Transparency, Disclosure and Early Resolution of Adverse Events

Jonathan L. Gleason, MD

VP, Clinical Advancement and Patient Safety

DISCLOSURES

I have no personal or professional financial relationships or interests with any proprietary entity producing healthcare goods/or services.

OBJECTIVES

- Describe and understand the evolution of healthcare from “deny and defend” to transparency and disclosure.
- Describe and understand the barriers to disclosure.
- List the steps of disclosure of medical errors.

Whence We Came…

Face of End Result Card

Name Mr. Edward James Gallison — Age 48 — M. W. S. — Date of Adm. 5|2|14 — Date of Operation 7|7|14 — Hosp. No. 201

Add. of Pt. 50 Crescent St., New York City, N.Y.

" " Pt's Phys. Dr. E. M. Black, 16 Grove St., Boston.

Perm. Add. of Pt's Fr'nd Mrs. George White, Elm St., Salem, Mass.

Prem. Diag. Duodenal ulcer, with grave doubt of cancer of pylorus and stomach.

Post-op. Diag. Ulcer lesser curvature of stomach about an inch from pylorus. Felt very hard and suggested cancer.

Came for relief of Epigastric pain soon after meals since September. Vomiting. Achlorhydria. No hematemesis but some melena.

Opr'r O. N. Meter. Asst. E. W. Jones and E. E. Cobb.

Anes. Ether and local novocaine. Ether by E. E. Lord.

Tumor size pigeon's egg on lesser curvature of stomach. Partial gastrectomy. Gall bladder felt as if full of stones. Duodenum normal except for slight induration of pylorus. Closed without drainage.

Compl. of Convales. None. Except that during convalescence he vomited several times without apparent cause.

Aut. No. Path. Report by J. H. Wright. Cancer.

Signed A. B. C.

