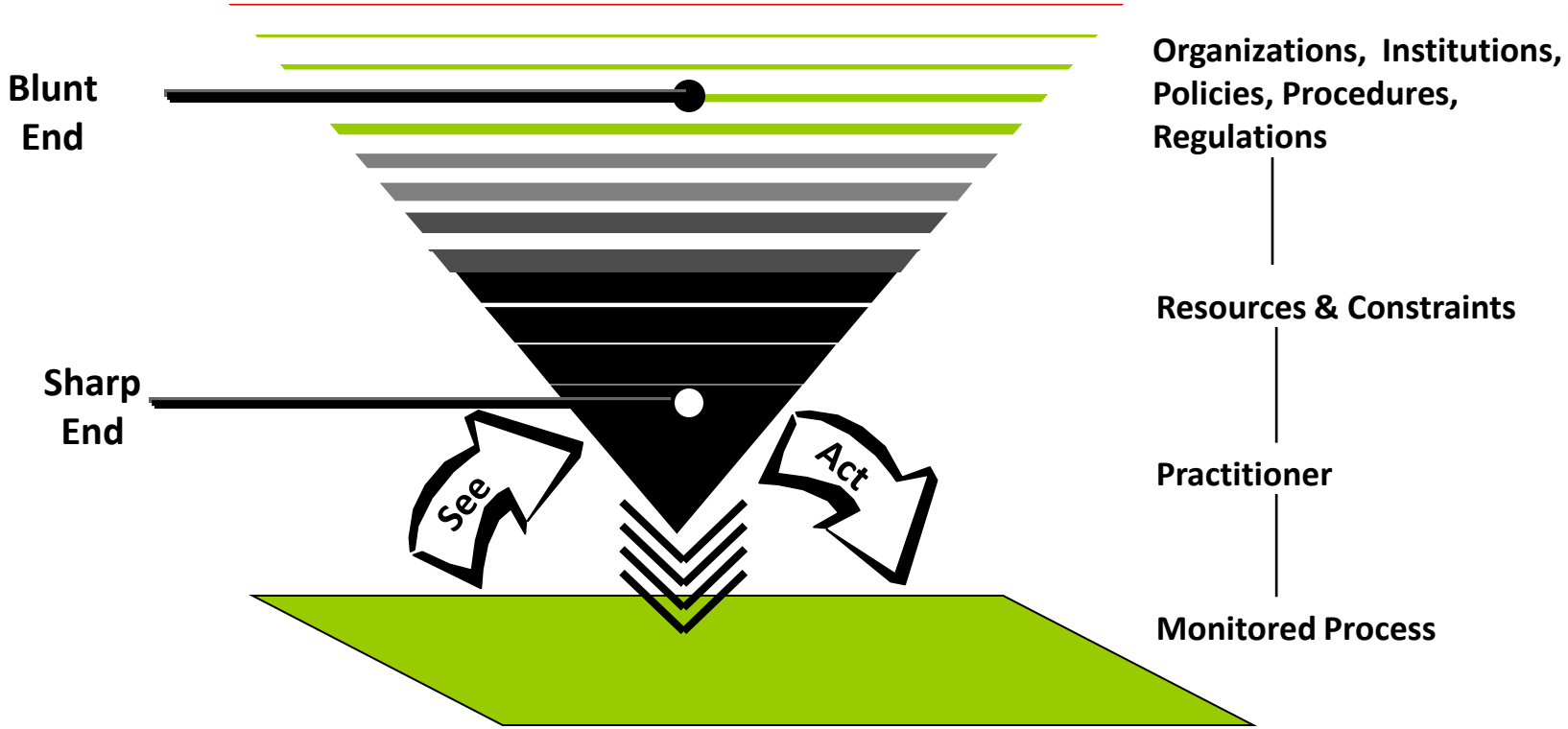


J. Reason

Hindsight Bias

Modified from Richard I. Cook, MD (1997)

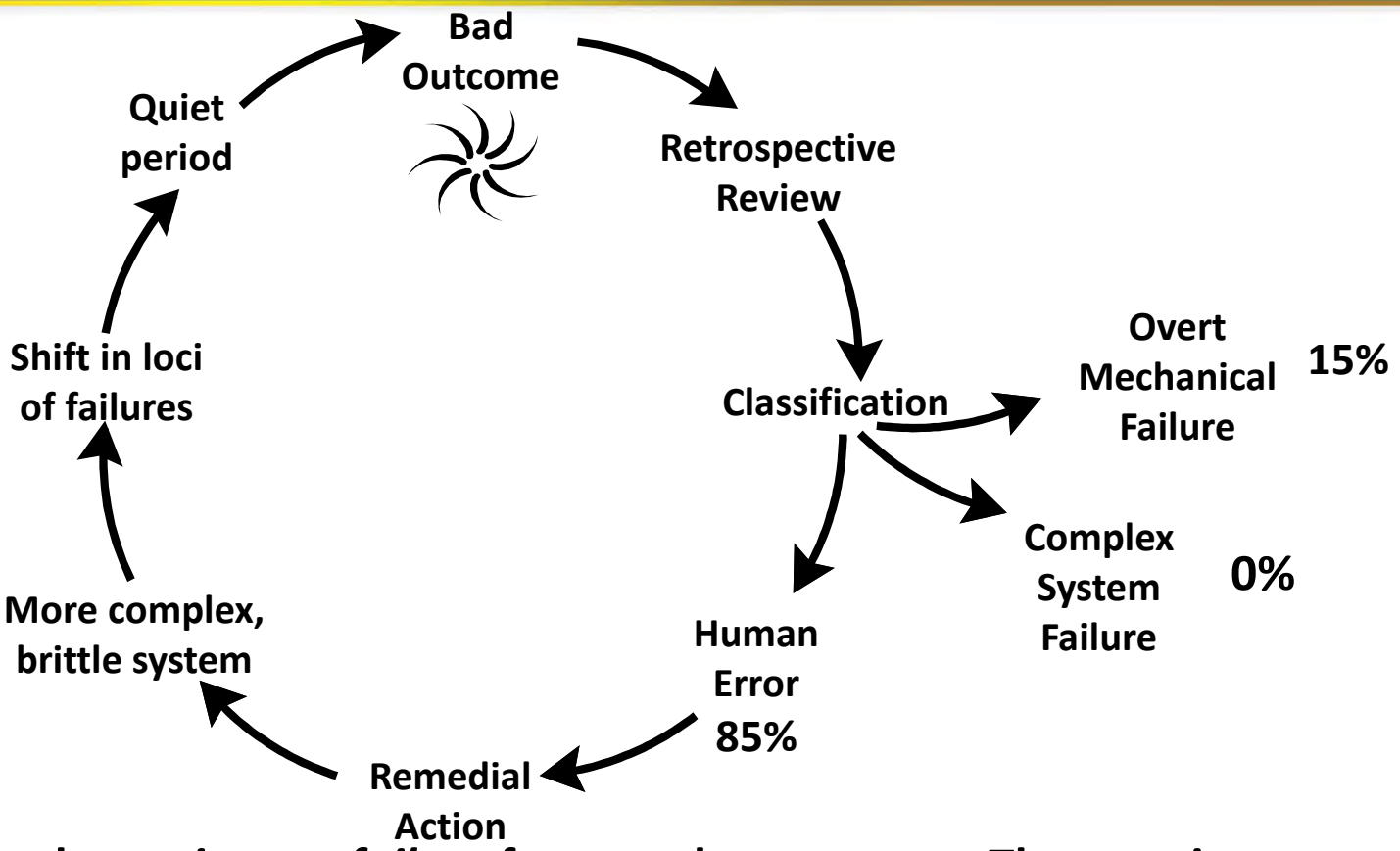




Practitioners at the *sharp end* of the system interact directly with the hazardous process. The resources and constraints on their technical work arise from institutional, management, regulatory and technological *blunt end* factors.

Modified from Woods, 1995

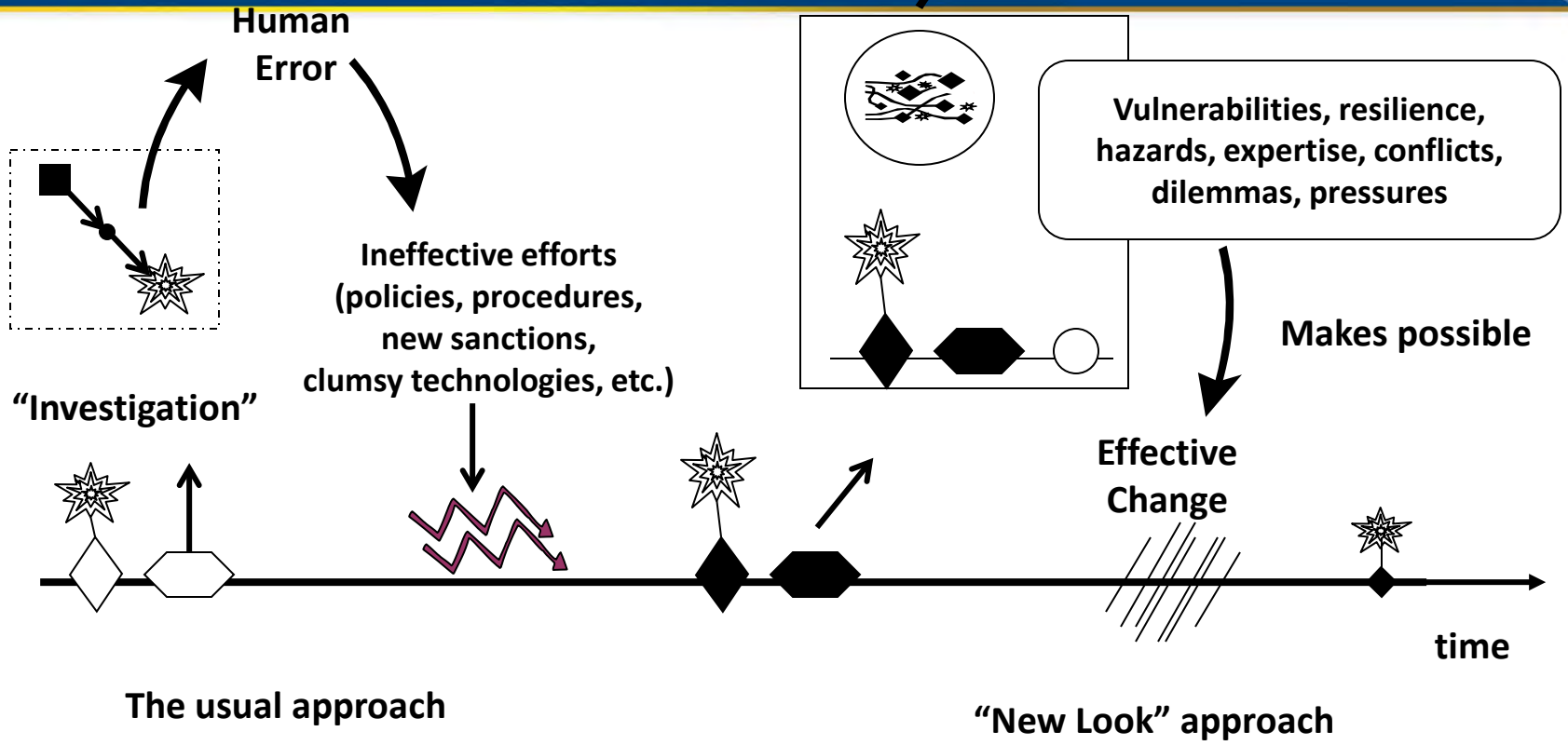
Old Cycle of Error



Organizational *reactions to failure* focus on human error. The reactions to failure are: blame & train, sanctions, new regulations, rules and technology. These interventions increase complexity and introduce new forms of failure. Cycle repeats.

Modified from Cook, 1999

"New Look" learning



People make safety. **Improving safety depends on understanding the details of technical work, how success is usually achieved, and how failure sometimes occurs. Effective change follows.**

Modified from Cook, 1999

Analytic Frameworks

- Root cause analysis (RCA) – primarily looks backward with focus on errors that occurred
- Failure modes & effects analysis – primarily looks forward at risk frequency, severity, & preventability with focus on errors
- Safety 2 – looks at what creates conditions for success

NYPORTS

Early History

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David Axelrod

He was Health Commissioner for the State of New York in the 1980s and 1990s (1979-1991). He was appointed by Governor Hugh Carey and served under Governor Mario Cuomo as well. He is considered to be the nation's foremost public health official of the 1980s. Resigned after a severe stroke.



Who Killed Libby Zion?

Since his teenage daughter checked into New York Hospital with a fever and died mysteriously, Sidney Zion has created a media blitz, accusing doctors of killing her. Now, after seven thousand pages of new testimony, M. A. FARBER pieces together what really happened that night—and finds that the story of Libby Zion is very different from the one her grief-stricken father portrays

It was on a cold February night, "right near the end," as the writer Sidney Zion recalls it, that he and his eighteen-year-old daughter, Libby, a Bennington College freshman, were walking down Fifth Avenue and she said she was going to be famous one day.

"Nobody says you have to be famous," Zion told her.

"But I'm going to be."

"And I said, 'What are you going to do?' "

" 'Well, I'm going to be a singer.' "

" 'Can you try something a little easier?' I said."

"And she said, 'Well, maybe I will be a journalist. How is that for easier?' "

Libby Zion *did* become famous, and because of what she became famous for, Dr. Luise Weinstein sits staring at the floor in a barren, windowless hearing room at the midtown-Manhattan offices of the New York State Health Department's Office of Professional Medical Conduct. It has been more than four and a half years since Libby Zion died at New York Hospital, and in the next weeks the first quasi-judicial judgment will be rendered on Dr. Weinstein, the intern who treated Libby and who is accused of gross negligence and/or incompetence. This is the doctor whom Sidney Zion has publicly called a murderer, who, along with other physicians, "executed" his daughter in the early-morning hours of March 5, 1984, "abandoned" her, "let her die there like a dog and worse than a dog."

What Libby Zion became famous for was dying, and the events surrounding her death—from the moment near midnight when she stepped into the emergency room to the moment upstairs nearly seven hours later when alarms went off and doctors came running and the resuscitation machines were thrown into motion and the nurses started crying and Libby slipped away—have been laden with controversy from the outset.

The issue before the Health Department panel hearing the arguments in the Zion case is not why Libby died, but whether the doctors' actions were in accord with generally accepted medical standards. Nonetheless, the cause of her death has been the leitmotif of the hearings and will be a key element in Sidney Zion's suit against the hospital, which is to go to trial in Manhattan Supreme Court. In many ways, the hearings have been a dry run for that trial. But, after thousands of pages of testimony, no one yes knows why Libby Zion died, and, strikingly, there is no hard evidence to support the claim by her father and the state that a drug improperly administered by the doctors was fatal. The hearings have made plain that the illness and death of this young woman, like the treatment she received at New York Hospital, is a far more complex



Libby Zion, the girl who wanted to be famous.

TSDAY JANUARY 17 1987

DA OVER TEEN'S HOSPITAL DEATH

By MIKE PEARL and MARIANNE GOLDSTEIN

AUTHOR Sidney Zion has lashed into District Attorney Robert Morgenthau for not indicting any one in the death of his daughter at a Manhattan hospital.

Morgenthau yesterday released a scathing grand jury report which condemned the "woefully inadequate" level of care received by Libby Zion, 18, who died at New York Hospital-Cornell Medical Center in March 1984.

The panel did not lodge criminal charges against the four doctors involved but claimed that actions of inexperienced and exhausted physicians contributed to her death.

SIDNEY ZION

cardiac arrest and died.

Doctors at the hospital initiated her reaction could have resulted from her taking cocaine.

But the panel said toxology reports detected no sign of cocaine in her system.

Although the panel found that Miss Zion received medically deficient care and treatment, said Morgenthau, no indictments were made because of "insufficient evidence" of her exact cause of death.

The report said that when she was admitted, "the level of expertise of the emergency room staff at this hospital was woefully inadequate."

"The only physician assigned to the ER was a junior resident [who] ... examined the patient to determine the source

Law and Regulations behind NYS Event Reporting

According to State law and regulations (Section 2805-l of the Public Health Law and Sections 405.8 and 751.10 of Title 10 of the New York Codes, Rules and Regulations), medical facilities in the State must report to the Department of Health (Department) certain types of adverse events, which are referred to as occurrences.

An occurrence is defined as an unintended adverse and undesirable development in an individual patient's condition, such as death or impairment of bodily functions in circumstances other than those related to the natural course of illness, disease or proper treatment.

The law and regulations, which have been in effect since 1985, apply to a total of 1,613 medical facilities: 263 hospitals and approximately 1,350 diagnostic and treatment centers (clinics). If a facility fails to comply with these reporting requirements, it can be fined up to $2,000 per reporting violation.

Law and Regulations behind NYS Event Reporting (cont.)

Certain incidents (e.g., patient deaths or impairments, fires, equipment malfunctions, poisonings, strikes, disasters, and termination of vital hospital services) are specified in the statute, comprising the foundation of NYPORTS reporting.

