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Brainstorming Solutions to Medical Harm: Creating a National Patient Safety Authority

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Welcome and Introduction

Sabah Bhatnagar
Co-Deputy Director
Healthcare Value Hub

Housekeeping

- Thank you for joining us today!
- All lines are muted until Q&A
- Webinar is being recorded
- Technical problems? Contact Elise Lowry at Elise.Lowry@altarum.org

Agenda

- Welcome & Introduction
- National Patient Safety Authority: What is it?
  - Karen Wolk Feinstein, PhD, President and Chief Executive Officer of the Jewish Healthcare Foundation
- Patient Perspective on a National Patient Safety Authority
  - John T. James, PhD, Founder, Patient Safety America and Former Chief Toxicologist at NASA Johnson Space Center
- What can states do?
  - Regina Hoffman, MBA, RN, Executive Director of Pennsylvania's Patient Safety Authority and Editor-in-Chief of Patient Safety
- Q&A

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National Patient Safety Authority: What is it?

Karen Wolk Feinstein, PhD
President and Chief Executive Officer of
the Jewish Healthcare Foundation

Healthcare Value Hub

A National Patient Safety Authority

October 16, 2020

Karen Wolk Feinstein, PhD

JHF Functions as a Public Charity with Three Operating Arms

“A Think, Do, Train, and Give Tank”

Advancing improvements in…

Women's Health	Seniors & Aging	Patient Safety	HIV/AIDS
Teen Mental Health	Infectious Disease	Health Innovation	Workforce Development

PITTSBURGH REGIONAL HEALTH INITIATIVE

Spreading Quality, Containing Costs.

Established in 1997
A regional, multi-stakeholder coalition

Focused on Patient Safety Challenges for 20+ years

… but progress has been minimal

3rd Leading Cause of Death in U.S.

250,000 deaths per year

It’s time for a ***swerve***:
a new solution to address this persistent problem

National Patient & Provider Safety Authority

A data-driven, non-punitive, collaborative approach to protecting patients and providers

The NPSA is Modeled After the NTSB

Independent Federal Agency

- Investigates accidents
- Proposes recommendations (solutions)
- Conducts research and education

Maintains a central database of accidents

The NTSB is About Solutions

The central problem-solving agency uses data to create solutions, including autonomous technologies:

- ✓ Airbags
- ✓ Autonomous slack adjusters
- ✓ Anti-collision equipment
- ✓ Autopilot
- ✓ Fail-safe thrust reversers
- ✓ Arrestor beds
- ✓ Automatic shutoff valves
- ✓ Autonomous internal inspection & correction devices for pipelines

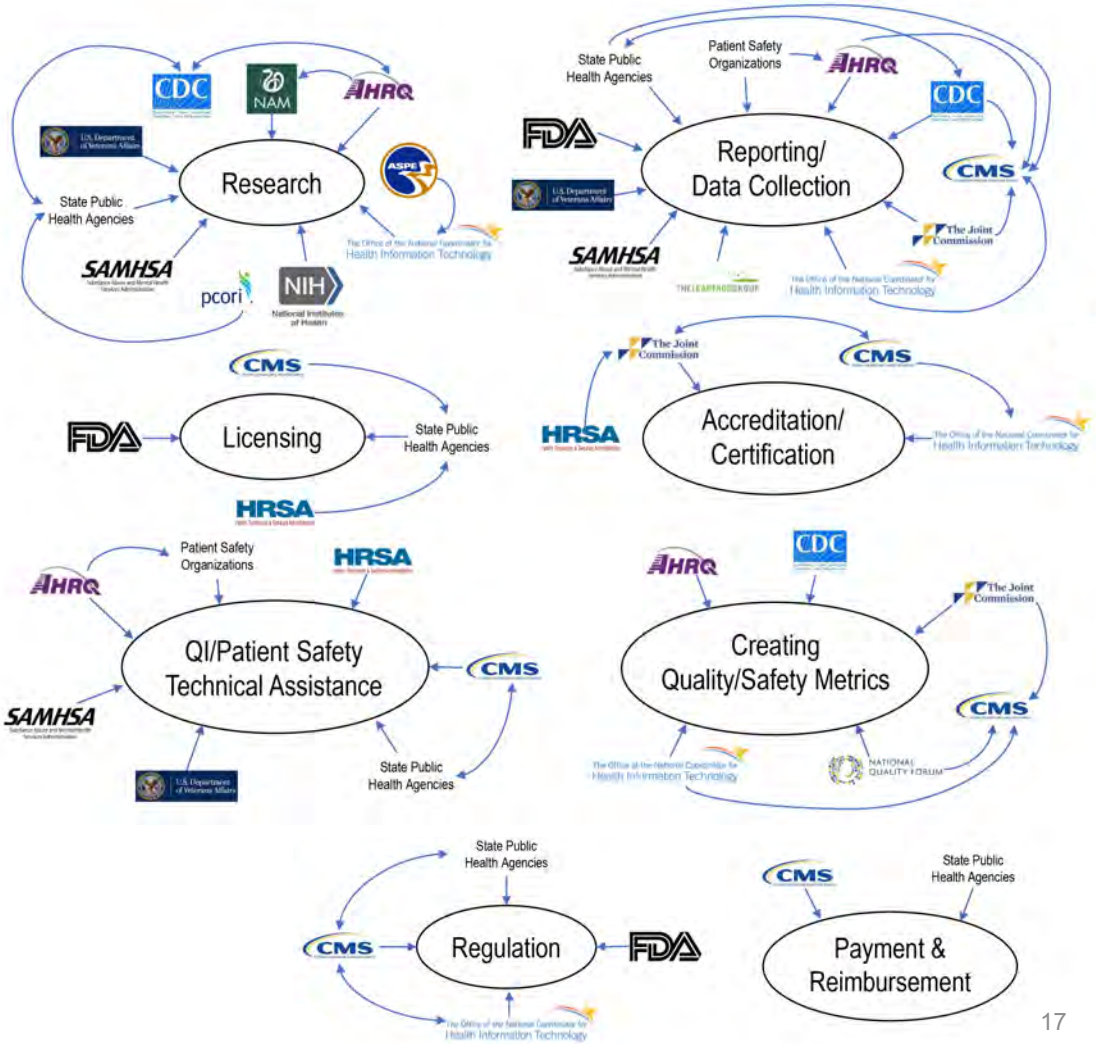
National Patient & Provider Safety Authority