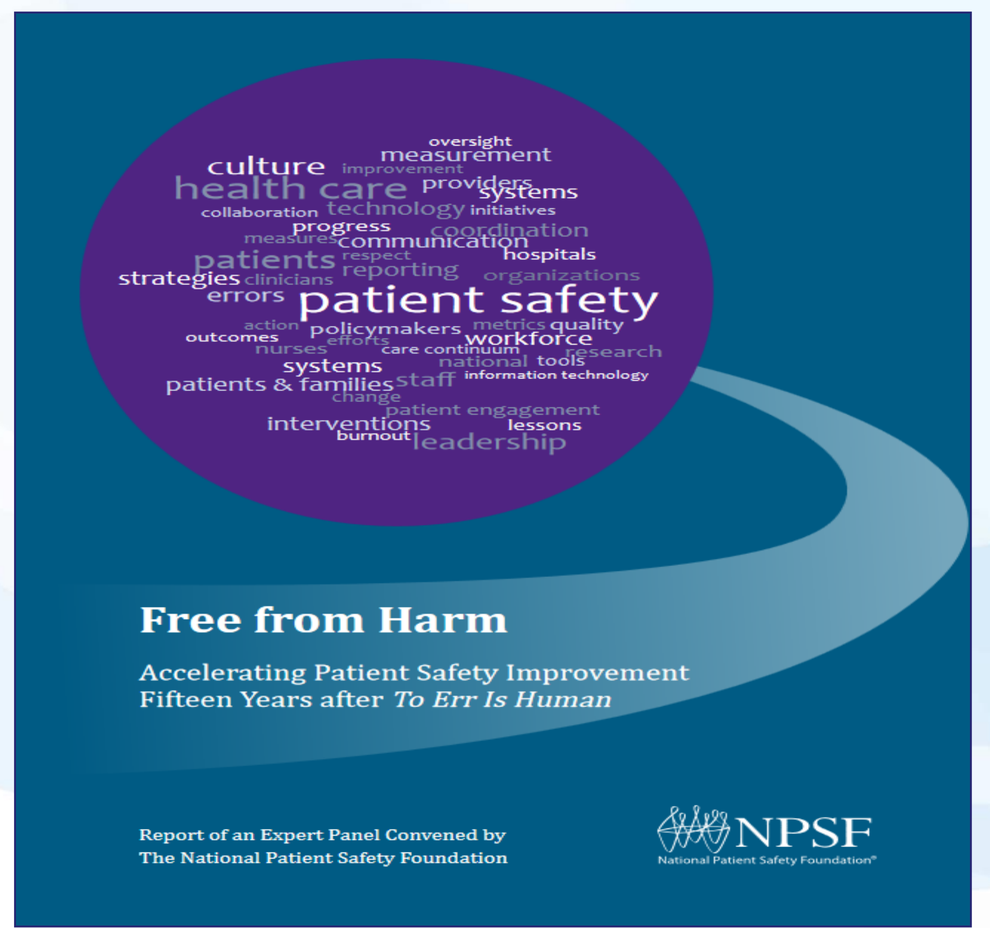
Reverse of End Result Card

Date	Results
July 15, '16	Remained well until March, 1916, since which time similar symptoms returned, and also hematemesis and epigastric tumor.
Re-entry	July 18th. Exploration showed numerous metastases in liver and abd. glands. No comp. Discharged two weeks later.

Pervasive Harm

Kohn L et al (2000). To Err is human: building a safer health system. Washington, D.C., National Academy Press..

Pervasive Harm



National Patient Safety Foundation. Free from Harm: accelerating patient safety improvement fifteen years after To Err is Human. Boston, MA: National Patient Safety Foundation; 2015.

Pervasive Harm

Medical error—the third leading cause of death in the US

Medical error is not included on death certificates or in rankings of cause of death. **Martin Makary** and **Michael Daniel** assess its contribution to mortality and call for better reporting

Martin A Makary *professor*, Michael Daniel *research fellow*

Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD 21287, USA

The annual list of the most common causes of death in the

...e problem?

...cited estimate of annual deaths from ...US—a 1999 Institute of Medicine (IOM) ...nd outdated. The report describes an ...98 000 deaths annually.[7] This conclusion

8.9% Percentage of physicians saying they had made a medical error in the previous three months. Within that group, **1.5%** of physicians believe the error resulted in a patient's death

—*Annals of Surgery, 2009*

Makary M et al. Medical error-the third leading cause of death in the US. BMJ 2016;353:2139.

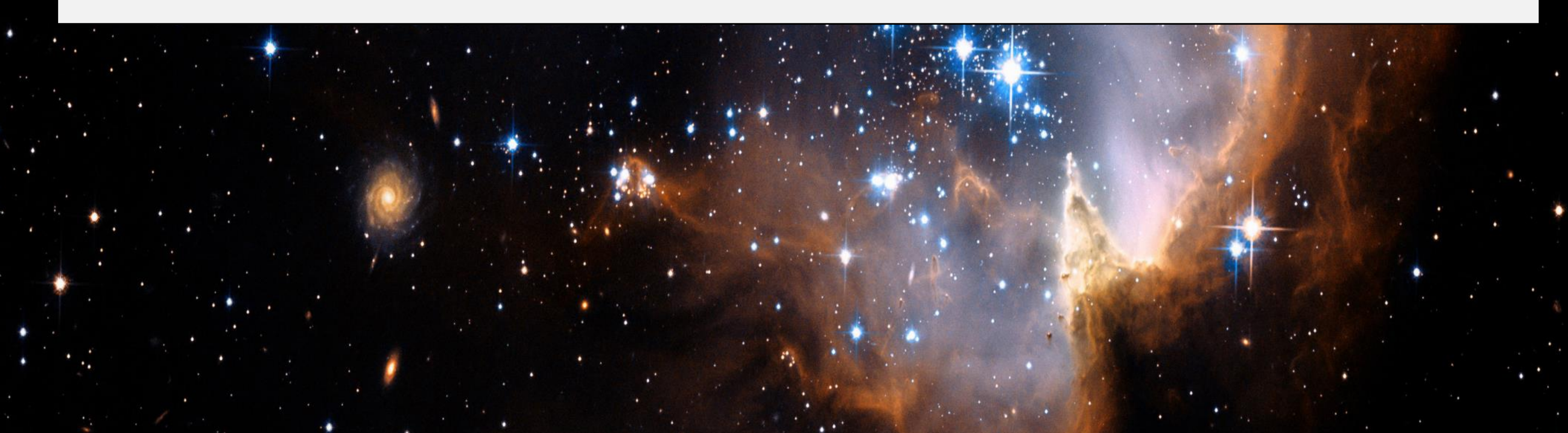
We are BUSY, in a RISKY business!