The statute further requires an investigation of a subset of these incidents to discern their root causes.

Unwritten Dual Purposes of NYPORTS

Reporting and tracking of occurrences

Communication about important events to NYS DOH and Government for their awareness and accountability

NYS Event Reporting Systems

HIRS – Hospital Incident Reporting System

- **Paper and mail**

PETS and PETS II – Patient Event Tracking System

- **Email**

NYPORTS – New York Patient Occurrence Reporting and Tracking System

- **Electronic web based**
- **Event- or outcome-based, not error-based**

Other results of the Libby Zion aftermath

NYS Bell Commission

- **Resident work hours**

NEJM article on medical error and harm

SPECIAL ARTICLES

INCIDENCE OF ADVERSE EVENTS AND NEGLIGENCE IN HOSPITALIZED PATIENTS

Results of the Harvard Medical Practice Study I

TROYEN A. BRENNAN, M.P.H., M.D., J.D., LUCIAN L. LEAPE, M.D., NAN M. LAIRD, PH.D., LIESI HEBERT, SC.D., A. RUSSELL LOCALIO, J.D., M.S., M.P.H., ANN G. LAWTHERS, SC.D., JOSEPH P. NEWHOUSE, PH.D., PAUL C. WEILER, LL.M., AND HOWARD H. HIATT, M.D.

Abstract *Background.* As part of an interdisciplinary study of medical injury and malpractice litigation, we estimated the incidence of adverse events, defined as injuries caused by medical management, and of the subgroup of such injuries that resulted from negligent or substandard care.

Methods. We reviewed 30,121 randomly selected records from 51 randomly selected acute care, nonpsychiatric hospitals in New York State in 1984. We then developed population estimates of injuries and computed rates according to the age and sex of the patients as well as the specialties of the physicians.

Results. Adverse events occurred in 3.7 percent of the hospitalizations (95 percent confidence interval, 3.2 to 4.2), and 27.6 percent of the adverse events were due to negligence (95 percent confidence interval, 22.5 to 32.6). Although 70.5 percent of the adverse events gave rise to disability lasting less than six months, 2.6 percent caused permanently disabling injuries and 13.6 percent led to death. The percentage of adverse events attributable to negligence increased in the categories of more severe injuries (Wald test $\chi^2 = 21.04$, $P<0.0001$). Using weighted totals, we estimated that among the 2,671,863 patients discharged from New York hospitals in 1984 there were 98,609 adverse events and 27,179 adverse events involving negligence. Rates of adverse events rose with age ($P<0.0001$). The percentage of adverse events due to negligence was markedly higher among the elderly ($P<0.01$). There were significant differences in rates of adverse events among categories of clinical specialties ($P<0.0001$), but no differences in the percentage due to negligence.

Conclusions. There is a substantial amount of injury to patients from medical management, and many injuries are the result of substandard care. (N Engl J Med 1991; 324:370-6.)

https://pubmed.ncbi.nlm.nih.gov/1987460/

Mark Chassin

NYS Health Commissioner from 1992-1994

Albert Siu

Deputy Commissioner from 1993-1994

Proposed what became NYPORTS Council



Barbara DeBuono

NYS Health Commissioner from 1995-1998

DOH established what became NYPORTS Council in 1995 (Key – Fred Heigel)

1995 Retreat Planning

- **NYSDOH**
- **HANYS**
- **GNYHA**
- **Hospitals (9)**

NYPORTS initiated in 1998



Antonia Novello

She was the first woman and first Hispanic to serve as Surgeon General.

NYS Health Commissioner from 1999 - 2006

Oversaw and funded NYPORTS

NYPORTS Council

- **NYS DOH**
- **HANYS**
- **GNYHA**
- **Hospitals (9)**
- **SUNY SPH**
- **Others interested**



NYPORTS RCA Framework

- Developed by NYPORTS Council
- Derived from JCAHO RCA format
  - JCAHO format asked to explain why each aspect was NOT a factor
  - NYPORTS inverted that to ask IF each aspect was a factor and if so, how
- Agreement with JCAHO liaison to NYPORTS
  - NYPORTS RCA format acceptable to JCAHO if needed to be shared
  - NYS DOH would share aggregate data on RCA's with JCAHO
    - At that point in time NYS received more RCA's per year than JCAHO for entire USA

AHRQ NYPORTS Grant 2002-2005

Extra core staff and web design funding

Subcommittees of NYPORTS Council (e.g. Medication related events). NYPORTS Council meetings with 70+ participants. Regional councils active in some NYS DOH regions.

Three subprojects funded 2002-2004:

- **Postoperative myocardial infarction prevention**
- **Surgical site infection (SSI) prevention**
- **Venous thrombo-embolism (DVT and PE) prevention**

Regular NYPORTS Newsletters several times per year

Later evolution of NYPORTS – eventual move away from most short form complication events and more emphasis on RCA's for detailed analysis

From NYS Controller Report on NYPORTS

…. the Department recognizes 54 different types of occurrences, 19 of which are classified as most serious and 35 of which are classified as less serious. Only five types of less-serious occurrences are systematically analyzed to identify unreported occurrences.

From NYS Controller Report on NYPORTS

We found that, while the Department has taken action to improve compliance with NYPORTS reporting requirements, the information on NYPORTS is not complete and often is not reported in a timely manner.

As a result, the NYPORTS database may not be as useful as it could be when it is analyzed during efforts that are intended to improve the quality of patient care.

Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems

Ellen Flink, C. Lynn Chevalier, Angelo Ruperto, Peg Dameron, Frederick J. Heigel, Ruth Leslie, Janet Mannion, and Robert J. Panzer.

Advances in Patient Safety: From Research to Implementation (Volume 3: Implementation Issues). Rockville (MD): Agency for Healthcare Research and Quality (US); 2005.

https://www.ncbi.nlm.nih.gov/books/NBK20547/

Accurate Event and Outcome Rates

Learned from NYPORTS (and our Event Reporting Experience)

- Are not identified through voluntary, semi-voluntary, or even most mandatory reporting systems
- Accurate rates can come from administrative data analyzed using administrative definitions, yielding accurate administrative (e.g. billing) rates
- Trigger tools can help create more consistent, more accurate rates over time (e.g. rescue medications help find overdoses or adverse reactions)
- Best accurate clinical rates can be obtained with fully implemented, comprehensive clinical registries (e.g. NYS CABG and PCI database, STS database, UNOS transplant registries, NSQIP, and many others).

Richard Daines

NYS Health Commissioner from 2007-2010

Emphasis on Berger Commission on capacity

De-emphasis on NYPORTS and its Council.

Entertained redesign and expansion to event reporting.



RCA +

MEDICINE of THE HIGHEST ORDER

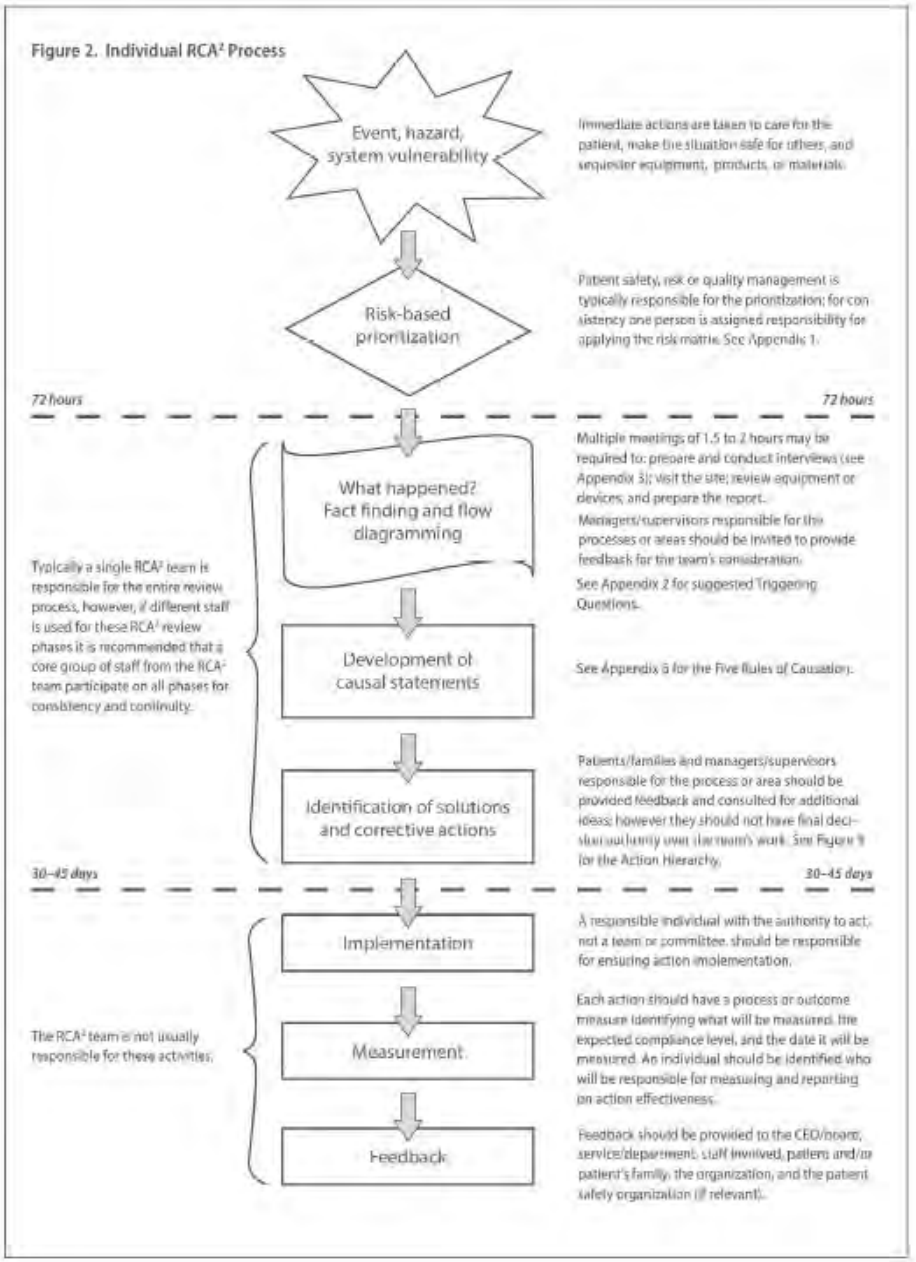
UNIVERSITY of ROCHESTER MEDICAL CENTER

RCA's at Strong Memorial Hospital

- Deploy RCA teams weekly and ad hoc
- Approximately 100 deployed at hospital level in 2022 (900 bed hospital)
- Roughly half NYPORTS and half "internal RCA's"
- From more to less common NYPORTS categories
  - 914 Misadministration of radiation (non-RCA) – mostly wrong site
  - 915 Fall with fracture or head bleed
  - 922 Suicide attempt
  - 915 MAT – most often unplanned hysterectomy due uncontrollable bleeding after delivery with health mother and baby
  - 913 Retained foreign body
  - 938 Equipment malfunction or misuse (also report to ECRI +/- FDA)
  - 911 Wrong site procedure
  - 915 PHL Death or serious injury NOS

RCA2 - Root Cause Analysis and Action

Figure 2. Individual RCA² Process



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Template: Action Hierarchy Tool

	Action Category	Example	Action
Stronger Actions (these tasks require less reliance on humans to remember to perform the task correctly)	Architectural/physical plant changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.	
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.	
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fittings that can only be connected the correct way (e.g., IV tubing and connectors that cannot physically be connected to sequential compression devices or SCDs).	
	Simplify process	Remove unnecessary steps in a process.	
	Standardize on equipment or process	Standardize on the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.	
	Tangible involvement by leadership	Participate in unit patient safety evaluations and interact with staff; support the RCA[2] process; purchase needed equipment; ensure staffing and workload are balanced.	
Intermediate Actions	Redundancy	Use two RNs to independently calculate high-risk medication dosages.	
	Increase in staffing/ decrease in workload	Make float staff available to assist when workloads peak during the day.	
	Software enhancements, modifications	Use computer alerts for drug-drug interactions.	
	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.	
	Education using simulation-based training, with periodic refresher sessions and observations	Conduct patient handoffs in a simulation lab/environment, with after action critiques and debriefing.	
	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiber optic endoscopes.	
	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the unit medication room.	
	Standardized communication tools	Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format.	
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.	
Weaker Actions (these tasks require more reliance on humans to remember to perform the task correctly)	Double checks	One person calculates dosage, another person reviews their calculation.	
	Warnings	Add audible alarms or caution labels.	
	New procedure/ memorandum/policy	Remember to check IV sites every 2 hours.	
	Training	Demonstrate correct usage of hard-to-use medical equipment.	

URMC RCA3 – Root Cause Analysis, Action & Anti-racism

(Page 1 for SMH internal use only)

Patient's Name (if applicable):	Medical Record Number:	RL ID #

Brief Desc:			
NYPORTS Code:	Sub-Code:	Medication code:	Fam/Pt Aware/Notified: ☐Y ☐N
Occurrence ID: 000413-	Date of Occurrence:	Date of Awareness:	Peri-Op Event: ☐Y ☐N
Date RCA Due:	Extended Due Date:	DEI issue(s) identified: ☐Y ☐N	IT related issue (s): ☐Y ☐N

Current Draft Number:	Current Draft Date:	Final Draft Date:	Date Sent to ME&RM:
Submission/Completion Date:	PSRM Presentation Date:		JMQC Presentation Date:

Department(s):		Team Leader:	OCMC Rep:
AQO Rep(s):		Facilitator:	DEI Rep:
Resident(s)/Fellow(s):			PFR Rep:
Team Members: (name/title)			

Official copy for Dept provider profile. list Dept Chair(s), cc QAL(s), others. (Incl titles)	Chair:	cc QAL:
	Chair:	cc QAL:
	Chair:	cc QAL:

SOC:	☐ Met	☐ Met: RFI	☐ Not Met: Systems	☐ Not Met: Individual	☐ Not Met: Team

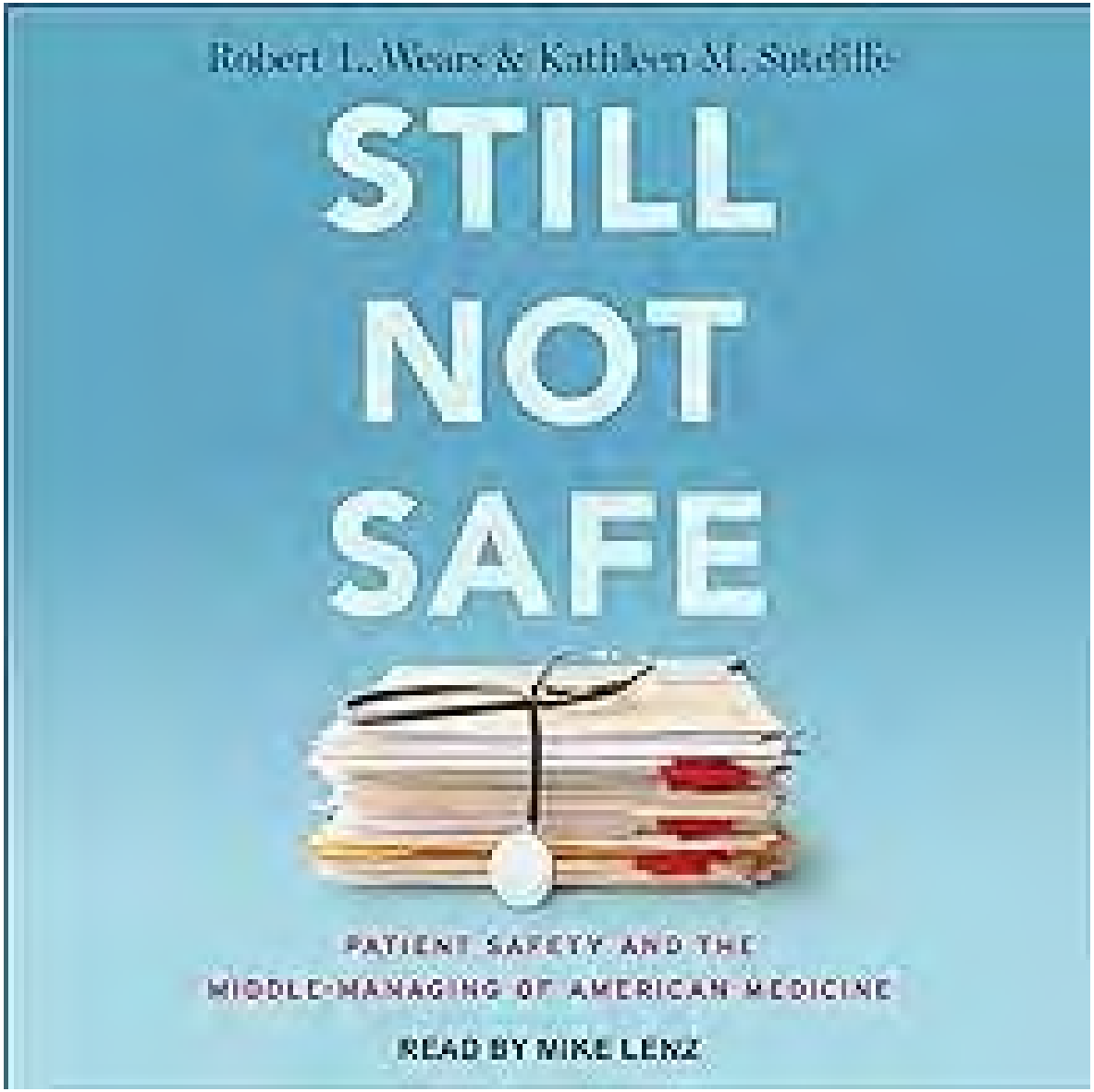
PSRM Invitee(s) for initial presentation: (name/title)		Resident Invitee:
JMQC Invitee(s): (name/title)		Resident Invitee:

Implementation Team Leader(s):				Implementation Date:
RFI Responsible Person(s):				Implementation Date:
DEI Responsible Person(s):				Implementation Date:
PSRM Report Dates	Initial:	@ 3 mos:	@ 6 mos:	@ 12 mos:

Looking to the Future

MEDICINE *of* THE HIGHEST ORDER

UNIVERSITY *of* ROCHESTER MEDICAL CENTER


Robert L. Wears & Kathleen M. Sutcliffe
STILL
NOT
SAFE
PATIENT SAFETY AND THE
MIDDLE-MANAGING OF AMERICAN MEDICINE
READ BY MIKE LENZ

Still Not Safe

Themes

- **Four potential futures for patient safety, not mutually exclusive**
  - **1) Bureaucracy**
  - **2) Rebranding**
  - **3) Extinction**
  - **4) Fundamental Change**





High Reliability Organizations

HROs "operate under very trying conditions all the time ***and yet manage*** to have fewer than their fair share of accidents."