- Modeled after the NTSB
- Central operations
- Mine big data from EHRs to monitor and anticipate medical errors with AI and Machine Learning
- Investigate major safety events with “Go Teams”
- Automate corrective action
- Issue recommendations
- Conduct research, education, and training

Health System Command Center

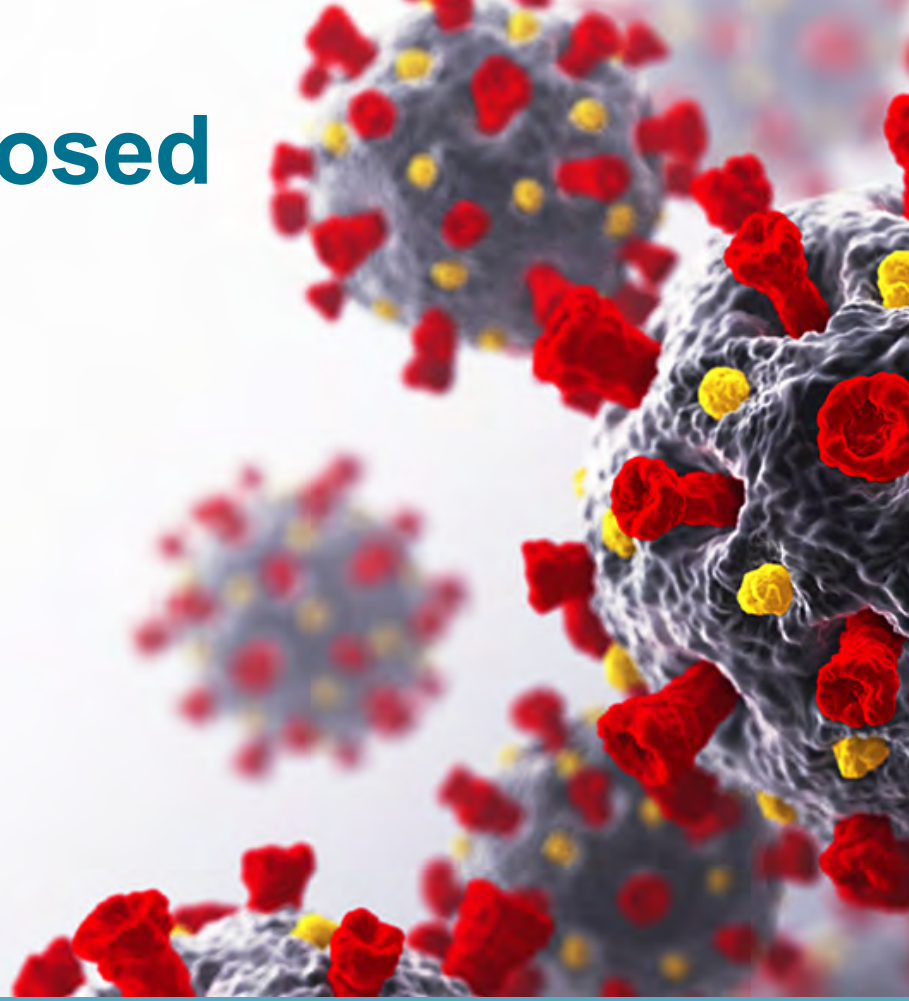
NPSA will Coordinate Federal & State Agencies

- Minimize federal redundancy and scatter of responsibilities
- Coordinate federal efforts across FDA, ONC, CDC, NQF, AHRQ, VA and OSHA
- Collaborate with industry non-profits like Leap Frog, ECRI, etc.