- 7.4% of physicians annually will have a claim[1]
- 1200+ providers
- 1,500,000 encounters
  - 921,000 primary care visits
  - 168,000 ER visits
  - 48,000 admissions

[1] Jena et al. NEJM. 2011

Paradigm Shift…

WHY?



Erosion of TRUST

Top five reported Sentinel Events, 2017

Event	Count
Unintended retention of foreign body	116
Fall	114
Wrong-patient, wrong-site, wrong procedure	95
Suicide	89
Delay in treatment	66

—The Joint Commission

OOPS!

WHAT THE...?

DANG IT!

MY BAD!

UH-OH...

OPERATING ROOM

HORSEY

HOSPITAL MEDICAL ERRORS KILL 98,000 AMERICANS EACH YEAR. -- HEARST NEWS INVESTIGATION

Regulators Weigh In

The Joint Commission

"The responsible licensed independent practitioner or his or her designee clearly explains the outcome of any treatment or procedure to the patient and, when appropriate, the family, whenever those outcomes differ significantly from the anticipated outcomes."

Professional Societies

- **American College of Physicians**

  "…physicians should disclose to patients information about procedural or judgment errors made in the course of care…"

- **American Medical Association**

  "Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all facts necessary to ensure understanding of what has occurred."

Quality and Safety Agencies

- **National Quality Forum**

  "Following serious, unanticipated outcomes, the patient and, as appropriate, family should receive communication about the event."

- **National Patient Safety Foundation**

  "When a health care injury occurs, the patient and the family or representative are entitled to a prompt explanation of how the injury occurred and its short- and long-term effects."

Expectation of Transparency

In the context of escalating COST!!!

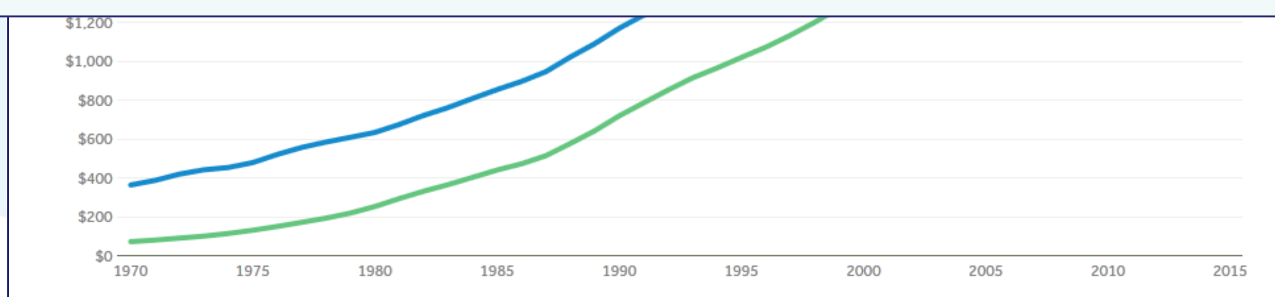
Total health expenditures have increased substantially over the past several decades

Total national health expenditures, US $ Billions, 1970-2015

Total National Health Expenditures
Constant 2015 Dollars

$3,200
$3,000

$3.7 Trillion



Source: Kaiser Family Foundation analysis of National Health Expenditure (NHE) data from Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group

Peterson-Kaiser Health System Tracker

HOW???