3 Principles of Anticipation

"Stay Out of Trouble"

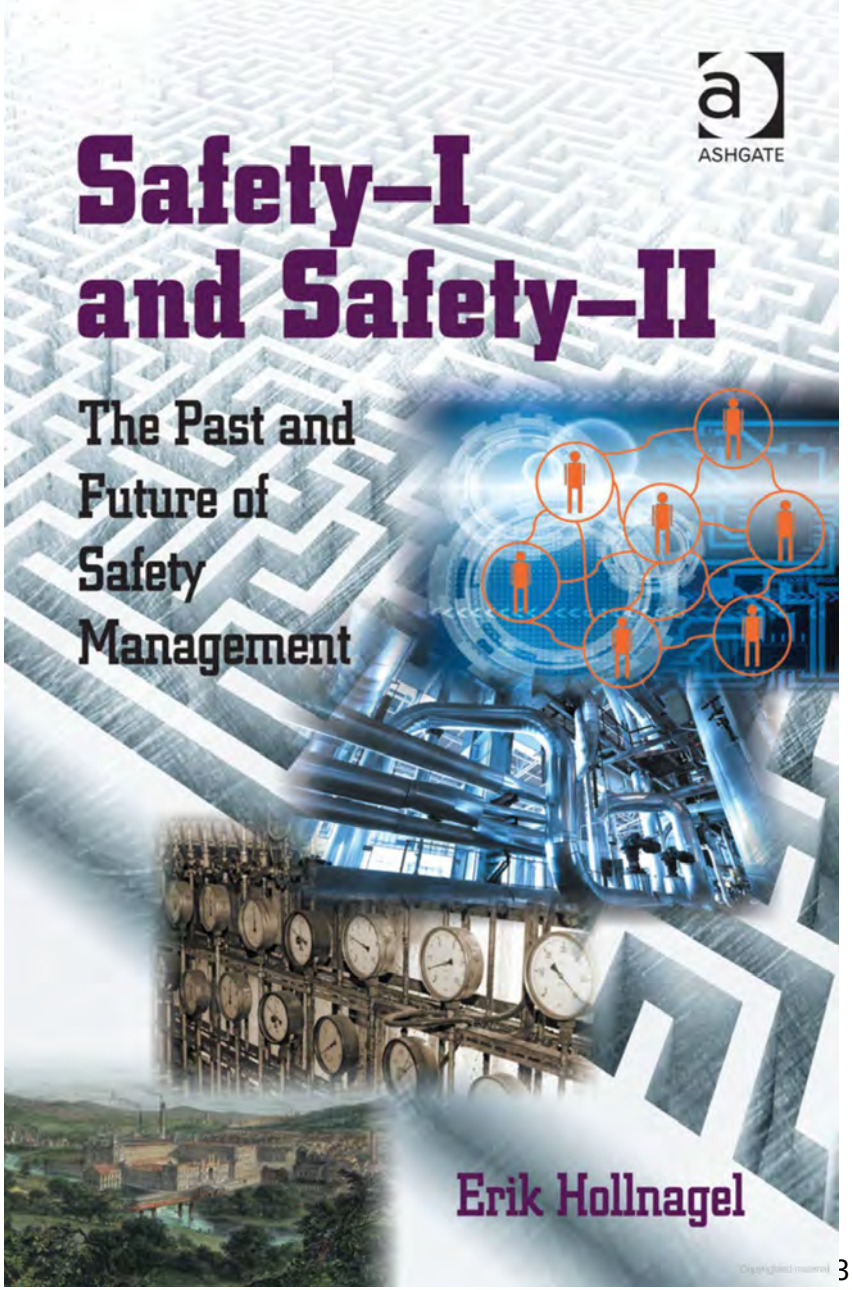
Sensitivity to Operations
Preoccupation with Failure
Reluctance to Simplify

2 Principles of Containment

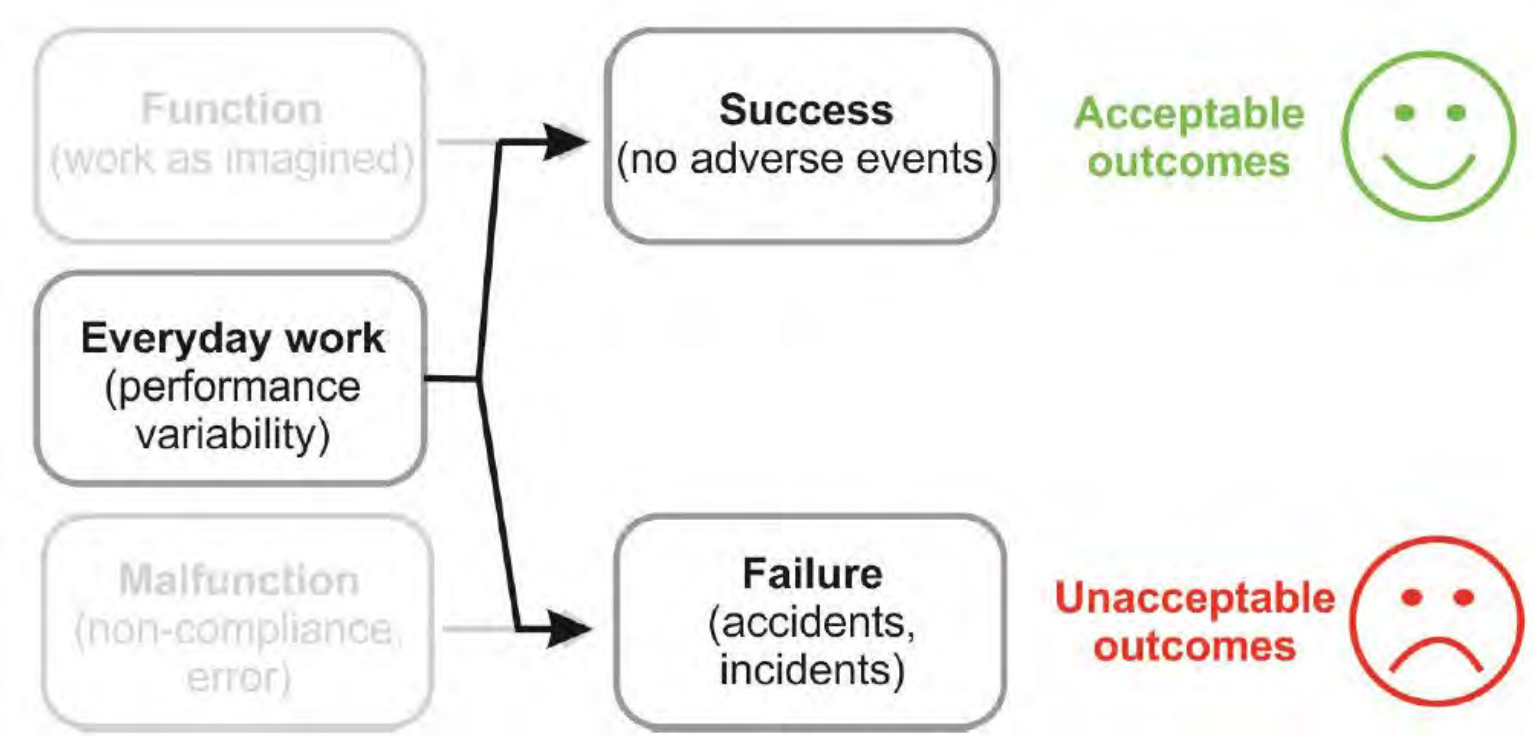
"Get Out of Trouble"

Commitment to Resilience
Deference to Expertise

HPI®


ASHGATE
Safety–I and Safety–II
The Past and Future of Safety Management
Erik Hollnagel

Safety I versus Safety II



Safety-2 vs Safety-1

Safety-2

- **Focus on both**
  - **Promoting processes that increase the likelihood of success**
  - **Promoting resilience when things inevitably go wrong due to error or unpreventable factors**





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MEDICAL CENTER

MEDICINE of THE HIGHEST ORDER

Tableau presentation backup slides

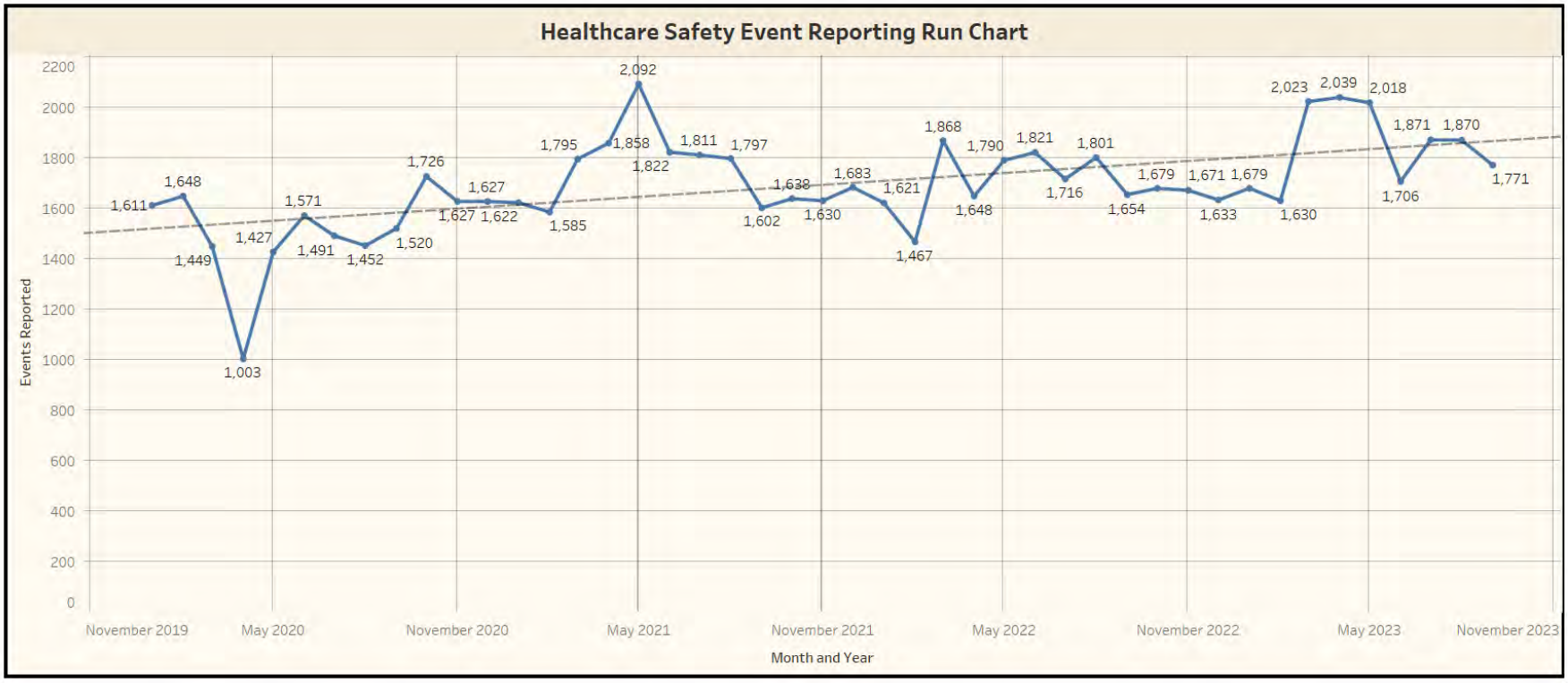
Event Data Sources and Severity Level

This set of Dashboards is design to review event reporting data for Strong Memorial Hospital and Highland Hospital, and their associated ambulatory practices.

Data Source:
RL Solutions: The event reporting system is a secure web-based tool that our staff to enter an unsafe condition or practice, near miss, adverse event, or error and stores them in a confidential database. The goal of this system is to improve patient safety and quality in healthcare.

Severity Levels:
<N/S>: Not Selected
A. Unsafe Condition: Circumstances exist with a capacity to cause an event/error or variance in care (a good catch), or, the department is conducting a QA case review of an unexpected or adverse outcome that did not occur as a serious event.
B1. Near miss - No Harm Didn't Reach Person Affected Caught by Chance: Event, error or omission occurred BUT it DID NOT reach the patient. Error was discovered by chance.
B2. Near miss (Good Catch) - No Harm Didn't Reach -Person Affected b/c of Active Recovery by Caregivers: Event, error or omission occurred BUT DID NOT reach the patient, actively prevented by actions of caregivers
C. No Harm: Reached Person Affected No Monitoring Required: Event or error reached the patient BUT caused no harm.
D. No Harm: Reached Person Affected Monitoring Required: Event or error increased the need for monitoring or intervention BUT caused no harm.
E. Harm: Temporary, Intervention Needed: Event or error increased the need for treatment or intervention AND caused TEMPORARY patient harm.
F. Harm: Temporary, Higher Level of Care Needed: Event or error that contributed to or resulted in TEMPORARY harm to the patient AND required a higher level or care or prolonged hospitalization.
G. Harm: Permanent: Event or error that contributed to resulted in PERMENANT harm
H. Harm: Permanent, Intervention Required to Sustain Life: Event or error that resulted in PERMENANT harm and required extensive intervention necessary to sustain life...

