Session 2: *Measuring Patient Safety in Value-Based Care*

Presenters:

Subject Matter Experts

- **Jeffrey J. Geppert** – Senior Research Leader, Battelle
- **Patrick S. Romano, MD, MPH** – Professor, Division of General Medicine and Division of General Pediatrics, University of California, Davis
- **Commander Karen Chaves, MHS** – Director, Division of Quality Measurement and Improvement, Center for Quality Improvement and Patient Safety (CQuIPS), Agency for Healthcare Research and Quality (AHRQ), and United States Public Health Service Commissioned Corps
- **David C. Classen, MD, MS** – Professor of Medicine, University of Utah, Lead, Utah Center for Health AI and the Health IT Safety Program, and Senior Advisor, PascalMetrics

Session 2: *Measuring Patient Safety in Value-Based Care*

Jeffrey J. Geppert

Senior Research Leader
Battelle

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Senior Research Leader
Battelle Memorial Institute

Session 2: Measuring Patient Safety in Value-Based Care

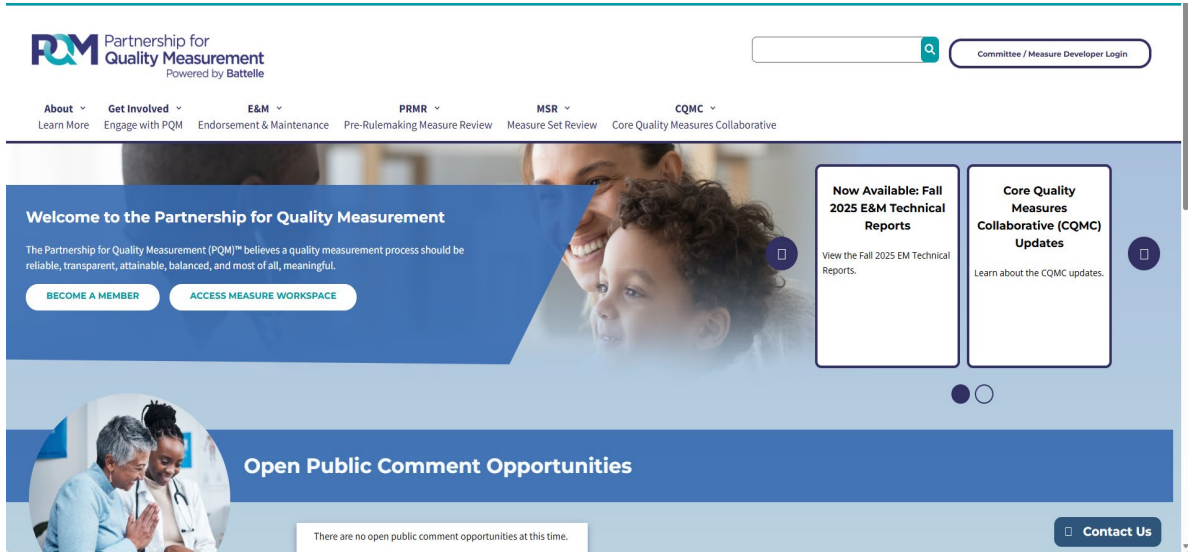
June 15, 2026

Public

Speaker

- Battelle CMS certified Consensus-based Entity (CBE) processes:
  - Endorsement & Maintenance (E&M) of Clinical Quality Measures (CQM)
    - Review of scientific acceptability of measures for general accountability use
  - Pre-Rulemaking Measure Review (PRMR)
    - Review of Measures under Consideration (MUC list) for recommendations for adding to CMS quality and payment programs
  - Measure Set Review (MSR)
    - Review of measures in CMS portfolio for recommendations for removal from CMS quality and payment programs
  - Website: www.p4qm.org

- Mr. Geppert is a Senior Research Leader at Battelle Memorial Institute and the CBE measurement science team lead
- Battelle is the world's largest independent, not-for-profit applied science and technology organization (Columbus, Ohio)



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Patient Safety: Accountability & Challenges

How do you know a patient safety measure is fit for purpose for an accountability use?