"A true friend stabs you in the front."

Oscar Wilde

What needs to be DISCLOSED?

CONTROVERSY!!!

Medical Error : "Act of commission or omission with consequences for the patient that would be judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were any negative consequences."

Patient / families: Unanticipated often is associated with error

Regulatory Agencies: Focus is on Harm

Adverse Events

Medical Errors

Preventable Adverse Events

Unpreventable Adverse Events

Near Misses

Minor Errors

Premises of Unanticipated Outcomes

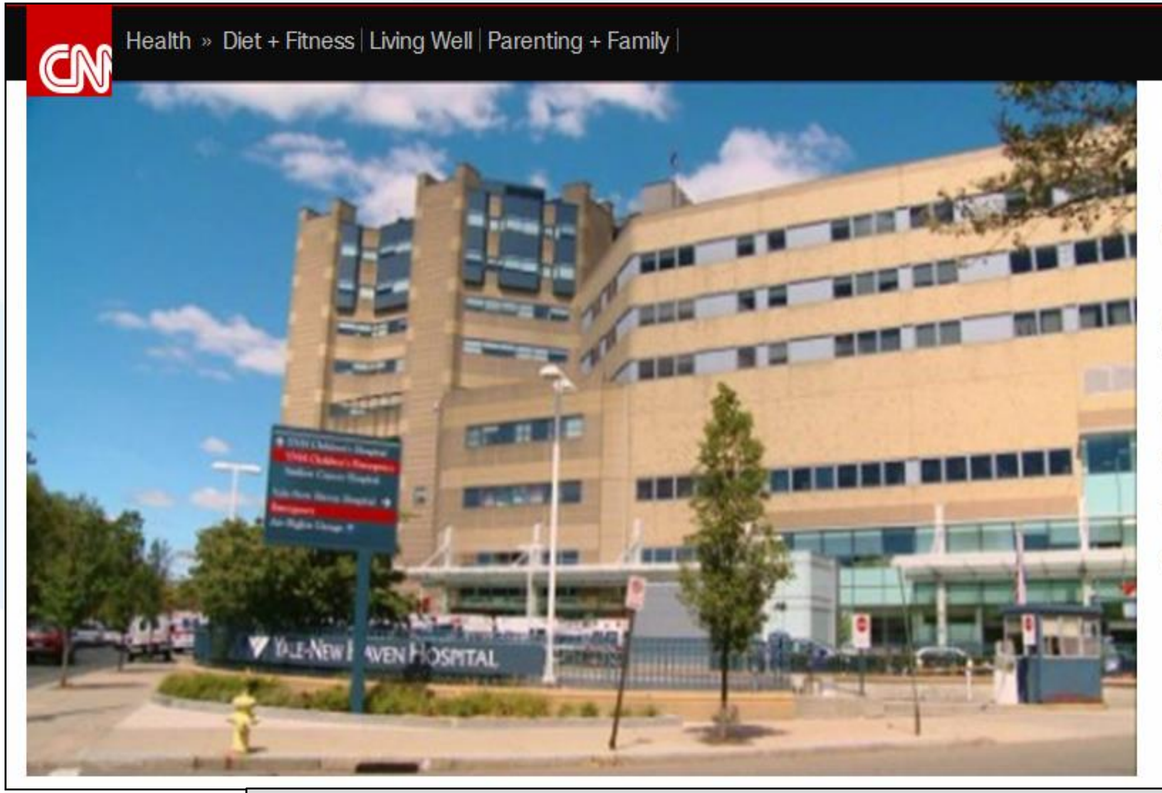
1. Uncorrected “unreasonable” expectations
2. Biological Variability
3. Low probability risks and side effects
4. Wrong judgements without negligence
5. Medical or systems errors.