Event Reporting Trends Overall



General Event Type
Multiple values

Specific Event Type
All

Campus
All

Entered Year
Multiple values

Entered Month
All

Clinical Area
All

Clinical Service
All

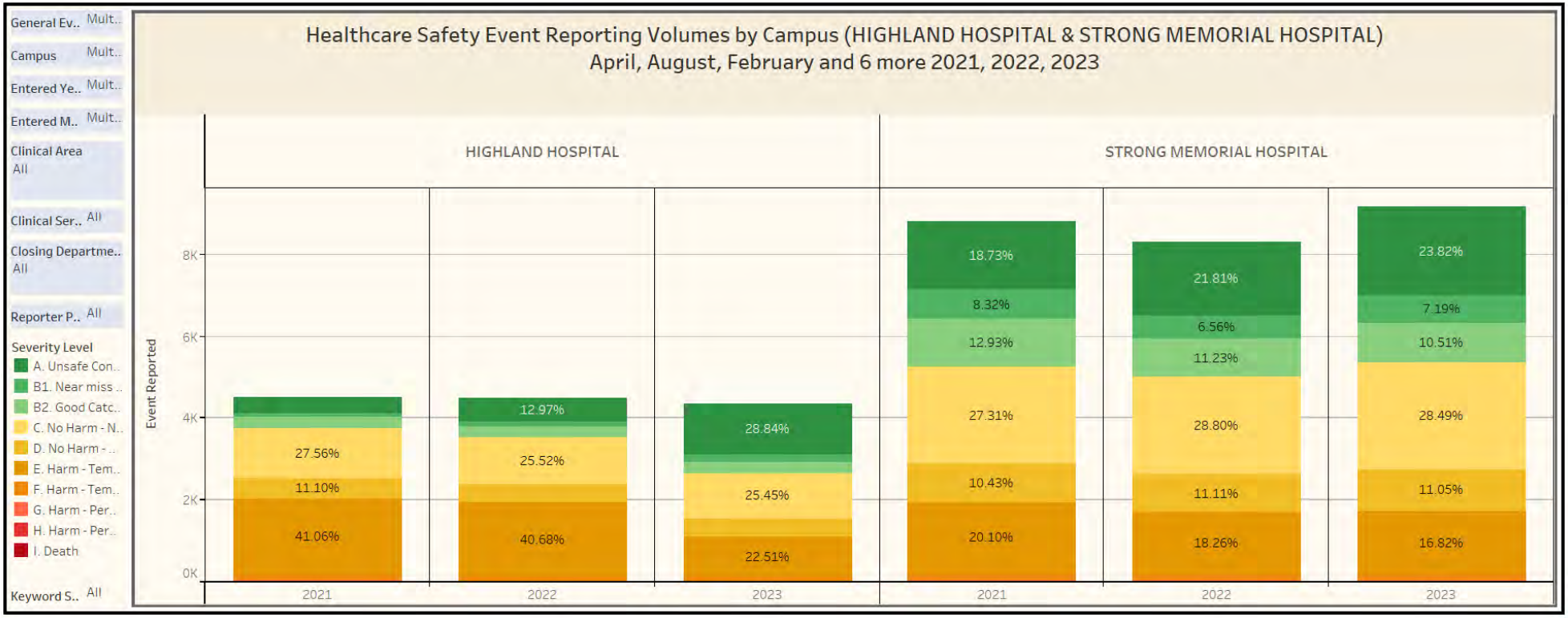
Closing Department
All

Reporter Position
All

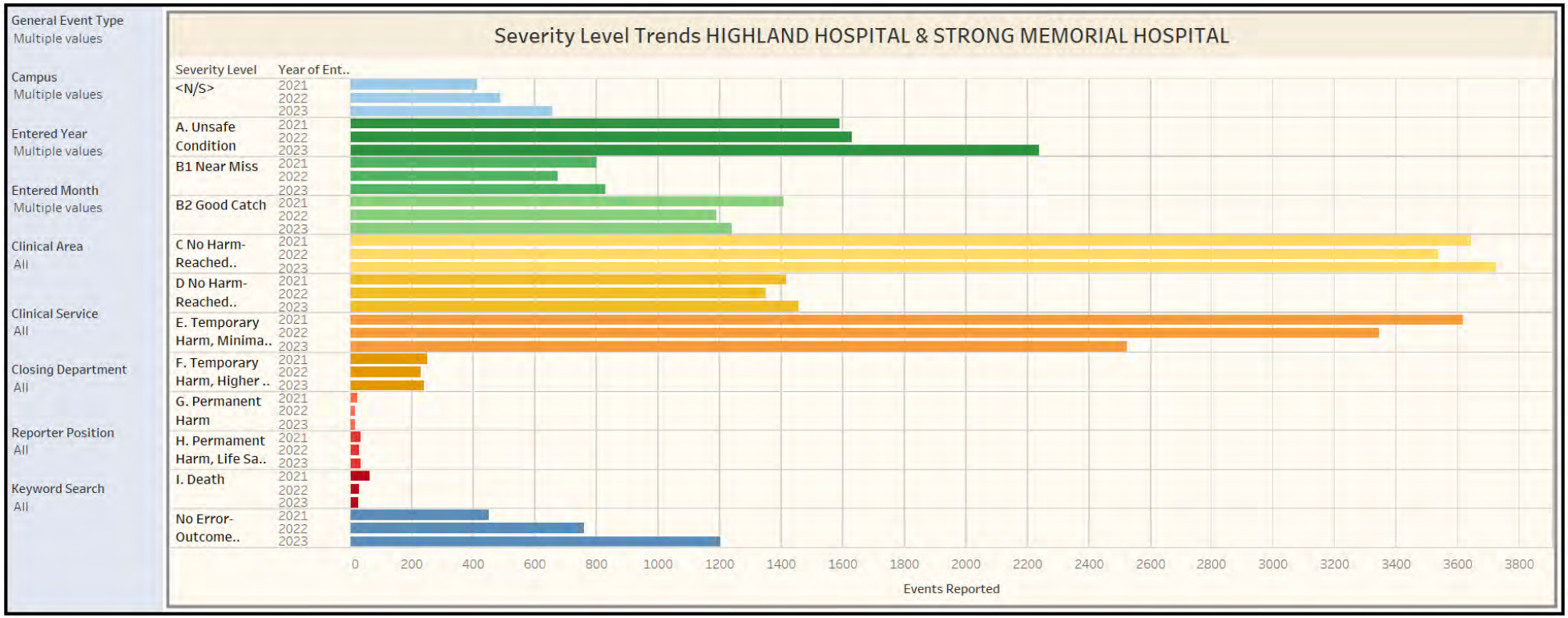
Entered Date
7/1/2014 to 10/5/2023

Keyword Search
All

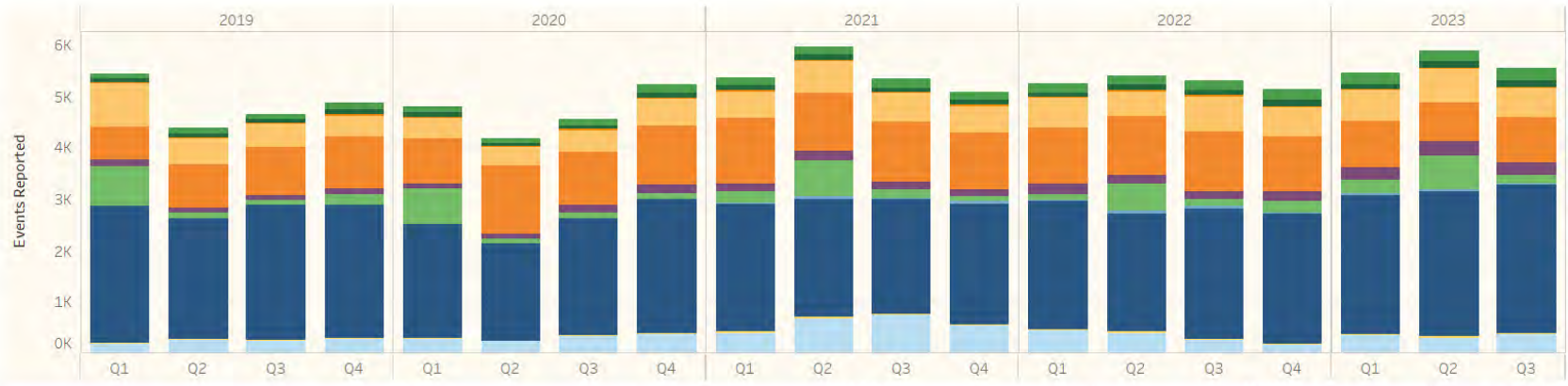
Event Volumes by Campus



Event Severity Level Trends



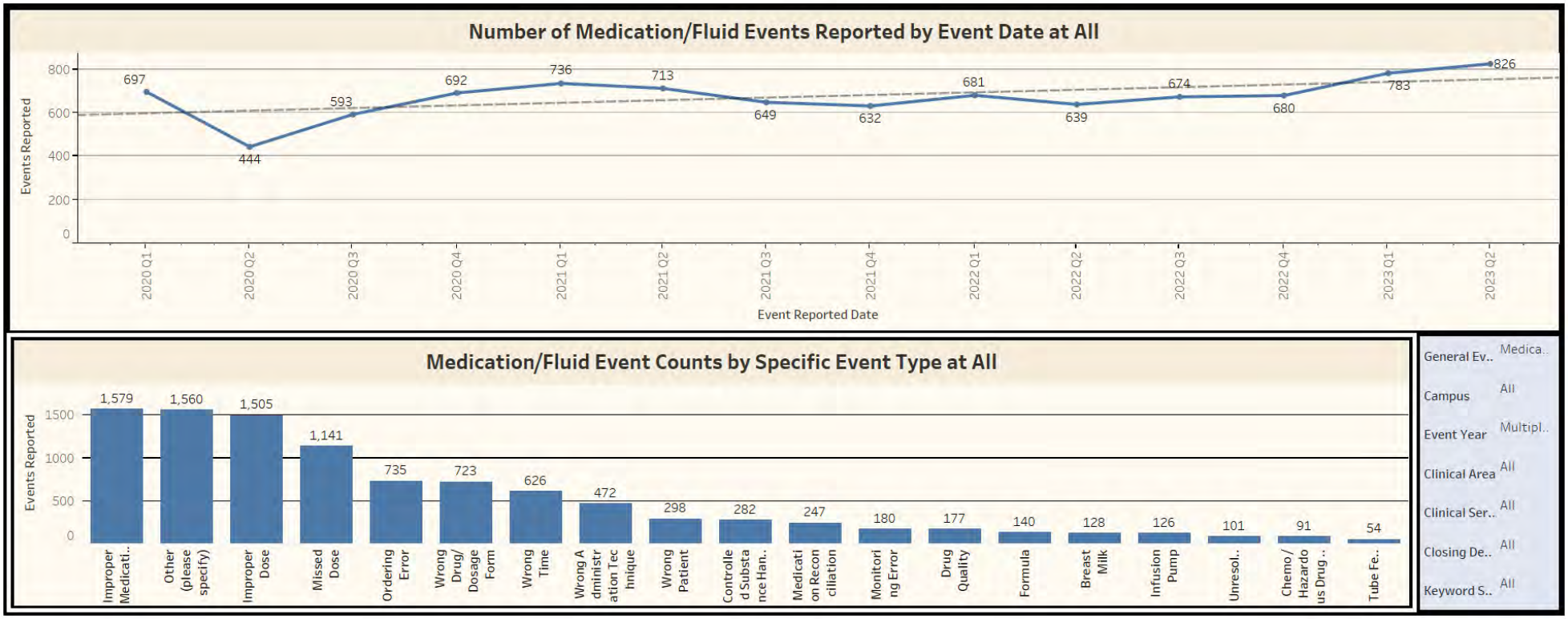
Events by Reporter Position



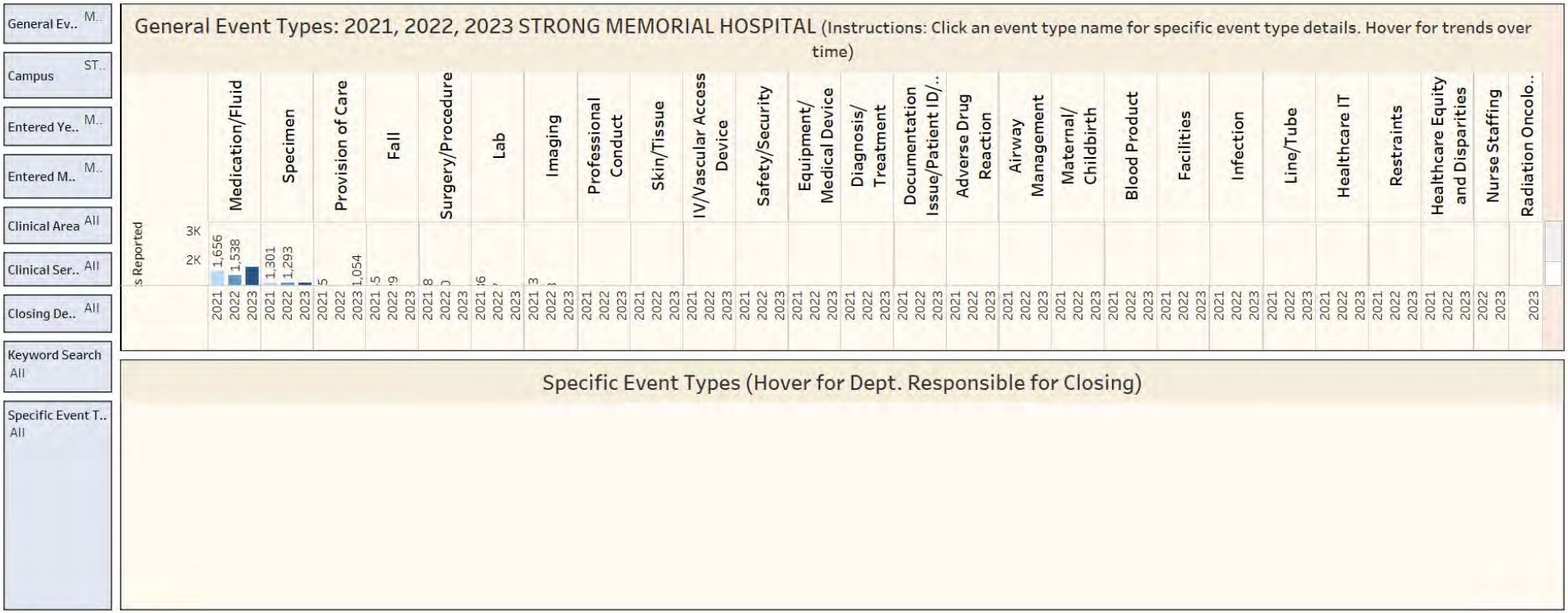
	2021				2022				2023			
Reporter Position	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Grand Total
APP	166	153	166	160	188	171	183	221	228	214	256	2,106
Attending	82	102	85	88	73	101	89	106	83	112	124	1,045
Other - Not Staff	5	3	2	7	2	6	4	6	11	8	6	60
Other Staff - Clinical	540	632	575	530	594	503	707	587	604	681	585	6,538
Other Staff - Non-Cli..	1,267	1,131	1,172	1,114	1,091	1,144	1,167	1,083	929	740	889	11,727
Pharmacist	158	181	152	137	198	157	152	175	228	294	214	2,046
Resident/Fellow	218	721	147	100	121	544	148	209	265	661	167	3,301
Respiratory Therapi..	5	27	26	32	33	37	32	33	30	35	22	312

General Ev..	All
Campus	All
Clinical Area	All
Clinical Ser..	All
Closing De..	Multiple values
Specific Ev..	All
Reporter P..	Multiple values
Keyword S..	All

Medication Events and by Event Type



Event Types by Year



Ameriquest video – don't jump to conclusions



Annie's Story – a good video to illustrate human factors and not jumping to conclusions



Improving Investigation Yields Large Savings in Lawsuit Settlements









NAM (National Arbitration and Mediation)
presents a CLE webinar to the
AHRMNY Fall Educational Conference and Reception
Monday, October 30, 2023 | 11:10 a.m. – 12:00 p.m.

Today's Presenter



Bob Worden, Esq.
Hearing Officer
NAM (National Arbitration and Mediation)

Introduction



Mediators help all sides to a lawsuit to reach an agreement to settle a case. In handling cases involving premises and facilities, I noticed that accident investigation materials are often lacking key facts and documents. This benefits no one, as inadequate investigation increases the uncertainty of how the case might be seen by a jury. Uncertainty often makes cases hard to settle and causes cases to go to trial which otherwise could have been settled.

Most cases are settled before they go to the jury, based upon the strength of the proof which supports each sides' claims.

As a mediator, I am involved in a lot of cases. The biggest issue for premises and facilities is the lack of information about what happened at the time.

Importance of a thorough investigation



The people who are responsible for handling these investigations at facilities usually have many other responsibilities within their organization. It is easy to perform a “less-than-thorough” investigation, especially of minor claims when other, urgent matters are pressing.

Yet, oftentimes, these minor accidents become major lawsuits when it is claimed that the accident aggravated an underlying condition and caused surgery to be necessary.

If the important information about what happened and the extent of the body parts involved is quickly documented when you learn about an incident, it will help the facility and its insurance company to assess any claims made later by the injured party.

Taking the case



Plaintiffs' attorneys also must assess whether to represent a person claiming to be injured.

When a person who has been in an accident comes into an attorney's office looking for representation in these types of cases, the attorney must first verify what the prospective client is saying. As plaintiffs' attorneys are only compensated out of the proceeds of a successful lawsuit, plaintiffs' attorneys' risks losing in Court after years of working on their cases.

Plaintiffs' attorneys need to pin down proof of the facts to be successful.

Taking the case (cont'd)



Plaintiffs' attorneys want to spend as little time as possible handling any case. The longer a case drags on, and the more cases that are forced to go to trial, the less money plaintiffs' attorneys are likely to make.

Neither side wants to go through a very expensive trial, which takes several hundred hours of attorneys' time and cost hundreds of thousands of dollars for experts and other expenses. Neither side wants the case to last any longer than it needs to last.

Good documentation by the defense helps plaintiffs' attorneys to see what the facility has documented.

Real-life case



Before getting into the details of what needs to be done, I want to review the facts of the first real-life case example with you:

Example 1 – No access

The insurance company for the owner of a premises occupied by an HMO receives an attorney's claim letter threatening a lawsuit on behalf of a nurse employed by a medical group at the HMO who received an electric shock using defective equipment while working. Her attorney claimed that the nurse developed RSD/Complex Regional Pain Syndrome as a result of the electrical burn to her arm and that she had been in and out of work for several months and wasn't getting better. Initially, the insurance company hired an investigator to find out what happened. The Investigator went to the HMO, but everyone at the HMO was too busy to speak with him. The investigator returned two more times but continued to be ignored by the HMO staff. The investigator reported his difficulties to the insurance claims adjuster.