Criteria	Accountability Requirement	Common Challenge
Purpose	Drives structural or system change, not behavioral change	Purpose often unstated; unclear structural vs. behavioral target
Importance	• Linked to a material outcome • Benefit outweighs data collection burden • Adverse effects identified and mitigated	• Limited impact or priority • Weak evidence linking to material outcome • High performance or little variation
Feasibility	Data readily available in structured fields via standard codes (ex. PROM and PREM)	• Data source limitations affecting accuracy • Reliance on unstructured or non-standardized data
Reliability	• Consistent relative to benchmarks • Stable across sub-populations and time • Resilient under perturbations	• Low volume entities • Rare events (<3 per entity) • Events spread across many entities
Validity	• Effective mechanisms within entity control • Competing causes accounted for and counter-acting mechanisms mitigated	• Insufficient criterion/construct validity evidence • Residual risks unexamined
Usability	Answers: how does the measure work, for whom, and under what circumstances?	• Limited actionability for some entity types • Results not meaningful for specific sub-populations (selection and choice)

Public

Emerging Approaches to Measuring Patient Safety

Interoperability & AI

FHIR/USCDI standards enabling seamless data exchange across systems

Composites

Combining multiple indicators into unified safety scores

Structural Measures

Assessing organizational systems, governance, and infrastructure

Patient-Reported Measures

Capturing patient experience and outcomes directly from those receiving care

Public

Beyond Measuring Harm: Assuring Safety in Complex Health Care Systems

Traditional Quality Measurement	The Core Limitation	Assurance Cases
Measures outcomes and adverse events	**Measurement alone cannot fully substantiate quality claims**	**A structured argument for acceptable quality and safety**
Falls, diagnostic delay	Measurement detects variation, but does not explain its source	Explicit hazard identification
CLABSI, CAUTI, Sepsis	Accountability requires distinguishing:	Explains why controls should work
Readmissions, failure to rescue	• Warranted vs. unwarranted variation • Controllable vs. uncontrollable risk	Defines acceptable residual risk
Medication errors, adverse events	• Signal vs. instability vs. randomness	Continuously updates evidence
Strengths: Benchmarking, accountability, payment incentives, transparency	**Need: Explicit reasoning about residual risk and sources of variation to substantiate quality and safety claims**	**Supports: Prospective safety assurance, Safer AI-enabled care, Continuous learning, Trustworthy accountability**

Measurement identifies variation. Assurance cases help to determine whether that variation represents unacceptable risk

Key Takeaways

Table 1. Principles of Pay for Transformation

Transform Finance Principles	Pay for Transformation
Those affected have the chance to design outcomes, govern processes, and share in ownership	Quality programs* should leverage meaningful **community** engagement • Accountability for quality and utilization at the community rather than the state and the market • Strengthened partnerships and alliances, expanded knowledge, improved health and health care programs and policies, and thriving communities
Investors add more value than what they extract as returns	Quality programs should **generate** value by: • Identifying and mitigating barriers to effort for low-performing entities • Creating and disseminating resources that emulate the ability of high-performing entities
Risks and returns are fairly allocated among stakeholders	Quality programs should **establish** value through a progressive understanding of how entities transform 1. Purpose: what works, for whom, and in what circumstances 2. Transform: structural support (e.g. financing, evidence generation) + agency (i.e., active engagement) 3. Static: evidence-based practice + implementation fidelity (e.g., monitoring) 4. Dynamic: sound practice + positive diversion (e.g., SCAMPs)

* *Quality programs* refer to any effort to improve outcomes for patients, standardize clinical practice, eliminate avoidable utilization, and reduce burden for the workforce.
SCAMPs, Standardized Care Assessment and Management Plans.

Source: Geppert JJ, Alexander PMA, Brennan N, Mate KS, Jenkins KJ. Generating Value Through Structural Investment: Rebalancing Value-Based Payment, Pay for Transformation, and Fee-for-Service. Jt Comm J Qual Patient Saf. 2025 Oct;51(10):673-678. doi: 10.1016/j.jcjq.2025.06.006. Epub 2025 Jun 12. PMID: 40707296.