Recognize Two Distinct Scenarios

- **Unanticipated without error**
  - clinicians have more experience discussing
  - can usually manage on their own
- **Unanticipated with medical error**
  - challenges one’s integrity, courage, humility
  - requires coordination with others at every step

We're going to focus on errors resulting in harm

CASE STUDY…



March 24, 2016

WHO???

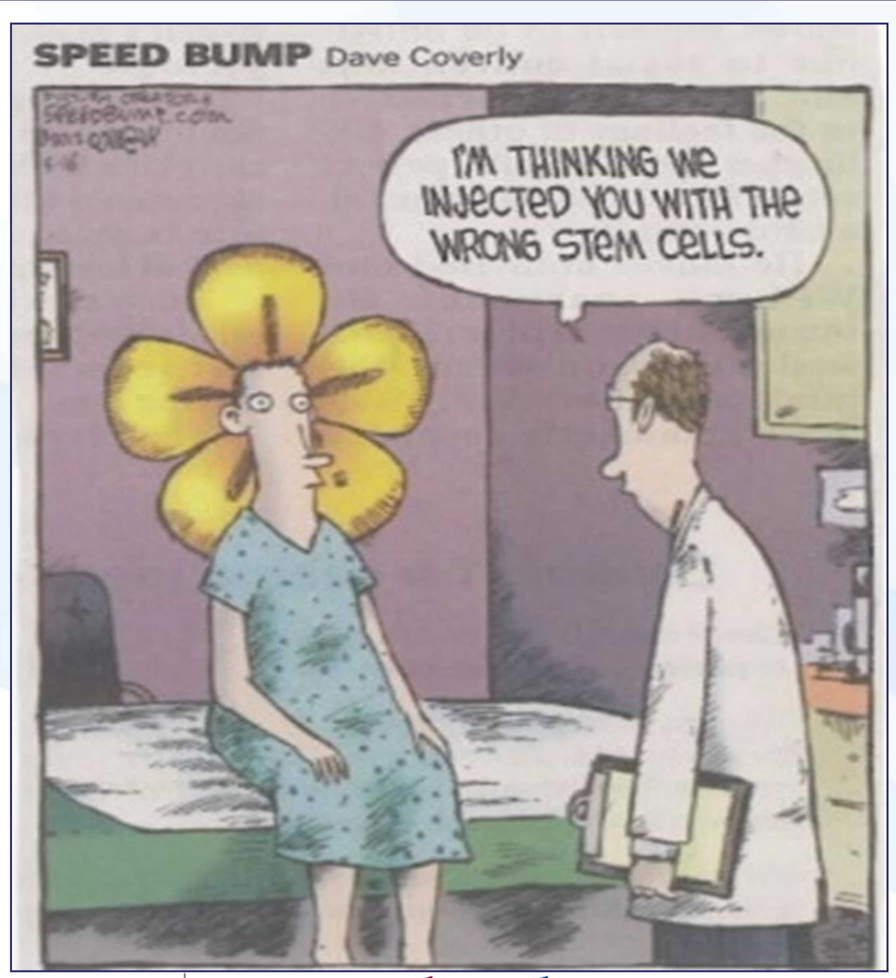
- <u>Joint Commission:</u> "…the attending physician, or their designee, should perform disclosure of unanticipated outcomes of care, treatment, and services related to sentinel events.

The Joint Commission. 2017 Hospital Accreditation Standards. TJC RI.01.02.01.

WHO???

- Contact Risk Professional prior to disclosure of serious safety events that result in harm – particularly when an error occurred.
- Leave the suits in their offices.
- Have a witness.
- Always try to be **OUTNUMBERED**.

WHEN???



WHERE???

"I'll have someone come in and prep you for the bill."

Not in a C-Suite!!!

HOW???