What should the insurance claims adjuster do next?

Real-life case (cont'd)



What should the insurance claims adjuster do next?

- Send a letter to the HMO advising them that their insurance coverage may be jeopardized for lack of cooperation in assisting with the investigation.
- Retain an attorney to undertake investigation.
- Wait to see if a lawsuit is filed. Then, an assigned defense attorney will learn what happened as the case proceeds in litigation.

Real life – Correct course of action

An attorney was immediately assigned to investigate and meet with the facility staff. He made an appointment, went to the HMO premises, dressed in a formal suit with a briefcase. The staff did not ignore him.

An HR supervisor showed the attorney the machine that caused the shock - an x-ray viewing box. Upon questioning the technicians in the radiology department, the attorney learned that the x-ray viewing box had been used for 15 years. Members of the staff plugged it in in the beginning of the day and other staff unplugged it at the end of every day.

The injured nurse had received a burn to her hand when she tried to unplug the box, and the insulation broke apart, causing the nurse's hand to grab onto the exposed wire as she pulled. The attorney also asked to speak to the nurse's supervisor if she was available. He learned from her supervisor that the injured nurse was top performer who had worked in that department for over a decade. The supervisor reported that the injured nurse was continuing to work when she was able, but she seemed to be getting worse, and was missing work more often. Back at the office, the attorney called an electrical expert and learned that HMO would be liable for failing to hardwire the x-ray box with a dedicated electrical switch. A switch was required by local building code, so as to avoid the very event that happened. If the case went to trial, a jury verdict in plaintiff's favor was certain.

After records of medical treatment were reviewed, the insurance adjuster was able to settle the case reasonably before a lawsuit was filed. The plaintiff's attorney was happy to settle the case. The facility saved considerable defense costs and paid less than they would have been required to settle the case years later. Most importantly, the injured nurse could focus on getting better. She avoided the stress and aggravation of years of lawsuit involvement and had better financial security in the event she had to retire early.

Moral for best practices in handling a claim

Benefits of a thorough intake of information



The earlier that complete information can be obtained about a claim the facility is likely to have to pay, the better the chances of an early reasonable settlement.

Accurate proof of a claim is vital

Our adversary legal system requires each side to present their proof at trial



If the plaintiff's attorneys don't work hard to get the facts and evidence, they won't do well for their clients. If the premises and facilities staff perform cursory or haphazard investigations, despite the best efforts of their able defense attorneys, the facilities will pay more than they should in lawsuit settlements.

NAM
NATIONAL ARBITRATION AND MEDIATION

The mystery fall



A lawsuit is brought against a lumber yard about an incident where it appeared that the plaintiff customer fell down recently installed stairs from a second-floor warehouse to the first floor of the retail building, receiving multiple fractures and claiming total lifetime disability. The defense attorney met with an engineer expert who examined the stairs and found that the stairs weren't properly constructed, due to uneven distances from one step to the next step on several of the stairs.

There was a pre-accident store surveillance video recorded of the plaintiff walking around the second-floor of the warehouse carrying some items, but there was no video camera which showed the stairs or the floor by the bottom of the stairs. When plaintiff testified at his pre-trial deposition, plaintiff surprised the defense with testimony that he did not fall down the stairs. Rather, he claimed that he had moved backwards while shopping and that he fell backwards over a second-floor railing onto the stairs, then bounced down to the concrete first floor or the staircase. Plaintiff denied carrying any items at the time he fell.

The mystery fall (cont'd)

What needs to be done by the defense with the new information that plaintiff claims he fell backwards over the railing?

- Schedule a mediation to try to settle. The case will turn on whether the jury believes plaintiff's story. It's better to settle the case now, save defense costs and get a discount on the value of the case, as it will be years before the case goes to trial. More money will have to be paid at the time of trial to settle the case.
- Wait to hear the testimony of the warehouse manager to see if that helps the defense.
- Tell the defense attorney to go back to the warehouse and check out the layout of the second floor in person, to see whether it is likely that plaintiff could have fallen over the railing.

The mystery fall – answer (cont'd)

When the attorney went back to look at the second-floor railing, he found that the railing was high enough that it was highly unlikely that plaintiff could have fallen over backwards. The defense attorney took the opportunity offered by the lumber yard to meet with a group of 6 warehouse staff who had been present on the date of accident. The attorney spoke with them as a group and learned that one worker had taken polaroid photos at the base of the stairs shortly after the accident, after the ambulance left, which showed 2 large items, a four-step stair stringer and a big roll of insulation on the floor in front of the bottom of the stairs, next to a pool of blood. The original polaroid photos were later located in the claims file at the insurance company.

The claims adjuster had thought than an investigator took those polaroid photos long after the accident and didn't know that they contained key evidence of the immediate post-accident scene which must be preserved for trial. The attorney then looked at the surveillance video clip from the second-floor camera which showed plaintiff carrying the roll of insulation and the stair stringer.

The combination of the surveillance video, and the polaroids showing those to items at the bottom of the stairs, proved that it was more likely that plaintiff fell down the stairs with his arms loaded. Plaintiff was likely to be perceived as lying.

The mystery fall – answer (cont'd)

The defense attorney sent plaintiff's attorney the copies of the newly-located photos and asked the plaintiff's attorney to view the video surveillance, showing plaintiff carrying the same insulation and stringer that were found at the bottom of stairs. The plaintiff's attorney agreed that this new evidence was not good for his case, as his client appeared to have lied about what happened. The case was then settled for nuisance value. The lumber yard closed its second-floor showroom after this event.

This story illustrates the important point that you won't know what you will find until you investigate. This was a serious case which warranted a careful investigation. The key proof in the polaroid photos might easily have been lost or misfiled by the insurance company. It was only luck the key person who knew about the photos was at work the day the attorney went back to look after plaintiff claimed he had fallen over the railing. This case also illustrates how less-than-truthful plaintiffs end up with less money than if they told the truth. Here, given the defect in the stairs, if plaintiff told the truth that he fell while he was carrying the items in both arms while descending the stairs, a jury probably would have found the lumbar yard liable in part, for having defective stairs on their premises. The problem with the investigation was that no one at the lumberyard had been interviewed in detail soon after this serious accident happened.

Understanding how lawsuits are evaluated



MORAL

When the accident is reported to the insurance company, it helps to speak with the claims adjuster directly to make sure all of your information and documents have reached the adjuster.

Make sure that the adjuster has the names of all people who are or might be witnesses for the defense in this case.

Understanding how lawsuits are evaluated

Your team members need to know the reasons why detailed information should be documented, even for incidents that appear to be minor.

First, let's review how lawsuits are usually evaluated by the people who have settlement responsibilities.

- Settlement value is calculated by the formula: Multiply the % chance of winning by the estimated value of damages. For example: if you have a 60% chance of winning a case where the value of the damages is estimated at $100,000, the case should settle for $60,000. The hard part is to figure out the chances of winning.

- The important thing to know is that these two calculations - the likelihood of winning and the value of the injuries and damages—are calculated based upon that documented facts supported by evidence which can be considered by a jury. Juries tend to believe detailed and thorough investigations which are made soon after the accident. If accident reports are vague, are susceptible to multiple interpretations, and fail to document the details, they will carry little weight with a jury.

Understanding how lawsuits are evaluated

The reason that most cases settle is that chance and luck play a big role in trials. Experienced people know that a “sure thing” at trial is rare, as there is no way to accurately determine which jurors will sit on a particular jury and how a particular jury will decide that case.

Where the defense has detailed proof regarding an incident, this information helps to support the defense calculation of settlement value. If the facts detailed in the accident investigation indicate that the facility is likely to be held liable, and that plaintiff did sustain the injuries claimed in the lawsuit, then the lawyers and insurance claims adjusters for the facility can undertake settlement talks with the plaintiff’s attorney immediately, saving defense costs.

These cases usually settle for more reasonable numbers if they are resolved quickly, as plaintiff’s attorneys almost always recognize the value of getting the money earlier and doing much less work to get it. The quicker that plaintiffs’ attorneys can get money for their clients, the more their clients will refer their friends, which leads to long-term success for those plaintiff’s attorneys. So accurate documentation can benefit both sides to a lawsuit.

The cop who didn’t follow protocol



Plaintiff police officer claimed that while she was patrolling the Brooklyn Bridge on an overnight shift, she came upon an active construction site on the Brooklyn end of the Bridge. She began to descend the stone stairs down to the street level near the site when she claimed she tripped over a tangle of electrical wires. The police officer claimed that the stairway from the bridge down to the street had not been blocked off. The accident, which occurred at the end of her shift at 4 a.m., seriously injured her left knee. The police officer called her precinct in Brooklyn for assistance. A fellow police officer arrived and drove the injured police officer to the hospital. This was contrary to police protocol which required injured police officers to return to the precinct to formally report the accident, which would have triggered an immediate investigation regarding the facts and circumstances of her injury.

The injured police officer underwent multiple knee surgeries, and retired, claiming that she could no longer work. Plaintiff never reported the accident to anyone at the construction site. A sub-contractor had been doing electrical work at that location. The general contractor was at a different area of the bridge and did not witness anything.

The cop who didn't follow protocol (cont'd)

During litigation, the police officer's attorneys exchanged a photograph showing a tangle of electrical wires on the stairway, which plaintiff testified accurately reflected the condition of the stairway at the time she claimed that she tripped and fell. Plaintiff testified that there were no witnesses to her accident. No one from the general contractor or the subcontractor knew anything about the accident. 3 years later at mediation, plaintiff's attorney made a very high demand for pain and suffering and loss for future earnings, due to the plaintiff's inability to find other work. Your settlement authority is to pay 10% of the number that plaintiff's attorney demanded. What do you do?

- The case must be tried as plaintiff's demand is unreasonable for this unwitnessed accident which plaintiff failed to report to the precinct.
- Obtain greater settlement authority as the case presents a "question of fact" for the jury which might decide in plaintiff's favor.
- Speak to the subcontractor workers involved with the work to try to find any missing evidence about what happened.

The cop who didn't follow protocol (cont'd)

Correct Answer

Meeting with the workers who had been on the job the night of the accident revealed that the tangle of wires on the stairway was a necessary part of their electrical work. All the workers there that night confirmed that, while the wires were on the stairway, the stairway was always blocked off so that no one could access them. But at the end of the electrical work at 3 a.m., the stairway was always cleared before reopening for the public at 3:30 a.m.

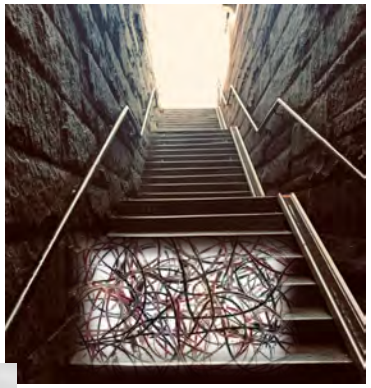
It appeared that the police officer, or someone on her behalf, had gone back on one of the following nights at a time while the construction work was being done to create a photo to support plaintiff's claim that the stairway looked that way at 4:00 a.m., even though the photograph was taken at an earlier time when the stairway was closed off.

This was not conclusive proof, but the police officer's attorney eventually accepted a settlement which was less than 10 percent of his former demand.

Documentation of accident investigation

Documentation of the accident investigation includes preserving:

- surveillance video from the premises/facility,
- photographs,
- post-accident video,
- detailed witness statements, and
- detailed statements from the person claiming injury.







Importance of documentation of details

Documenting the extent of injuries claimed shortly after the accident caused injuries or aggravated pre-existing injuries. Also, there may be questions as to whether the healthcare services which the plaintiff received, post-accident, were caused by the accident, or whether the services were solely related to pre-existing conditions, or that the services received were completely unwarranted.



Importance of documentation of details



EVERYBODY LOSES

A 4 -year-old girl in Brooklyn receives 50% second and third degree burns to her body. Her mother claims that she (the mother) was cooking a pot of beans on a stove, but was watching her other children outside the kitchen, when she heard the little girl scream. When the mother came to the kitchen, she said she saw that her daughter had opened the door to the oven and had stood on it which caused the stove to tip towards the little girl, spilling the simmering beans upon her. Litigation was quickly started. The plaintiff's attorney hired an expert to inspect the stove. He found that the stove was improperly installed without an "anti-tipping" device. After depositions of the mother and the manager of the premises, the case was placed upon the Court calendar to await trial.

Neither the defense attorney nor plaintiff's attorney had done much other work on the case. Six months before trial, plaintiff's attorney made a high demand for settlement, as what happened was a "question of fact" which a jury would have to decide.

Importance of documentation of details

If you were the person who had to decide whether to settle the case, what do you do?

- Call the plaintiff's attorney and see if she will make a lower demand.
- Retain a new, high-powered, attorney to review defense counsel's file to see if anything else can be done to defend or lower the settlement value or try the case if necessary.
- Meet with insurance claims supervisors to obtain sufficient authority to settle the case.

Importance of documentation of details

CORRECT ANSWER

All of the above.

The newly-assigned, high-powered, defense attorney interviewed all of the EMTs and police officers who responded to the accident. They were consistent that no mention of the stove tipping over was made at the time of the accident. The mother had told the first responders that her daughter had grabbed onto the handle of the pot of beans and pulled the pot over onto herself. When the jury heard this testimony at trial, they were convinced that the mother was lying.

A defense verdict was obtained.

Was this a success?

While it sounds like a success story for the defense, this was not. A different jury might have awarded several million dollars. The insurance company for the defendant took a big risk by trying the case.

The insurance company and the defendant would have been better served if this investigative information was ascertained early on. The plaintiff's attorney would likely have accepted a very reasonable settlement early on if she were aware of the problems with her case. The cost of settlement, early on, could have been less than the expenses of litigation.

The plaintiff's attorney was harmed by failing to uncover the deception by the mother of her client. The plaintiff's attorney spent a huge amount of time and effort trying this case. She paid out her own money for litigation costs and experts which she would never recoup. It would have been better off for everyone if the case had settled early on for a reasonable number on the basis of the inconsistency of the mother's story at deposition, compared to what the first responders said at trial.

Takeaways

Lawsuits often start years later, after memories have faded. Clear information about the details of the accident, and the complaints of pain and injury at the time of the incident are important.

- *Detailed statements include writing down what the person claiming the accident said happened, in quotes of the actual description by the injured party, if possible. Also make sure to write down all parts of the body which hurt or were injured.*

- *If the injured claimant does not return to work the next day, telephone the claimant and take detailed notes of what happened and the injuries, complaints and limitations and make a recording of what happened if possible. Save this evidence where it will not be lost, e.g., email it to multiple co-employees with supervisory responsibility.*

- *Identify and speak with all persons at the facility who were aware of what happened and document what they say happened before, during and after the accident.*

Thank you!



Questions?

bworden@namadr.com

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AHRMNY
The Association for Healthcare Risk Management of New York, Inc.

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Strategic Plan 2022-2024

CORE PURPOSE: To advance safe and trusted health care.

MISSION STATEMENT: To lead and represent health care risk professionals and support them with resources and knowledge to manage enterprise risk across the health care continuum

Goals

Goal 1: Advance Risk Professionals

Advance risk professionals by providing clearly defined learning pathways and valuable resources to position them to advance within their organizations.

Goal 2: Establish Authority in the Field

Establish authority in the field and drive innovation and change in the evolving health care environment by encouraging collaboration for diversity of thought.

Goal 3: Elevate the Profession

Elevate the risk management profession by leveraging AHA connections to reinforce the value of having a leadership-level risk professional as a trusted advisor.

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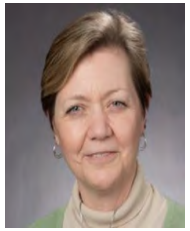
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ASHRM 2024 President Elect
Director of Compliance & Privacy Medically Home Group, Inc



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2024 New Advisory Board Member
Executive Director, Clinical Risk Management Services, Advent Health



Josh Hyatt, DHS, MBE, MHL, DFASHRM, CPHRM, HEC-C, CPPS
2024 New Advisory Board Member
Manager, Risk Management & Analytics at Coverys



Karen Garvey, MPA/HCA, BSN, DFASHRM, CPHRM, CPPS
2024 New Nominations Committee Member
VP, Safety & Clinical Risk Management
Parkland Health & Hospital System



Elaine Ziemba, MHA, JD
2024 New Nominations Committee Member
VP & Chief Risk Officer
Stanford Medicine Enterprise



Lisa Ramthun, RN, MSN, CPHRM, FASHRM, CPHQ
2024 New Nominations Committee Member
Enterprise Vice President Clinical Risk and Claims Management
Thomas Jefferson University Health

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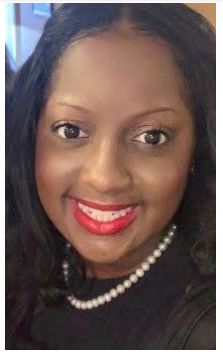
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Executive Director



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Creating meaningful learning, collaboration, and recognition

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Recognizing organizational excellence & celebrating individual success



North American Partners in Anesthesia "Anesthesia Risk Alert (ARA) Program"

Patient Safety Award 2023



Tracy L. Melina, DFASHRM

Health Care Risk Professional of the Year 2023



Margaret R. Garrett, JD, CPHRM, DFASHRM

Presidential Citation Award 2023



Georgene Saliba, RN, BSN, MBA, FASHRM

Distinguished Service Award 2023

"A Failure in the medication delivery system- how disclosure and systems investigation improve patient safety.""