- Complement VBP with P4T in APMs
  - Finance is a tool to enable and sustain transformation to ensure that providers have the necessary evidence, infrastructure, workforce, and systems in place before being held accountable

- Patient safety measurement faces inferential limits for accountability
- Complement safety measures with assurance cases in select contexts
- Leverage AI to make measures more
  - Predictive, mechanism-based, evidence-informed

AI-enabled CQM Development, Evaluation, and Implementation
Predict → test selectively
Fewer, targeted CQM
Continuous evaluation
Acceptance criteria (AC) based
Less waste and lower risk

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It can be done

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Professor, Division of General Medicine and
Division of General Pediatrics
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Measuring Patient Safety in Value-Based Care: Provider Perspectives

Patrick S. Romano, MD MPH

Professor, UC Davis Division of General Internal Medicine (and General Pediatrics)

Physician-Focused Payment Model Technical Advisory Committee; June 15, 2026

Who am I?

- General internist (and previously, general pediatrician) with broad inpatient, consultation, primary, and urgent care experience → now limited to team-based/urgent care
- Fellowship-trained health services researcher (UCSF/UCB)
- Member of (but not speaking for) ACP, AAP, SGIM, CMA, AcademyHealth, AHIMA
- Former co-editor-in-chief, journal HSR (2014-20) and AHRQ's Patient Safety Network (PSNet, 2019-25)
- Clinical lead, AHRQ Quality Indicators/Patient Safety Indicators
- Clinical lead, CMS eCQMs for Eligible Clinicians in QPP/MIPS, formerly CMS eCQMs for Hospital Harms in HIQR program (AIR)
- Member, Leapfrog Hospital Safety Grade Technical Expert Panel

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IOM/NAM Framework and CMS Meaningful Measures 2.0

Crosscutting Dimensions	Components of Quality Care	Type of Care		
		Preventive Care	Acute Treatment	Chronic condition management
EQUITY / VALUE	Effectiveness			
	Safety			
	Timeliness			
	Patient/family-centeredness			
	Access			
	Efficiency			
	Care Coordination			
	Health Systems Infrastructure Capabilities			

- Person-Centered Care
- Closing Gaps in Care
- Safety
- Affordability and Efficiency
- Chronic Conditions
- Wellness and Prevention
- Seamless Care Coordination
- Behavioral Health

Individual and Caregiver Voice

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PTAC's working definition for patient safety

See also https://psnet.ahrq.gov/patient-safety-101
https://www.ncbi.nlm.nih.gov/books/NBK43629/
https://www.who.int/news-room/fact-sheets/detail/patient-safety

Freedom from **errors** that could cause patient harm *(during the delivery of)* health care

- "ZERO preventable harm" (causes identifiable, modifiable, c/w evidence)

Errors may be either errors of **commission**, in which an incorrect action was taken, or errors of **omission**, in which a correct action was not taken

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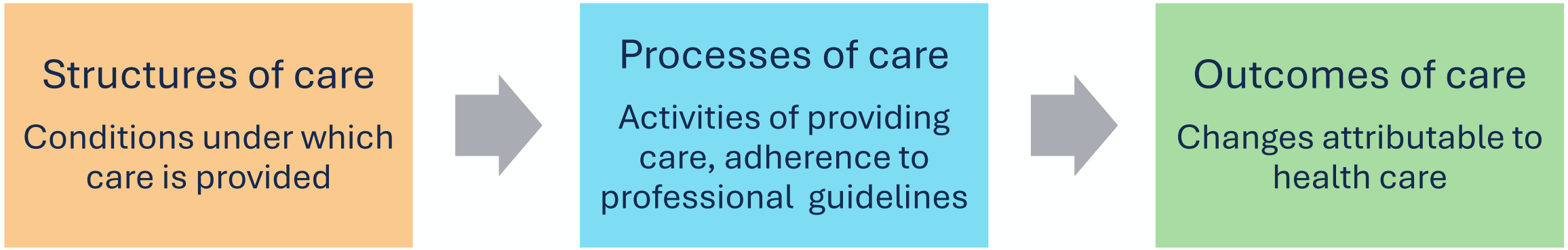
Donabedian quality framework