- **Team:** Who is involved and why?
- **Truth:** Present only **FACTS**.
- **Empathy:** Patient ventilation, clinician empathy
- **Apology:** offered & responsibility taken
- **Management:**
  - Patient care
  - Follow-up plan proposed

HOW TIPS:

- **PRACTICE!!!**
- **Avoid being drawn into complex conversations.**
- **Do NOT Assign Blame** – it is unlikely that the situation is completely understood at this time.
- **Prepare** for the following Questions
  - ***How did this happen?***
  - ***How could you let this happen?***
  - ***I thought you said that this was safe?***

NEVER Blame the Patient

off the mark.com by Mark Parisi

THE OPERATION WENT WELL, HOWEVER, X-RAYS SHOW THERE'S A CLAMP STILL INSIDE YOU...NOW, DID WE LEAVE IT THERE OR DID YOU EAT IT?

offthemark.com

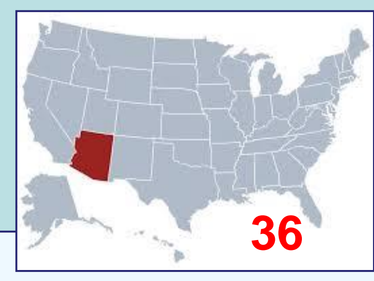
CARILION CLINIC

HOW TIPS:

"You are asking all of the right questions. We do not have the answers to all of these questions at this time, but we will be seeking to understand the event over the coming weeks."

DOCUMENT

"I'm Sorry"



"…**any statement, affirmation, gesture or conduct expressing apology, responsibility, liability, sympathy, commiseration, condolence, compassion or a general sense of benevolence** that was made by a health care provider or an employee of a health care provider to the patient, a relative of the patient, the patient's survivors or a health care decision maker for the patient and that relates to the discomfort, pain, suffering, injury or death of the patient as the result of the unanticipated outcome of medical care is **inadmissible** as evidence of an admission of liability or as evidence of an admission against interest."

https://www.azleg.gov/ars/12/02605.htm

Does Apology Reduce Med Malpractice Exposure??

McMichael BJ, et al. Standford Law Review; Weber DO. Physician Exec

THE WALL STREET JOURNAL

Hospitals Find a Way to Say, 'I'm Sorry'

When things go wrong, communication and resolution programs help patients get an apology, an explanation and, sometimes, monetary compensation

Hospitals are trying out a new approach to disclosing and resolving errors, but will it work? WSJ's Laura Landro joins Tanya Rivero to discuss. Photo: Corbis

February 1, 2016

Let's talk about a CASE…

Introduction

"I would like to take a few minutes to talk about something that may have occurred that we did not expect."

Explain the Facts

"The levels of magnesium sulfate in your blood indicate that there may have been a problem with the magnesium sulfate infusion that we were giving you to prevent seizures. We are working to better understand what may have occurred."