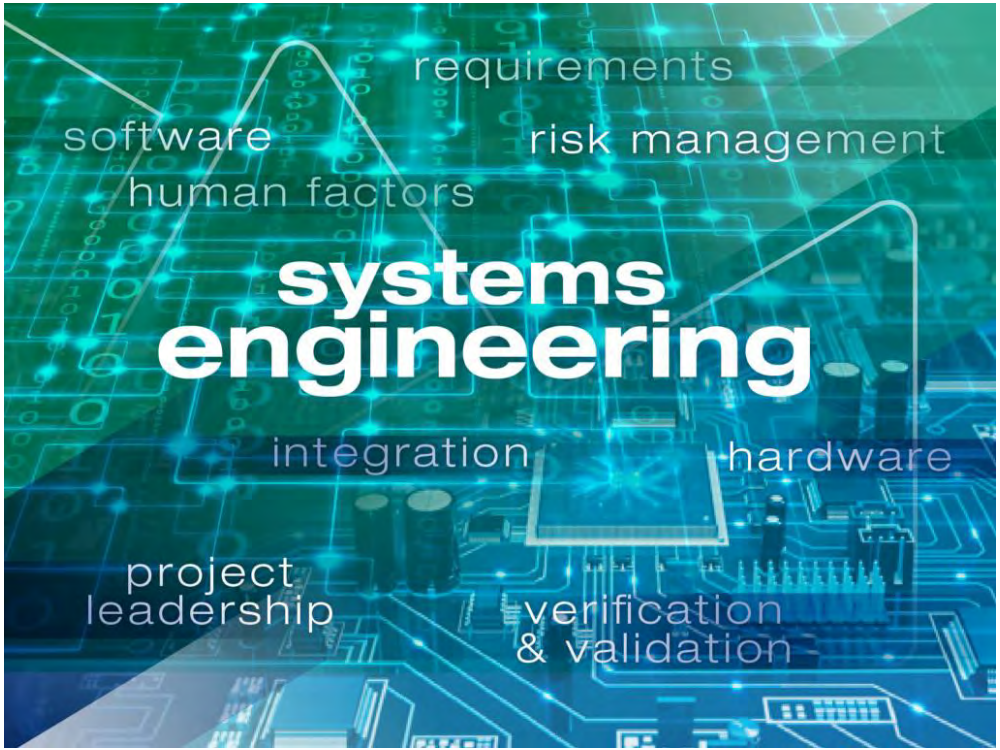
Fix deficiencies exposed by COVID-19

- Distributing substantial resources, including PPE and testing, staffing, and funding
- Provider and patient safety
- Best practice dissemination



Other Industries Use Technology to Improve Safety

- Communications Infrastructure
- Data driven
- Machine based Intelligence
- Automation
- Interoperability and Integration
- Systems Engineering



Why Technology is the Key to Unlock Autonomous Reporting and Action

Manual chart review (photocopies or CDs) is antiquated and time intensive

- CDC National Healthcare Safety Network (e.g., MRSA, CLABSI, etc.)
- AHRQ Quality and Safety Review System
- Medicare Patient Safety Monitoring System

Retrospective claims data miss adverse events

- CMS Patient Safety and Adverse Events Composite

Self-reports of incidents miss even more adverse events

- AHRQ's network of patient safety databases (94 Patient Safety Organizations)