Authors:
Scott R. Lucas, PhD, PE
Ed Pollak, MD, FASA, CPPS
Charles Makowski, PharmD

John C. West Writing Excellence Award 2023

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In Person Learning & Networking



> *The ASHRM Annual Conference is consistently the best source for qualified, credible and current information relevant to health care risk managers.*
>
> *- Past ASHRM Annual Conference Attendee*

Also, in-person:

- ***ASHRM Academy***
- ***ASHRM Express***
- ***Pre-con***

Annual Conference (virtual option as well,..)

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Publications addressing risk within 8 crucial domains





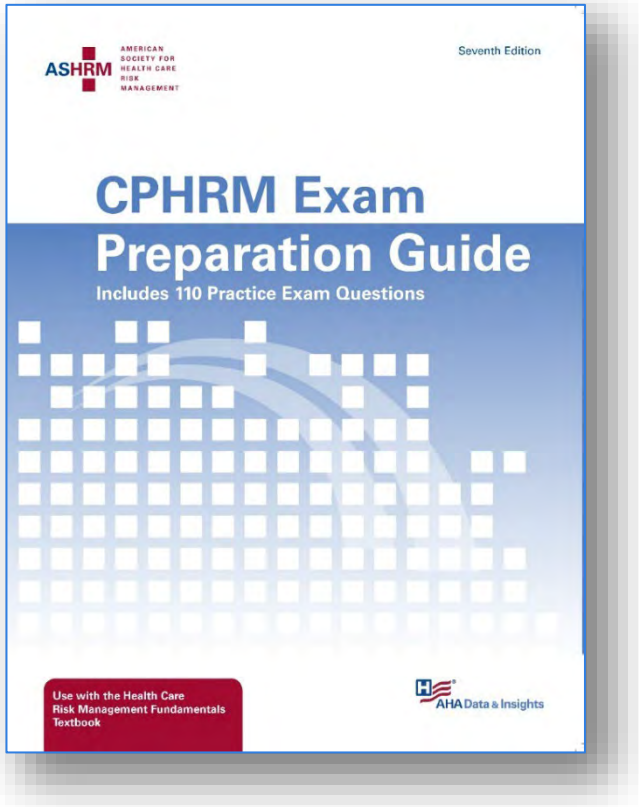
Ask the right questions of stakeholders, don't forget anything… & succession planning

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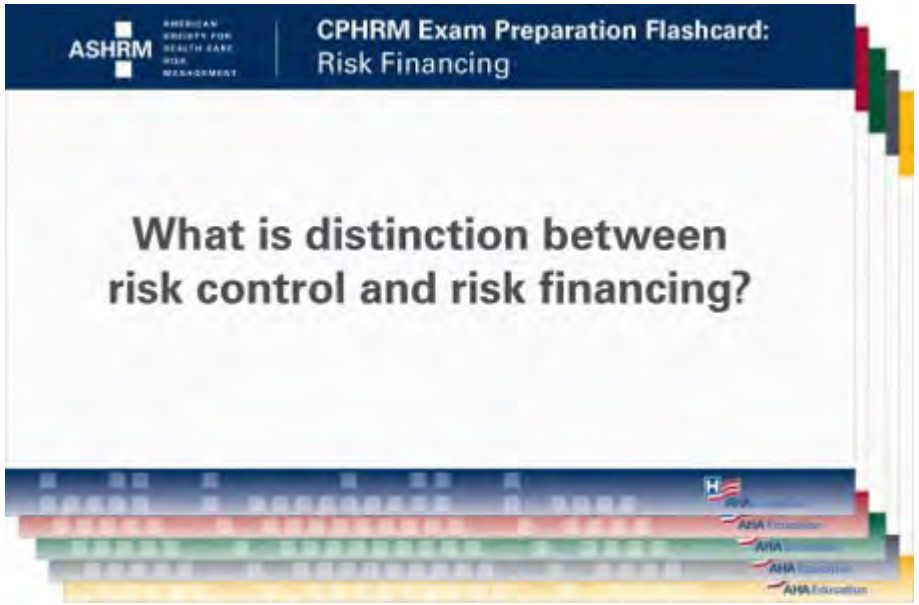
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A Space to Connect

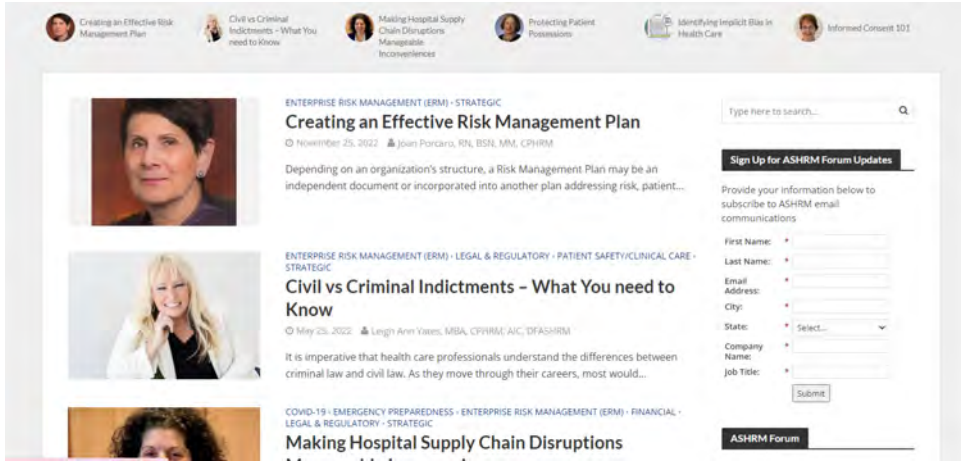
24/7 Access to Risk Management Advice

- Discussion Boards
- Resource Library
- Networking
- Member Directory
- Event Announcements
- Emailed Digest

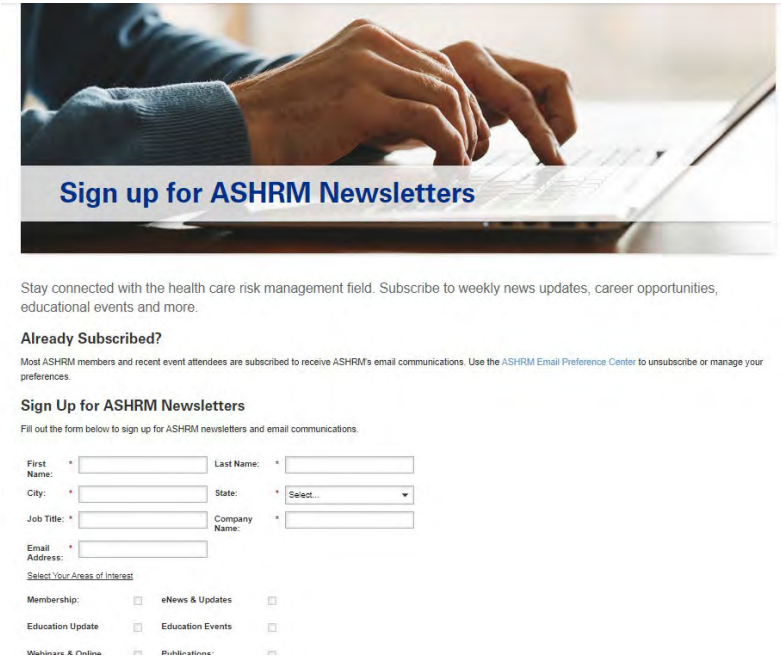


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Timely Content



ASHRM.org/Forum



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Award Winning Journal

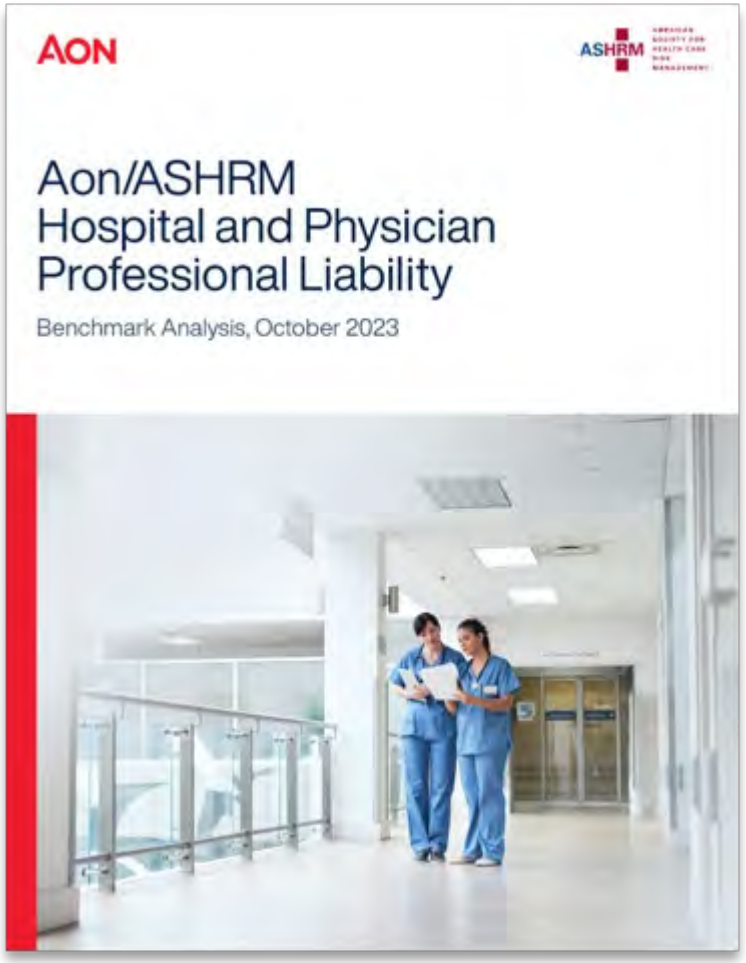
WINNER
2023
APEX®
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- Insightful, peer-reviewed content
- Published quarterly
- Opportunities for contributing
- Awards CEs
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Benchmark Report



- 2023 report is available
- 105 participating health care systems – collectively comprise 29% of the hospital exposures in the country
- A data-based tool for better estimating and understanding self-insured medical malpractice costs relative to those for your peers

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Resources for the C-Suite



Supporting Resources & Tools

ERM Quick Reference Tool

A two-page document to help keep the ERM domains and guiding principles top of mind Download Tool

Enterprise Risk Management: Readiness Assessment Tool

Gain insight into your organization's readiness to implement ERM practices, or the maturity of ERM initiatives already initiated with this helpful tool. Download Tool

ERM Enterprise Risk Management: Implementing ERM

For more in depth information and insight into ERM implementation, this white paper outlines the implementation of an ERM program, defines its key structural components in any health care setting, and will help to build consistency in your efforts to develop or move forward your ERM efforts. Download White Paper



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What Questions Do You Have?



MARSHALL DENNEHEY

Liability Risks of AI in Healthcare

Melissa Dziak and Matthew Keris

AHRMNY Fall Educational Conference

October 30, 2023

The Next Step in EMR Evolution

- Pre ChatGPT, $67.4 billion in projected spending by 2027 ($6.9 billion in 2021)
  - Artificial Intelligence in Healthcare Market by Offering (Hardware, Software, Services), Technology (Machine Learning, NLP, Context-aware Computing, Computer Vision), Application, End User and Geography - Global Forecast to 2027
- EMRs have ≥ 15 years of patient medical data to be leveraged
- Ultimate Goal
  - Attempt to have EMR system achieve human level decision making through application of algorithm to data
  - *Amazon* experience applied to medicine

Overview of AI Use in Health Care

- Patient Monitoring
  - Use of smart devices, watches and home assistants
- Administrative
  - Voice recognition technology for dictation to the EMR
  - Automated appointments; reminders; test results
- Computer Aided Diagnosis (CAD)
  - Computerized interpretation of imaging studies and pathology specimens
- Clinical Decision Support (CDS)
  - The chart is now a “tool” and not merely used to document
  - The chart can be considered a new participant in physician/patient relationship

Smart Devices Assist with Monitoring and Predicting

- Predicting/Reporting
  - Falls; acute medical emergencies; diagnosis; tracking infectious diseases.
- Monitoring
  - Listening devices; cameras; bluetooth medical devices (EKGs, Glucose, Pulse Oximetry);wearables.
- Virtual hospitals
  - Nurses and doctors talk with and monitor patients by looking at screens with graphs of data from the patients
  - No beds, all patients monitored remotely
  - AI surveillance algorithms pick up warnings and alert the clinicians

Dependency Breeds New Responsibilities

- Recommended Checklist for Patients Using Devices
  - Calibration
  - Training
  - Vulnerability/security/malware
  - Internet/WiFi/cellular access
    - How good?
    - Can you afford?
  - Battery health
  - Documentation—how to prove the above?
  - Device preservation when claim is anticipated
  - *Unique partnerships developing—Geisinger and Best Buy's Geek Squad?!*

AI and Medical Dictation

- Siri/Alexa dictation later reviewed by others for medical accuracy
  - Pro
    - Frees physician to focus time on patient
    - A way to help with physician dissatisfaction with EMR
  - Con
    - 95% accuracy still not good enough in medicine:
      - Recording background
      - Microphone use
      - Language accents
      - Use of medical/text abbreviations
- Will physicians proofread their work, or will they rely on others to correct their documentation errors?

ChatGPT—Natural Language

- At core, it predicts next words to use in responding to an inquiry
- Made public—investors included Microsoft, Musk and the usual suspects
- Use has skyrocketed
- ChatGPT technology now being integrated in other platforms
- "Our world will look completely different by Christmas 2023"-Prof Dan Katz, University of Chicago School of Law
- Will probably assist with documentation.
  - Caution: ChatGPT can make things up and lie
  - What is healthcare providers' information and what is AI's contribution?
  - 20th Century concept still applies—will doctors proofread?

Examples of Clinically Significant Dictation Errors

SR Technology	Intended
Verapamil 4 mg po daily	Rapamune 4 mg po daily
Adequate evaluation to exclude neoplasia	Inadequate evaluation to exclude neoplasia
Allergies: Yellow dye	Allergies: Furosemide, gabapentin, oxcarbazepine, yellow dye
The patient did agree with this recommendation	The patient disagreed with this recommendation
There is no distal biliary obstruction observed	There is distal biliary obstruction observed

Zhou et al, 2018

Automated Communications/Scheduling

- Will automated scheduling/test results/reminders further erode the physician/patient relationship?
  - Elderly patients and inability to have online relationship
    - Cost/familiarity with online communications/lack of smartphone
  - Reminder fatigue
  - Will patients believe what they want to hear if they get an incorrect or contradictory test result?
  - Will scheduling take into account acute medical visits between routine appointments?
    - Mixed messages to patient if scheduling not changed after interim acute visit

Health Care Risks With CAD

- Early success with imaging and pathology
  - Improved accuracy
  - Reduced human workload
  - In some instances, AI is better than humans

- AI fooled by image tampering attacks
  - UPMC submitted false mammography images and fooled AI 69% of time; humans 71%
    - https://www.upmc.com/media/news/121421-wu-ai-safety

Health Care Risks With CAD

- Training
  - Will the next generation be as honed as their predecessors if CAD-dependent?
- Reviewer bias
  - Initial positive finding by AI can increase number of false positives
  - Initial negative finding may provide false assurance that study is normal
  - May need three reviews to be certain of read (computer; human reviewer with results of computer finding; final human blind review)

Warning with AI

ECRI's Top 10 Health Technology Hazards for 2022

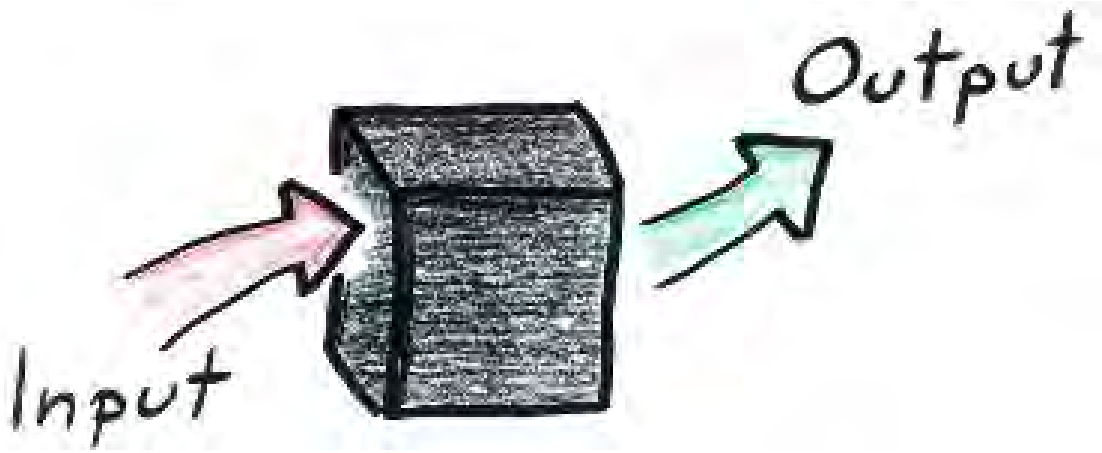
- Number Seven – AI Based Reconstruction Can Distort Images, Threatening Diagnostic Outcomes
  - Problems are not rare
  - Can be triggered by normal anatomical variations or patient movement