Next Steps

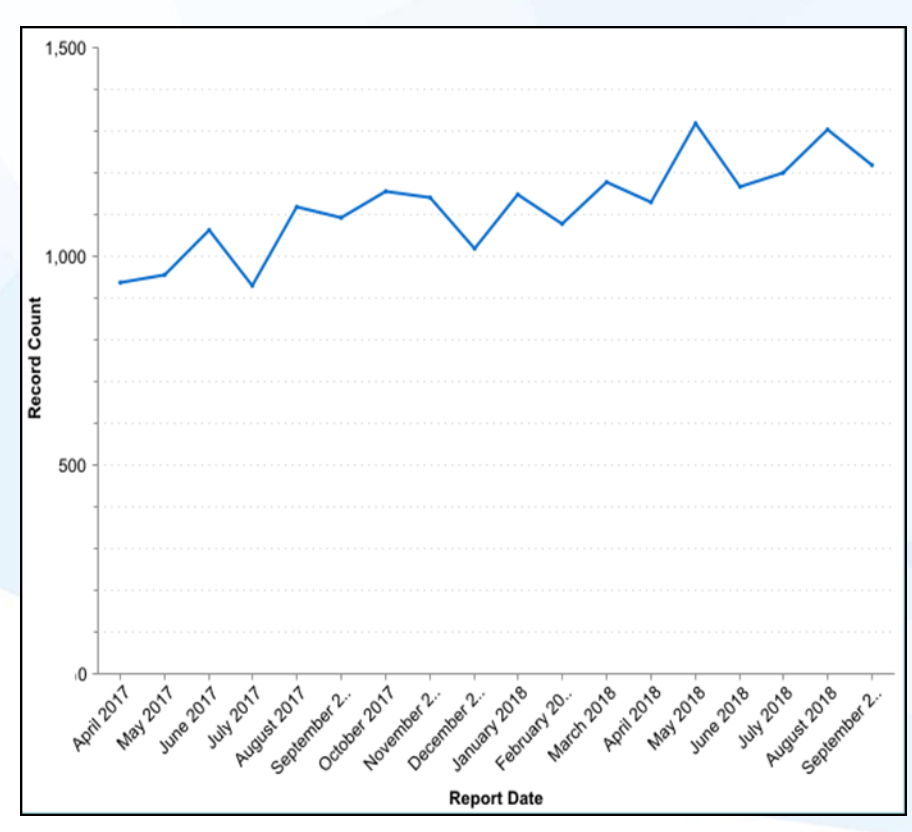
"Right now, you are receiving appropriate medications to prevent another seizure, and your most recent blood level indicates that all of this is working as expected."

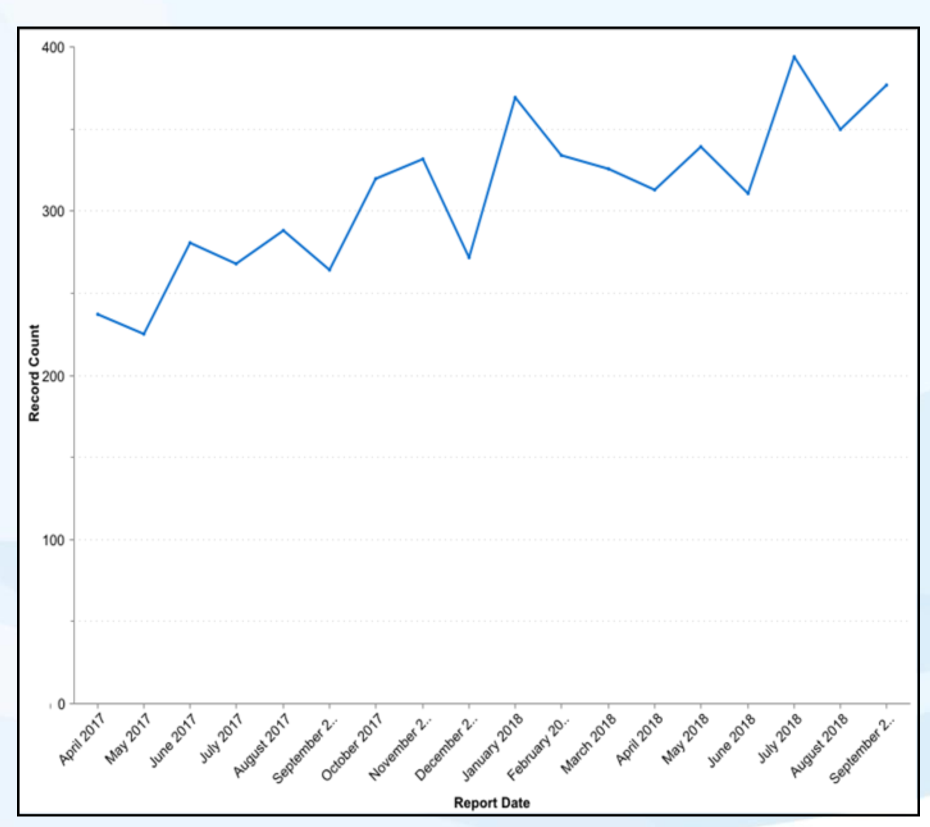
Invite Questions

"What questions do you have?"