We have the ingredients

Data

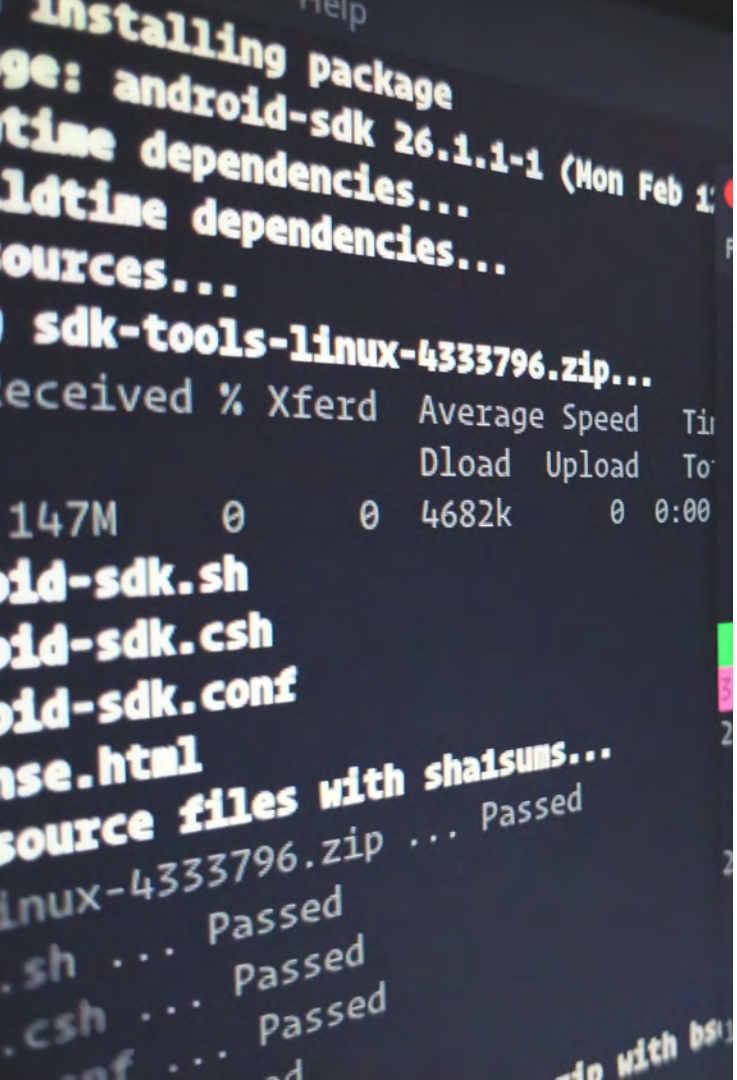
Structured and unstructured, charted, and real time, terminology mapping, NLP, and data fusion techniques.

AI

Any computer/machine based sytem that takes data inputs and creates intellgence via more meaningful outputs.

Automation

Turning over tasks, decisions, and control of actions to the computer/machine.



Can Medical Error Data Be Automated?

77% of quality and safety information can be automated using today's tech

23% requires natural language processing

2016 AHRQ Study

Amenable to Autonomous Interventions

ECRI Top 10 2018

1. Diagnostic errors
2. Opioid safety across the continuum of care
3. Internal care coordination
4. Workarounds
5. Incorporating health IT into patient safety programs
6. Management of behavioral health needs in acute care settings
7. All-hazards emergency preparedness
8. Device cleaning, disinfection and sterilization
9. Patient engagement and health literacy
10. Leadership engagement in patient safety

Adapted from Michael McShea

ECRI Top 10 2019

1. Diagnostic stewardship and test result management using EHRs
2. Antimicrobial stewardship in physician practices and aging services
3. Burnout and its effect on patient safety
4. Patient safety concerns involving mobile health
5. Reducing discomfort with behavioral health
6. Identifying changes in a patient's condition
7. Developing and maintaining skills
8. Early sepsis recognition across the care continuum
9. Infections from peripherally inserted IV lines
10. Standardizing safety efforts across large health systems

ECRI Top 10 2020

1. Misuse of Surgical Staplers
2. Adoption of Point-of-Care Ultrasound Is Outpacing Safeguards
3. Infection Risks from Sterile Processing Errors in Medical and Dental Offices
4. Hemodialysis Risks with Central Venous Catheters—Home Dialysis
5. Unproven Surgical Robotic Procedures May Put Patients at Risk
6. Alarm, Alert, and Notification Overload
7. Cybersecurity Risks in the Connected Home Healthcare Environment
8. Missing Implant Data Can Delay or Add Danger to MRI Scans
9. Medication Errors from Dose Timing Discrepancies in EHRs
10. Loose Nuts and Bolts Can Lead to Catastrophic Device Failures

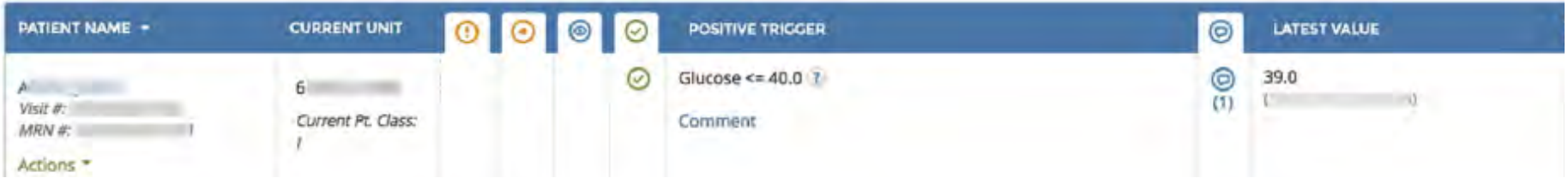
Does Similar Technology Exist Today?