The *Amazon* Experience: Clinical Decision Support (CDS)

Two AI Components

- EMR Data
  - Patient demographics; disease process; treatment provided; care results
- Algorithms
  - Equations applied to EMR to diagnose or provide treatment
  - Sometimes referred to as the "*black box*"
    - *Makes complex decisions without explaining rationale*
    - Complicated as variables are added to the algorithm

The Black Box



Early Results of AI-Supported Diagnosis

- Computer algorithm scanning echocardiograms increased cardiac death risk prediction accuracy by 13%.
  - Geisinger Researchers Find AI Can Predict Death Risk, Geisinger News Release, Feb. 8, 2021, https://www.geisinger.org/about-geisinger/news-and-media/news-releases/2021/02/08/20/10/geisinger-researchers-find-ai-can-predict-death-risk
- AI accurately predicts patient mortality for patients facing a transfer to a facility to obtain higher acuity care
  - UPMC Develops AI Tool to Predict Mortality for Patients Facing Hospital Transfer, Beckers Hospital Review, Feb. 8, 2021, https://www.beckershospitalreview.com/artificial-intelligence/upmc-develops-ai-tool-to-predict-mortality-for-patients-facing-hospital-transfer.html
- Algorithm trained to predict pain levels from x-rays corroborated increased reports of pain that human reviewers did not not see.
  - Pierson, E., Cutler, D.M., Leskovec, J. *et al.* An algorithmic approach to reducing unexplained pain disparities in underserved populations. *Nat Med* 27, 136–140 (2021). https://doi.org/10.1038/s41591-020-01192-7

Implications Of CDS

- Pros
  - A computerized “second opinion” can reduce medical errors
  - Better care
  - Shorter hospitalizations
  - Less claims
- Cons
  - As long as AI is used to augment (*not replace*) a physician’s decision making, there is no real clinical downside
  - However, CDS is not immune from bias and error
  - Little FDA oversight in CDS adoption

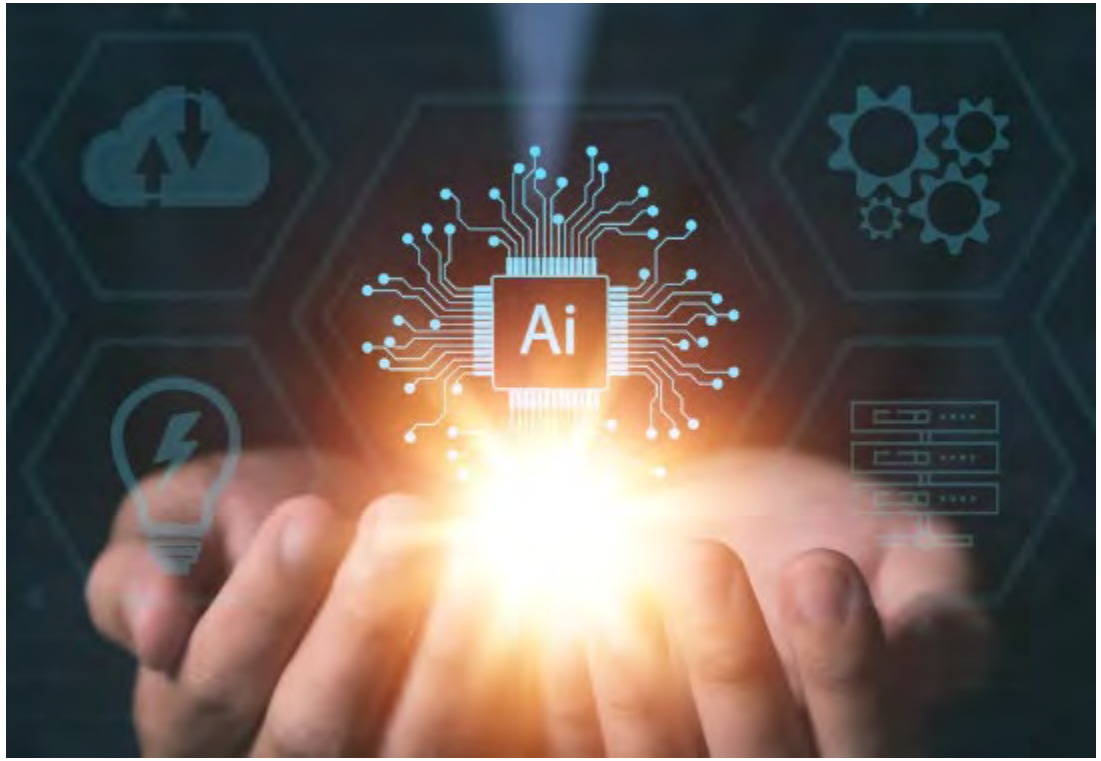
Lack of FDA Oversight Requires Greater Scrutiny on AI Adoption and Results

- CDS can evade FDA oversight altogether
  - Certain software not considered a “medical device” so not reviewed
  - “Medical devices” can be fast-tracked FDA approved with less transparent 510(k) exception (no clinical trials)
- Result
  - U of Michigan researchers determined that Epic’s Sepsis Model (ESM) in identifying sepsis missed 67% of sepsis cases and had frequent false alarms contributing to alert fatigue in clinicians.
  - Contributes to skepticism towards AI by HCPs.
    - External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalized Patients; JAMA Intern Med 2021 Aug 1; 181(8):1065-1070. doi:10.1001/jamainternmed.2021.2626

Giving Pause to CDS

- STAT Health and the Massachusetts Institute of Technology conclude AI could do more harm than good
  - *Subtle shifts in data fed into popular health care algorithms can cause their accuracy to plummet over time*.
  - "The signs of dysfunction are often faint, making it difficult to root out faulty information before it bleeds into decision-making."
    - Stat and MIT rooted out the weaknesses in well being care algorithms. Here's how we did it. www.statnews.com/2022/02/28/data-drift-machine-learning, February 28, 2022

MARSHALL
DENNEHEY



NEW YORK

AI in NY

The Icahn School of Medicine at Mount Sinai

First Department of Artificial Intelligence and Human Health:

AI is predicting malnutrition, delirium and ICU admission and Chatbot communicates directly with patients regarding symptoms and subsequent treatment (office visit vs ED presentation)

New York City Health + Hospitals

Algorithm to canvass brain scans of stroke patients quickly flagging patients who are candidates for thrombectomy

AI in NY

Rensselaer Polytechnic Institute and **Albany Medical College**

$3.3 million grant in May 2023 by National Cancer Institute to use AI to improve targeted drug therapy in breast cancer treatment

Albany Medical Health System, Crouse Health (Syrcause), Kaleida Health (Buffalo)

Currently using **Viz.AI** computer-aided triage system to facilitate early detection of strokes and access to advanced care for treatment

AI in NY

Cornell and **New York-Presbyterian**

Weill Cornell Medicine and Columbia University entered into a $15 million collaboration agreement to employ AI for use in improving outcomes for people with cardiovascular disease

Northwell Health

In 2023, Northwell launched an AI-enhanced pregnancy chat app to screen patient symptoms, provide personalized advice and connect them with a healthcare workers or prompt them to call 911

AI in NY

University of Rochester Medical Center and Rochester General Hospital

AI technology used to read mammograms to assist in detecting tumors in dense breasts

University of Buffalo

QAS.AI software uses live video data analysis during operations on intracranial aneurysms to provide neurosurgeon with date and predictions to help surgeon make real-time, informed decisions

The New Litigation Realities

To err is human, to really foul things up takes a computer.

- Paul Ehrlich, *The Farmers' Almanac* (1978)

Physicians Will Make Errors Based on AI Recommendation

- Health care providers will remain primarily accountable
  - New defense?— *"Reliance on AI recommendation was reasonable under the circumstances"*
- Potential class action if large patient population injured due to AI-based treatment recommendation
- The focus will then shift to the institution with respect to the AI
- Informed consent for use of AI in HC?

AI Vendors—Friend or Foe?

- Reluctance to assist defense
  - Disclosure of negative proprietary information
  - Costs/time associated with participating in defense
  - Even more reluctance if the vendor is no longer associated with defendant
- Joinder of AI/Algorithm vendor as a defendant?
  - Can/should you join vendor?
    - “Garbage in/garbage out” vendor defense – scrutiny on documentation to defend algorithm
    - It may already be too late—indemnity provision in contract?

The EMR is Now a “Medical Device”

- *Lowe v. Cerner:*
  - Clear charting error regarding continuous pulse oximetry monitoring
  - Doctor claims she was confused; picked “lesser of two evils”; was not properly trained on EHR; wishes she had been trained
  - Medical malpractice case settles; products liability case then pursued against EHR vendor; Plaintiff survives MSJ in products case
- Things to Come:
  - Increased requests for live interaction with EHR
  - Focus on EHR training and HCP competency
  - Joinder of EHR vendor?

AI Information Will Be the Next Audit Trail Request

- Will require even greater collaboration with attorneys, risk management, medical records, IT and software engineers
- More expensive to produce/explain with no upside
  - Who/what/when/where of algorithm and changes thereto?
  - Who is maintaining archived algorithm?
  - How will algorithm be produced?
- Lack of legal precedent
- Will your judge want to be educated on these issues?
- Who will provide testimony on algorithm use/creation?

Physicians Will Disregard AI Recommendations

- Reluctance to Accept AI Recommendations
  - Generational bias or bad initial experience
  - If not considered, it can support criticism that physician failed to utilize all tools offered to ensure proper care
- AI may fatigue EMR users
  - We see this already with “warning fatigue” resulting in workarounds

Some Will Over Rely on AI Recommendations

- Unnecessary, incorrect or excessive treatment
- New criticism that health system knew or should have known its physicians routinely deferred to AI, rather than make their own decisions
- We know from EPIC that AI recommendations are not immune from scrutiny
  - Cal Berkeley School of Public Health reported that algorithm guiding diabetic care gave Caucasian patients priority of treatment over minorities.
    - *Widely Used Health Care Prediction Algorithm Biased Against Black People*, Berkeley News, October 24, 2019.

There Will Be Fallout When AI was Correct and Physician Was Wrong

- No-Win Scenario for Health System
  - AI is a built-in expert for plaintiff against the physician
  - Making things worse, health system can be liable (vicarious/ostensibly) for actions of physician
  - If that isn't enough, unified defense with doctor and institution in jeopardy

Anticipated Institutional AI Liability Issues

- Large patient population injured due to AI-based treatment recommendation may lead to class action
  - Constant need for retrospective evaluation because of “black box”
- Health system can be criticized that they knew or should have known that physicians were intentionally disregarding AI-based recommendations
- New criticism that health system knew or should have known its physicians routinely deferred to AI, rather than make their own decisions
- Dual exposures for HCP and system when AI right and HCP wrong

Last Thoughts About AI in Healthcare

- Stay on top of AI--its growth and use is growing lightning fast.
- Maintain history of changes to EMR platform and “black box.”
- Documentation on AI interaction will be difficult.
  - *This is all new and EMR templates lack standards for AI and physician interaction—particularly when AI recommendation is rejected.*
- Use of your QA AI—will it be discoverable?
- Be mindful of patients and the need to share how AI is being used.
- In the distant horizon--the Plaintiff’s lawyer’s request to have their AI review your data!
- How will jurors perceive AI in healthcare?

THANK YOU!

Matthew P. Keris, Esq.
570.496.4602
mpkeris@mdwcg.com

Melissa A. Dziak, Esq.
570.496.4618
madziak@mdwcg.com

Risk Management and Defense Counsel

Gina E. Kittek, MJ, CPHRM

Jury Selection and Trends/Risk Managers in the Courtroom

Terry O’Connor

Risk Management and Defense Counsel

- A match made in heaven
- How we became prom dates



Unified Defense

- One primary defense counsel firm
- All defendants (if no conflicts)
- Shared expenses among entity and employed providers



Defense strategy

- Defend cases with no liability
- Settle cases early when liability is evident



Partnership & Communication

- Risk Management, Insurer and Defense Counsel
- Very important to work together and communicate



Insurance Program and Organizational Structure are relevant

- Captive: Entity, staff, residents and some providers (primary and excess)
- Commercial carrier: Medical Group providers



RFP for Commercial PL Carrier – Medical Group

- Understood and agree to single defense counsel strategy with partnership with Risk Management otherwise eliminated from selection process



Benefits of one primary Defense firm:

- Understand our corporate structure
- Awareness of defense philosophy
- We know what each other needs
- No need to re-educate a new firm with every case
- Back up counsel is the same as well
- All counsel used are on panel counsel with commercial carrier



Jury Selection and Trends/Risk Managers in the Courtroom

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“Never forget almost every case has been won or lost when the jury is sworn.”

- Clarence Darrow



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What colors do you see?



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COVID Concerns

- Over a million deaths have been reported in the United States.
- Initially, “aura of goodwill”.
  - Healthcare heroes.
  - Nurses and dentists/doctors were initially seen as heroes.
  - This seems to have worn off.
- Post-COVID Jury Research/Post-Trial Interviews – Hospitals are irrationally blamed for contributing to the COVID mess.



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Scientific evaluation of juror damage awards post COVID

- COVID-19 Aftermath – Heightened state of emotion – These jurors are less cognitive and more prone to gut decisions.
- Overreliance on emotion has led to speculation that post-COVID damage awards may increase because juror empathy and sympathy.
- Contra Review – Damage awards may actually decrease because jurors may view pain and suffering as insignificant compared to others.
- Regardless, the likelihood of nuclear verdicts have not diminished.

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COVID/Bipolarization of Society

- COVID pandemic has exacerbated skepticism towards scientists and medical experts.
- Fauci example.
- Increased Stress and Uncertainty – Leads to further polar
- Stress/Fear – Reinforces
-
- mode/









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Millennial Jurors

- Increased presence in the jury pool.
- Lack of elderly jurors.
- It is all about the internet.
- Give-a-sh!t meter is low.
- Gaming generation.
- The ESPN juror.



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Sampling of Verdicts Since 2000

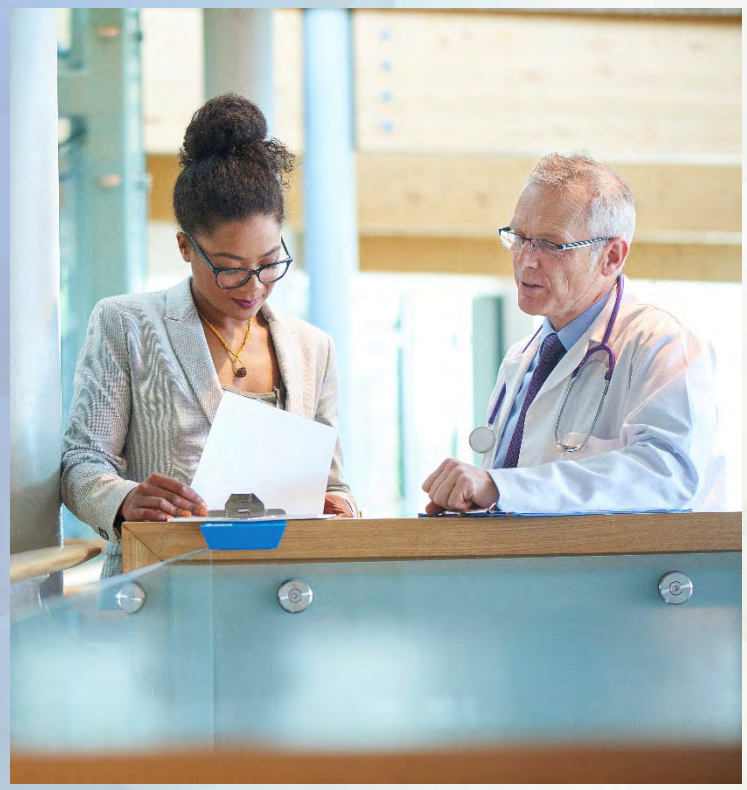
- **$185 million** – *Erickson, et al vs. Monsanto.*
- **$43 million** – *Lipp v. Philip Morris.*
- **$13.5 million** – North Country New York (Jefferson Supreme).
- **$8 million** – Albany, New York.