One Last Thing…

SAFETY CULTURE





	Benchmark	2018	2017	Trend	Variance
HSOPS Patient Safety Grade	78.0	80.0	78.7	1.3	2.0

Triaging Events

Future State – RIE Event

Phase

Key:
Black boxes = process steps
Yellow Sticky = Just Do It's Fixed in that process step
Yellow Sticky w/Red Text = Just Do It's fixed in that process step but need to answer the answer
Purple Starbursts = barriers that need further addressing

Reporter

Event Report Submitted

Reviewer

Address all Reviewer Barriers

Reviewer assigned based on location

Reviewer completed

Reviewer assigned manually

PSS Facilitators (Brenden & Greg)

Unassigned Event Report → Update Event type and location → Notify QPS or CRIF? → PSS owner? → Assigned as the owner → Select Harm: AHRQ, SAC, NQF, & Preventable → SSE? → Was this preventable → Increase LOS? → SAC Score → Bill occurred that shouldn't? → Concerned about patient being upset → Do Work → Criteria for Peer Review? → List View: all parts completed? → Update Event Status to Closed based on list view

Update Quality Status and/or CRM status to New

System should send email

Assign decentralized facilitator as owner

SSE is an synonymous with NQF, never event, sentinel event, etc.

Automatically Update Quality Status, CRIF & CRM to New

Automatically update Quality Status to New

Update to Yes

Automatically update CRIF and Quality status to new

Not a field in SafeWatch

Manually update CRIF status to New

Manually update CRIF status to new

If we have multiple event types, what do we do?

Send to designated contact

Is it ambulatory?

Send information to MSPROC

CRIF Facilitator (Dawn)

No longer working from patient event status
No longer being assigned event owner
Continue using Clinical safety fields

What is the handoff process? Timely communication of

Receive Event Email → >24 hours since assignment? → Update dept Status to In Review → Agree/Update Harm score → Review patient chart → Document interviews in Notes section → Do Work → Peer Review needed? → Disclosure, SSE or Bill? → Update status to close

Send reminder email to Quality_Facilitators and Wes

Send to designated contact

Is it ambulatory?

Automatically updated CRM status

CRM Facilitator (Amy)

No longer working from patient event status
No longer being assigned event owner
Will have their own fields

Receive Event Email → >24 hours since assignment? → Change dept status to In Review → Agree/Update Harm score → Document interviews in Notes section → Do work → to close and date closed

Send reminder email to Quality_Facilitators and Wes

Resolution is ESSENTIAL

QPS Facilitator (Josh's Team)

No longer working from patient event status
No longer being assigned event owner
Will have their own section - include fields
Quality Facilitator name (TBD), Comments/Chart Review (free text), Disposition (Drop down), QPS complete (check box), SAC box for RCA2/IA

Receive Event Email Notification → Is the assigned owner incorrect? → >24 hours since assigned? → Update dept status to In Review → Document interviews in Notes section → Do work → Agree/Update Harm score → Confirm/Update SAC Score → SSE → Discussion with Josh → Update disposition → Peer Review needed? → In drop down menu, fill in appropriate outcome of quality review → Check box for quality review complete, fill out date closed

Reassign to correct QIF

Send email to Josh, Brandon, Cherie (distribution)

Populate recommended disposition with IA

Populate recommended disposition with RCA2

Populate recommended disposition with IA

Send to designated contact

Is it ambulatory?

Send information to MSPROC

Heal the Healer…

2015 2016 2017 2018

Number of Referrals · Successful Resolution · Decline Outreach

QUESTIONS?