Pascal Metrics Patient Real-time Interoperable Metrics Engine (PRIME)

A cloud-based engine mines and displays EHR data in real-time

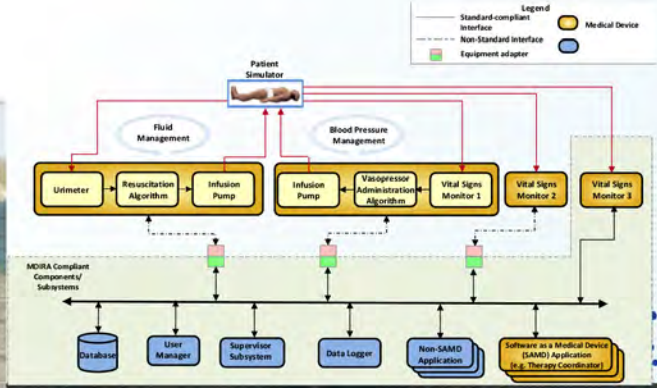
Pascal Metrics Risk Trigger Software

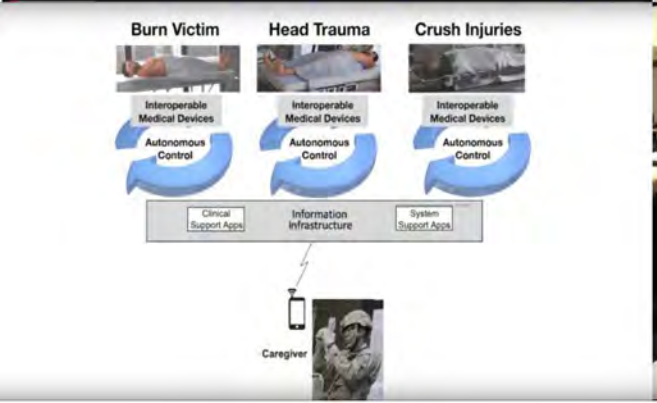
A machine learning model with AI technology predicts all-cause harm



Autonomous Care – MDIRA

The Medical Interoperability Reference Architecture Research Collaboration





Standardize Care Delivery
Optimize Patient Outcomes
Improve Patient Safety
Focus on Patient

Now is the time for a

National Patient & Provider Safety Authority

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PATIENT PERSPECTIVE ON A NATIONAL PATIENT SAFETY AUTHORITY

John T. James, PhD
Founder, Patient Safety America
and Former Chief Toxicologist at
NASA Johnson Space Center

Patient Perspective on a National Patient Safety Authority

John T. James, PhD

16 October 2020

Overview with Focus on Patient Worries

- Risks to me while hospitalized? Estimating lethal, preventable adverse events (PAEs) depends on how carefully one looks for them
- What am I not getting that I need? Lethal PAEs due to omission of needed treatment.
- Critical interface: improving informed consent and shared decision-making according to the wishes of a reasonable patient
- Promise of a NPSA to citizens & patients
- How to make the NPSA represent the people's wishes

https://thehealthcareblog.com/blog/2020/02/06/patient-worries-as-a-central-feature-of-their-health-care-experiences/

Estimating lethal, preventable adverse events depends on how carefully one looks for them

- Old IOM estimate from 2000/1984 excluded errors of omission
- Improved estimates using the Global Trigger Tool developed by the IHI early 2000s
- My estimate in *Journal of Patient Safety* (James, 2013)
- Contemporary denials of the extent of harm (Rodwin, et al. 2019)

To Err is Human. National Academy Press, 2000
http://www.ihi.org/resources/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx
http://journals.lww.com/journalpatientsafety/pages/articleviewer.aspx?year=2013&issue=09000&article=00002&type=abstract.
https://pubmed.ncbi.nlm.nih.gov/31965525

Will I get ***all*** the care I need? PAEs of omission

- PAE's due to omission of optimal care appear to be poorly measured, but likely are an important source of avoidable harm
- Typically result in premature death outside hospitals
- Heart-attack patients that did not receive beta-blockers in 2000
- Contemporary harm due to suboptimal care
  - Tobacco cessation care
  - Management of high blood pressure
  - Release from hospital before patient is stable

https://health.clevelandclinic.org/beta-blockers-why-you-need-them-for-heart-failure/
https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2770817
https://jamanetwork.com/journals/jama/article-abstract/2770252
https://link.springer.com/article/10.1007/s11606-016-3826-8

Improving informed consent and shared decision-made according to the wishes of a reasonable patient

- Informed consent, if genuine, has the potential to greatly reduce PAEs and reduce the overall cost of medical care
- Currently, informed consent is poorly documented (Spatz et al. 2020)
- The wishes of a reasonable patient are not being met (James, et al. 2019)
- A NPSA should consider a focus on this problem

James study of reasonable patient wishes during informed consent (2019): https://bmjopen.bmj.com/content/bmjopen/9/7/e028957.full.pdf