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Hospital Representatives/Clients in the Courtroom During *Voir Dire*

- Upstate versus Downstate
- Local flavor with jury selection
- Caring/competent/conscientious
- The flesh and blood of the hospital
- Using the hospital representative as a prop
- Make sure to prepare the hospital representative



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Rules of the Road



- Enjoy *Voir Dire.*
- Relax.
- **Shut up and listen** – 90/10 rule.
- Identify leaders out of the chute and have them talk first.
- Never interrupt.
- Always lower barriers.
- Always advise them there is no correct answer.
- Honor the answer.
- **Don’t ask for promises**.

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Stealing The Reptile

- Please tell me.
- Please tell me more.
- Some folks/other folks.
- Which are you closer to, even if a little?



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Voir Dire – You are on their side

- Ask about fears of being on a jury.
- Ask about their own confidence to learn the case in the midst of unfamiliar rules and procedures.
- Ask about times in their life that they were thrust into a new situation and how they handled it.
- Harvard study.



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Introduction

- Introduce myself and client.
- No bad answers – Lower the bar.
- Case-specific questions.



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Employment Questions

- What is your workday like?
- Tell me what makes you like your job?
- What makes you good at your job?
- What supervisory roles and/or leadersh roles do you have at your job?
- Ascertain entire employment history.



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Other Broad-based Questions

- Tell me what you do when you are not working - evenings/Saturdays/Sundays.
- What makes you good at being a parent?
- Other than honesty, what is the best thing that you learned from your parents?
- Other than honesty, what is the best thing that you have taught your children?
- Children – Tell me about them.
- Values – What are the most important values that you have passed on to your children?



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Case Specific Questions

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Medical Treatment



- Tell me what types of medical treatment and/or medical procedures you have had in the past and your experiences in this regard.
- Complications/side effects.
- Some people think that medical procedures can cause complications/side effects without anyone doing anything wrong. Other people think that, if there was a complication/side effect, someone must have done something wrong. Which are you closer to, even if a little?
- Tell me more.

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Surgical Procedures

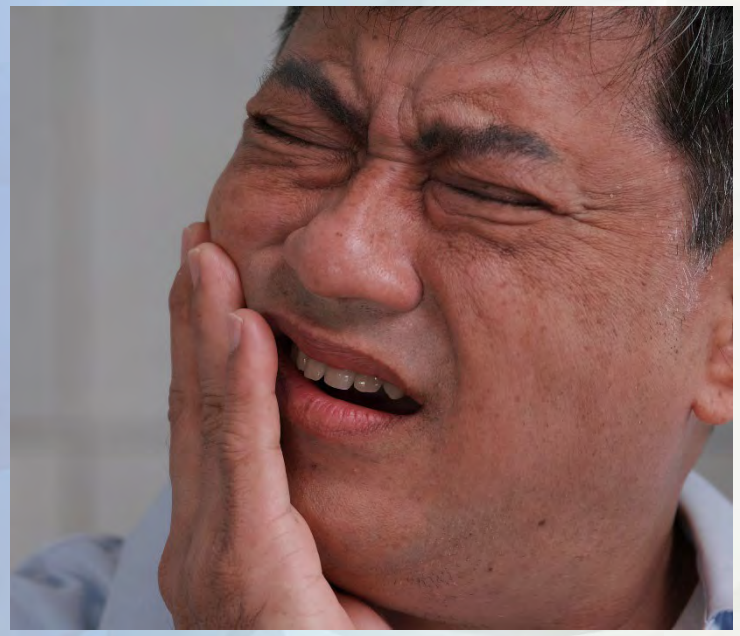
- What types of surgery have you undergone?
- Complications.
- Some people think that a surgical procedure can have complications without a doctor having done anything wrong. Other people think that if there was a complication, the doctor must have done something wrong. Which are you closer to, even if a little?
- Tell me more.



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Nerve Injury

- This whole case revolves around a nerve injury sustained by the plaintiff.
- Some people might think that if someone suffered a nerve injury during a dental procedure, the dentist must have done something wrong. Other people might think that a complication such as a nerve injury can occur without dental malpractice and/or as a recognized complication. Which are you closer to, even if a little?
- Tell me more.



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Cancer

- Have any of your or your family been diagnosed with any type of cancer?
- Oral cancer?
- Some people think that if a patient has cancer and it wasn't immediately diagnosed by the doctor – then the doctor must be at fault. Other people might think that cancer might be a difficult diagnosis to make and that a delay in diagnosis is not necessarily the doctor's fault.
- The same basic questions can be applied to a failure to diagnose an infection.



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Medical Anesthesia Consent Form

- Have you signed such a form before?
- Tell me about that.
- Some people think that if a patient signs a medical consent form, they should review that form and educate themselves as to the risks and complications. Other people might think that a patient does not have a duty to read the form and that signing the consent form is just a formality. Which are you closer to, even if a little?
- Tell me more.



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Science/Medicine is the Key to a Defense Verdict

- You will be hearing expert testimony in this case from a board-certified surgeon who will address the issue of standard of care.
- Some people believe that expert testimony from a board-certified surgeon is important to arrive at a verdict in a case such as this. Other people might think that testimony from an expert is not as important.
- Which are closer to, even if a little?
- Tell me about that.



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Hospital/Physician Specific *Voir Dire*



- Some people think that the medical profession/ hospitals provide quality medical care. Other people don't think so. Which are you closer to, even if a little?
- What bothers you about the way medicine is practiced today, if anything?
- Some people think that doctors/hospital personnel listen carefully to their concerns. Other people think that is not the case. Which are you closer to, even if a little?
- Some people think that medical care has gotten much better over the past decade. Other people think that is not the case. Which are you closer to, even if a little?
- Some people think that doctors take their concerns seriously. Other people think that is not the case. Which are you closer to, even if a little?

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Hospital/Physician Specific *Voir Dire* *continued*

- Complication – Some people think that just because a patient suffered a complication (nerve injury/late diagnosis of cancer/anesthetic complication) during the course of a procedure/treatment that they are entitled to monetary damages. Other people think that is not the case. In other words, the complications and injuries can happen without someone doing something wrong and, therefore, patients are not entitled to money. Which are you closer to, even if a little?
- Some people think that doctors/hospital personnel are up to date in their field. Other people think that this is not the case. Which are you closer to, even if a little?
- Some people think that doctors/hospital personnel spend an appropriate amount of time with their patients. Other people think that this is not the case. Which are you closer to, even if a little?



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Hospital/Physician Specific *Voir Dire* *continued*

- Some people feel that when there is more than one doctor/nurse/technician involved in their care, these people do not always communicate with each other. Others say that this is not their experience. Which are you closer to, even, if a little.
- Some people feel that their doctor/clinic/hospital gives them sufficient information. Others say that this is not their experience. Which are you closer to, even if a little?
- What do you wish your doctor/hospital would do that they are not doing?
- What makes you a good patient?



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Poisoning the Jury

- Anyone here ever sign a medical consent form?
- Who here has ever kept something important from their own dentist/doctor?
- Does anyone think it is okay for a person to exaggerate trying to get a jury to give them money?



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Dos and Don’ts

- Don’t be lawyerly/no legalize.
- Don’t wear power clothes.
- Don’t forget the silent juror.
- Don’t ask people to speak up.
- Listen and nod.
- Do not ask closed-ended questions.
- Do use the juror’s answers as follow-up questions.
- Do not cross examine.
- **Do not seek promises/guarantees.**
- **Ears like an elephant and sh!t like bird – 90/10 rule revisited.**



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Illegitimi non carborundum!

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Upstate AHRMNY

Healthcare Resource Management: A Patient Safety Crisis



Panelists:

Cody Baldwin, MBA, MSN, RN, CNOR

Karen D. Tunis-Manny, Esq.

Susan Starr

Moderator: Joyce McCormack, Senior Risk Management Consultant

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Opening remarks

- **New York's healthcare industry is facing an unprecedented resource crisis:**
  - Our panel discussion will offer insight into identifying the significant state-wide resource challenges affecting the healthcare industry; how these resource challenges impact patient safety and the financial strength of healthcare organizations; and the risk management strategies you can implement to maximize patient safety and minimize the professional liability risks associated with managing resource challenges.

Cost of Care Report

April 2023

- **Overall hospital expenses increased 17.5%:**
  - Medicare reimbursement only increased 7.5%
- **Overall hospital labor expenses increased 20.8%:**
  - Labor expenses per patient increased 24.7%
- **Temporary contract labor rates were up 258% in 2022:**
  - Rates hospitals were charged for contract employees increased 56.8%
- **Drug expenses per patient increased 19.7%:**
  - This exceeds 18% when accounting for patient case mix and acuity, suggesting the increase stems from drugmaker pricing strategies

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https://www.beckershospitalreview.com/finance/hospital-costs-then-and-now-14-numbers-to-know.html

Cost of Care Report

April 2023

- **Purchased services expenses (i.e.: IT, food and nutrition, and environmental services) increased 18%**
- **Food and nutritional expenses per patient increased 15%**
- **Hospital supply expenses per patient increased 18.5%:**
  - Emergency departments saw these costs increasing 33%
- **Laboratory expenses per patient increased 27.1%:**
  - Emergency department saw these costs increasing 31.9%

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https://www.beckershospitalreview.com/finance/hospital-costs-then-and-now-14-numbers-to-know.html

Cost of Care Report

April 2023

- **"This is not just a financial problem; it is an access problem. When healthcare providers cannot afford the tools and teams they need to care for patient, they will be forced to make hard choices, and the people who will be impacted the most are patients."**

AHA President and CEO Rick Pollack

- Our discussion today will be focused on supply chain, staffing and medication shortages

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https://www.beckershospitalreview.com/finance/hospital-costs-then-and-now-14-numbers-to-know.html

Meet the Panel

- **Karen D. Tunis-Manny**
  Buffalo Medical Group
- **Cody Baldwin**
  Cayuga Medical Center
- **Susan Starr**
  Adirondack Medical Center



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Supply Chain

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Supply Chain

- **If we learned anything from the pandemic, it is that we must be prepared, should another catastrophic event happen:**
  - The pandemic did shine a light on the importance of supply chains to an organization
  - Supply chain endeavors require an investment as in any other operating department
- **Savings must always be a priority**
- **Not just about saving money:**
  - Time saver for all if staff are not searching or even having to think about finding the supplies they need to do their job
  - Look to technology for assistance in these endeavors

Supply Chain

- **In looking at your organization's supply chain issues, can you discuss:**
  - What was the item/issue?
  - What was its impact on daily operations and patient safety?
  - What was done to remedy the situation?

Supply Chain

Adirondack Health

Materials Management team does a great job with supplies



Pictured from left are the members of the Materials Management team, including (back row) Karen Dekkers, John Druce and Eric LaQuay; (front row) Joe Aveni, with Director Courtney Reynolds, Joanie Corliss, Julie Walker and Eric Sternberg. Paul Wood and Janice Chester are missing from the photo.

Pandemic changes the world of supply chain

Supply Chain

Risk Management Strategies

- **Have a goal of getting the right talent interested in supply chain management:**
  - Tap into materials management in the organization
  - Always look for opportunities to reward and advance from within
- **Always:**
  - Integrate inventory management
  - Redefine visibility and transparency
  - Plan proactive
  - Collaborate freely



The Staffing Shortage

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The Staffing Shortage

- **The critical nursing shortage in the United States is going to get worse—much worse….**

  National Council of State Boards of Nursing and the National Forum of State Nursing Workforce Centers study released on April 13, 2023

- **About 800K nurses say they intend to leave the workforce by 2027:**
  - 24% of which will be new, younger nurses
  - Typically see this more with nurses at or near retirement age
- **Equated to 1/5 of the 4.5 M nurses we have today**

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The Staffing Shortage

- **Around 100K nurses were lost during the pandemic years:**
  - Workload increased (62%)
  - Feeling emotionally drained (50.8%)
  - Used up (56.4%)
  - Fatigued (49.7%)
  - Burned out (45.1%)
  - At the end of their rope (29.4%)
    - Reported a few times a week or every day

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https://www.beckershospitalreview.com/nursing/crisis-looms-as-800-000-more-nurses-plan-to-exit-workforce-by-2027-study.html?origin=QualityE&utm_source=QualityE&utm_medium=email&utm_content=newsletter&oly_enc_id=1693D9222956C8U

The Staffing Shortage

- **Over 145,200 clinicians exited the workforce in the past two years (2021—2022), with physicians at the head of the line:**
  - Nearly 7% of the country's active physician workforce of 71,300 doctors
- **Reasons cited include:**
  - Concerns about Covid-19 infections
  - Untenable hours
  - Emotional toll and stress
- **By the numbers:**
  - 8700 internal medicine
  - 7800 family practice
  - 6000 clinical psychology

Definitive Healthcare Report, Fierce Healthcare, 10.18.2023

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The Staffing Shortage

- **By the number$:**
  - Decreased HCAHPs scores = decreased reimbursements by CMS
  - Patient falls ($17,500)
  - Pressure injuries ($37,800)
  - The average cost of turnover for a staff RN ($52,350)
  - Over the course of the pandemic, staffing shortages have cost hospitals ($24B)

The Staffing Shortage

- **From a staffing perspective, what have you had to do to keep essential services going?**
  - What was successful?
  - What still needs to be done?

- **What impacts have you seen this particular issue have on staff morale and operations?**

- **Are there any particular achievements/solutions you have had in addressing this issue at your home base?**

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BMG V.I.B.E.



BMG Medical Director swims for a good cause: Raised $5600 for the Alzheimer's Association
$1 for one try, $5 for 6, and $20 for an instant dunk

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Cayuga Medical Center: CHESS program



Tier A (50 each)	Tier B (30 points each)	Tier C (20 points each)
Med Surg CMC	ICU	Vascular Access
BSU	NICU	PMRU
ED CMC	ED Psych Nurse	ED CN/Triage
Endo	SNF	
ED SH	MED-SURG Schuyler	House Supervisor
L&D	Mother Baby/Ped	CMA Outpatient Services
OR CMC		
OR SH		
		6/27/2023

Points system used to enter the CHESS program

The Staffing Shortage

Risk Management Strategies

- **Restore that sense of passion that drew staff to healthcare**
- **Consider incentives that attain organizational commitment**
- **Clinicians want to work and have work/life balance:**
  - Working professionals want more flexibility (96%)
    - Expect flexibility about as much as they do a 401(k)
- **The importance of flexibility in staffing solutions:**
  - Adopt a gig economy to staffing, using real time technology and apps:
    - Attract younger talent—increases the size/length of learning curves
- **Allow everyone to work at their full licensure:**
  - This allows PAs, NPs, and RNs to focus on the care they uniquely provide

The Staffing Shortage

Risk Management Strategies

- **Build your own internal staffing program or "agency":**
  - Offer flexibility to existing employees as a retention tool or attract new staff seeking short-or long-term contract work or gig work
- **Tap into your community's workforce for those who are:**
  - Searching for flexible work arrangements
  - Home between travel assignments
  - On contract in your area
  - Returning to the workforce
- **Untapped resources:**
  - Men - overcome gender stereotypes in nursing

Pharmacy and Medication Shortages

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Pharmacy and Medication Shortages

- **Supply is not meeting demand:**
  - Oversimplifies the issue at hand:
    - Shortages of raw materials used in compounding
    - Market concentrations
    - Labor issues
    - Natural disasters
  - When talking medications, care delivery is at risk:
    - Alternatives may not work as well
    - Substitutions may not exist
    - Hard decisions may have to be made
  - Liability standpoint: Does this align with the standard of care?



Pharmacy and Medication Shortages

- **How have drug shortages impacted the care you provide?**
  - How has your pharmacy addressed these shortages?
  - What of your providers?

- **Were you able to leverage your connections/relationships with other organizations to address some of these issues?**

Pharmacy and Medication Shortages

Risk Management Strategies

- **Patient safety and medication management go hand in hand:**
  - Leverage AI to assist with all aspects of medication management, from supply and administration to patient teaching:
    - Improved error detection
    - Stratify patient information
  - Standardize all processes:
    - Allows for deviations to be identified in real time
  - Engage a multidisciplinary tactic to resolutions:
    - Improve staff situational awareness:
      - Communicate on hand supplies, especially for at-risk medications (antibiotics, analgesics, cancer therapies and treatment)
      - Strive to approach from a proactive and not reactive posture

The Risk Management Trifecta

Risk Management Strategies

- **Documentation:**
  - Notes and records should always endeavor to “tell the story”, regardless of the subject matter
- **Communication:**
  - Skills here are a critical part of setting and managing realistic expectations
  - Define acceptable modes of communication and document all exchanges
- **Follow-up:**
  - Important part of accountability, responsibility and moving forward
  - Track actions taken as this will always be your best defense in a legal action

Thank You!

Joyce McCormack, Moderator

Senior Risk Management Consultant

MLMIC Insurance Company

jmccormack@mlmic.com

518.786.2816

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a Berkshire Hathaway company