Spatz study of informed consent documents in hospitals (2020): https://bmjopen.bmj.com/content/10/5/e033299

Promise of A National Patient Safety Authority

- Independent source of dealing with PAEs in hospitals and ambulatory surgical centers
- Must have investigative powers built on root-cause analysis
- Must be controlled by leaders with no direct connections to the medical industry
- Must have sufficient public awareness that its decisions to focus on specific problems are drivers of improved care throughout the industry

How to make the NPSA Responsive to people

- Leaders directly elected from regions of the country (n=12)
- Leaders are supported by paid technical experts
- Existence must be independent of political and funding limitations
- Education of the public is a key goal of the NPSA
- Recommend national standards for safe and cost-effective care
- Measure improvements in PAEs and cost reductions

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What can states do?

Regina Hoffman, MBA, RN
Executive Director of Pennsylvania's
Patient Safety Authority and
Editor-in-Chief of Patient Safety

Patient Safety Authority - Pennsylvania's Approach to Patient Safety

Presented by:

Regina M. Hoffman

Executive Director

Patient Safety Authority

Pennsylvania Patient Safety Authority

- Created under MCARE Chapter 3
- Independent State Agency
  - 11-member Board appointed by the Governor and General Assembly
- Dedicated Funding Stream
  - Facility assessments

Patient Safety Authority

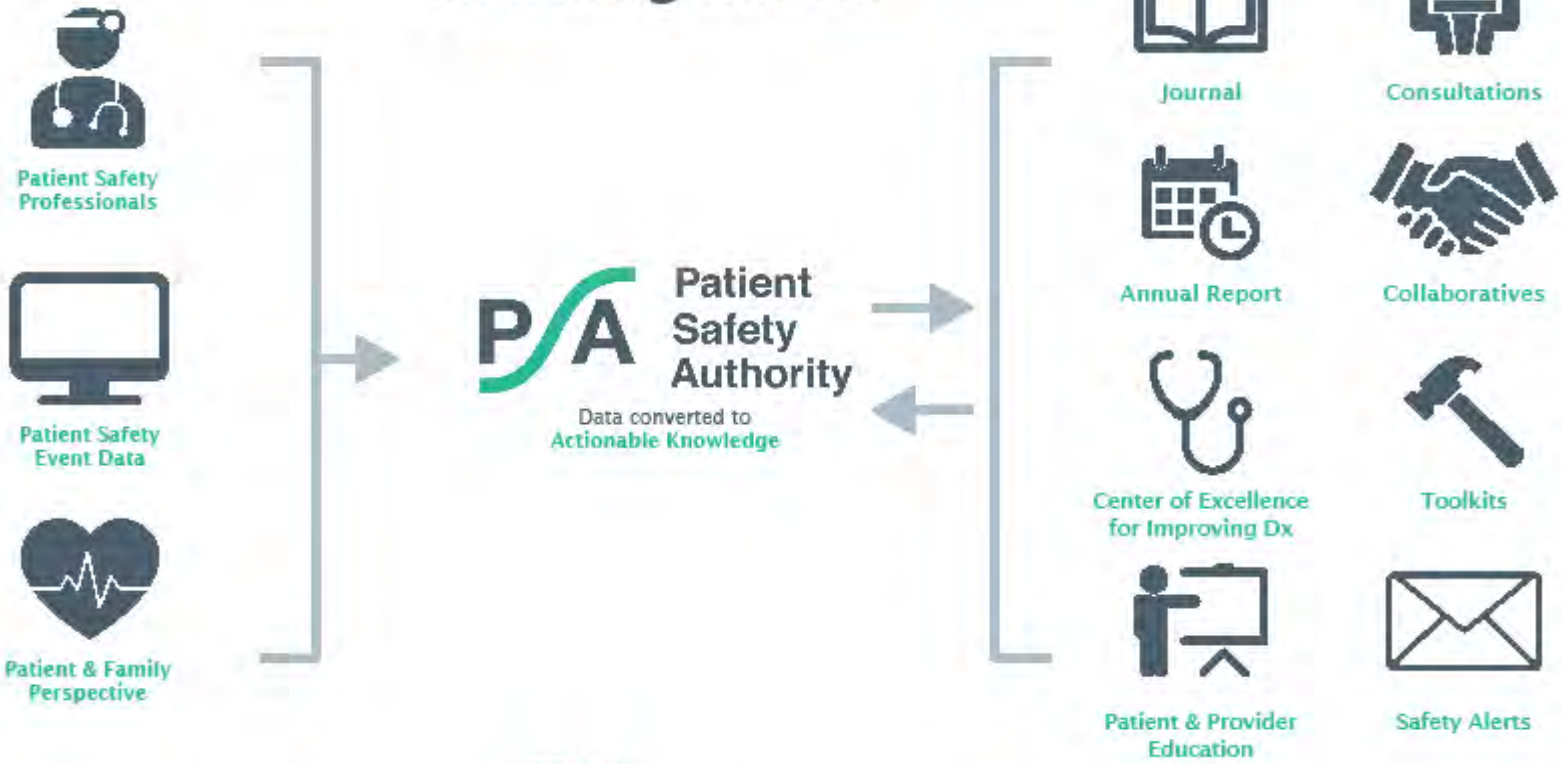
Pennsylvania Patient Safety Authority

Non Punitive

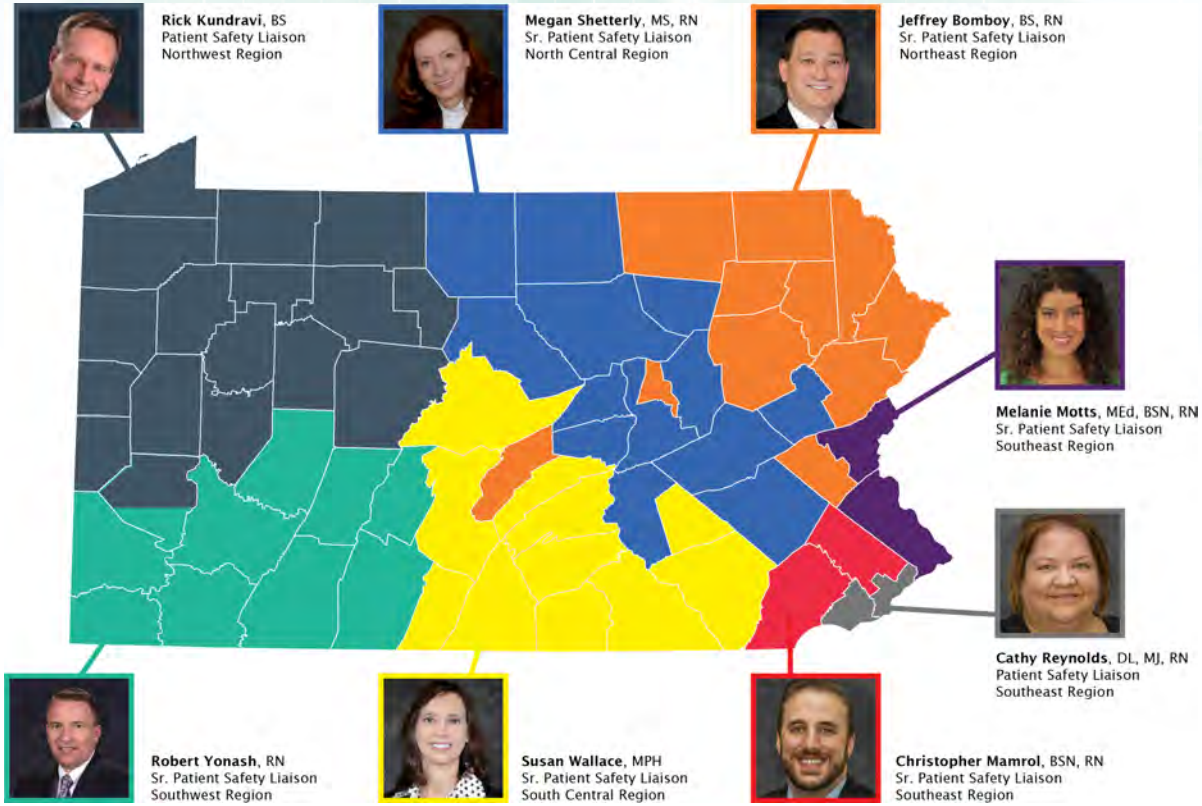
Non Regulatory

Patient Safety Authority

Pennsylvania Patient Safety Learning Model



Field Staff



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Northwest Region

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Patient Safety Authority

Complementary Relationship

Patient Safety Authority

Questions for our Speakers?

- Use the chat box or to unmute, press *6
- Please do not put us on hold!

Resources from the Hub

Easy Explainer: National Patient Safety Authority

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Keeping Patients Safe: Establishing a National Patient Safety Authority to Reduce Medical Harm

Healthcare services and procedures that cause patients bodily harm are major drivers of excess spending, waste and patient suffering. Though difficult to measure, medical harm—injury resulting from largely preventable events caused by human error in healthcare facilities—is suspected to be the third-leading cause of death in the U.S., despite ongoing work to address patient safety concerns.

An untested strategy with great promise is the establishment of a National Patient Safety Authority (NPSA) to safeguard the interests of patients by monitoring, investigating and promoting health system changes to reduce medical harm events.

What is a National Patient Safety Authority?

In November 1999, the Institute of Medicine documented a staggering number of patient deaths related to preventable medical errors and later advocated for a "fundamental, sweeping redesign of the entire health system." Recent studies have indicated that one in 20 patients are exposed to preventable harm through their interactions with the medical system. Moreover, 12 percent of these harm events were serious or led to death. There has been an appalling lack of progress in reducing medical harm in the two decades following the Institute's call to action—highlighting the need for bold measures.

Patient safety advocates are exploring the creation of an overarching authority to identify and enforce rigorous safety standards for healthcare providers. This strategy is modeled on successful efforts like the Federal Aviation Administration (FAA) and the National Highway Traffic Safety Administration (NHTSA). National oversight provided by these entities has been the catalyst for quantum leaps in airline and traffic safety. For instance, safety standards implemented in 1966 by a precursor to the NHTSA led to the design of new safety features in vehicles and roads, resulting in fewer motor vehicle–related deaths per year by 1970. Meanwhile, the FAA's oversight activities led to a 95 percent decrease in commercial aviation deaths between 1997 and 2018. While the details are still being fleshed out, a National Patient Safety Authority would monitor medical harm events, creating patient safety protocols and enforcing their adoption in the United States.

Promising practices from existing federal safety authorities can shed light on how to design a National Patient Safety Authority. Specifically, the entity should have the authority to: define harm events; require mandatory reporting; require data alignment; investigate or audit causes of safety or security lapses; make and enforce recommendations; and provide public access to reports and findings.

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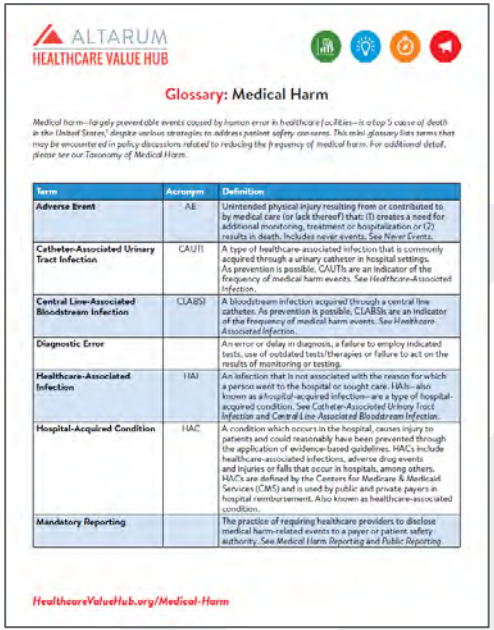
Medical Harm Glossary



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Glossary: Medical Harm

Medical harm—largely preventable events caused by human error in healthcare facilities—is a top 5 cause of death in the United States,[1] despite various strategies to address patient safety concerns. This mini-glossary lists terms that may be encountered in policy discussions related to reducing the frequency of medical harm. For additional detail, please see our Taxonomy of Medical Harm.

Term	Acronym	Definition
Adverse Event	AE	Unintended physical injury resulting from or contributed to by medical care (or lack thereof) that: (1) creates a need for additional monitoring, treatment or hospitalization or (2) results in death. Includes never events. See Never Events.
Catheter-Associated Urinary Tract Infection	CAUTI	A type of healthcare-associated infection that is commonly acquired through a urinary catheter in hospital settings. As prevention is possible, CAUTIs are an indicator of the frequency of medical harm events. See *Healthcare-Associated Infection*.
Central Line-Associated Bloodstream Infection	CLABSI	A bloodstream infection acquired through a central line catheter. As prevention is possible, CLABSIs are an indicator of the frequency of medical harm events. See *Healthcare-Associated Infection*.
Diagnostic Error		An error or delay in diagnosis, a failure to employ indicated tests, use of outdated tests/therapies or failure to act on the results of monitoring or testing.
Healthcare-Associated Infection	HAI	An infection that is not associated with the reason for which a person went to the hospital or sought care. HAIs—also known as a hospital-acquired infection—are a type of hospital-acquired condition. See *Catheter-Associated Urinary Tract Infection* and *Central Line-Associated Bloodstream Infection*.
Hospital-Acquired Condition	HAC	A condition which occurs in the hospital, causes injury to patients and could reasonably have been prevented through the application of evidence-based guidelines. HACs include healthcare-associated infections, adverse drug events and injuries or falls that occur in hospitals, among others. HACs are defined by the Centers for Medicare & Medicaid Services (CMS) and is used by public and private payers in hospital reimbursement. Also known as healthcare-associated condition.
Mandatory Reporting		The practice of requiring healthcare providers to disclose medical harm-related events to a payer or patient safety authority. See *Medical Harm Reporting* and *Public Reporting*.

HealthcareValueHub.org/Medical-Harm

Thank you!

Robert Wood Johnson Foundation

- To our Speakers: Karen Wolk Feinstein, John T. James and Regina Hoffman
- To the Robert Wood Johnson Foundation

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