Stronger structures with better material and human resources, and more robust organizations, enable better processes of care and adherence to “best practices,” leading to fewer preventable errors and better outcomes



BUT too linear – process improvement drives structural change, structures mediate effects of processes on outcomes, optimal structures only facilitate better care

Outcomes are what really matter to patients, families, and communities; they reflect not just what was done but how well it was done

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Targeting Improvements in Patient Safety through Alternative Payment Models: Does it make sense?

Conceptual challenges

- Alternative payment models have traditionally focused on efficiency (TCOC), population health outcomes, and aligning incentives for care coordination
- Safe care is an ethical and legal imperative ("primum non nocere," tort liability)
- Professionalism demands attention to patient safety and creates distress (even burnout) when errors occur
- So… do we really need PFPM penalties/rewards for providing safe care?

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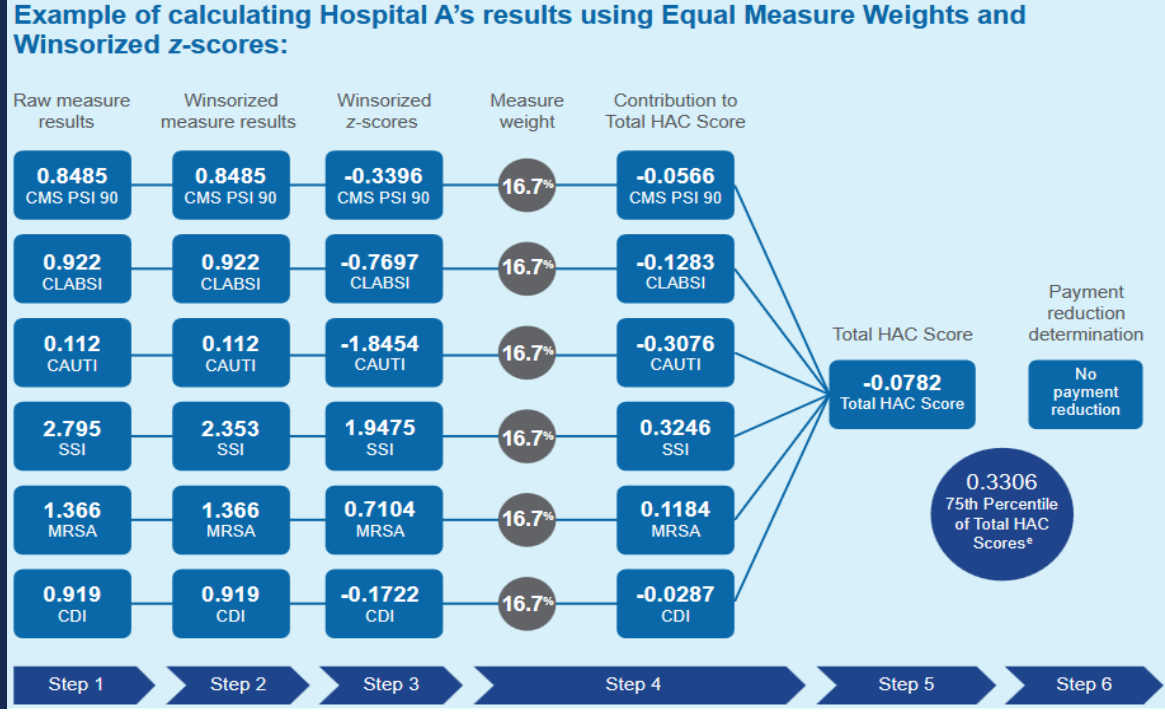
Targeting Improvements in Patient Safety through Alternative Payment Models: Does it make sense?

Counterexample: Medicare's Hospital-Acquired Conditions Reduction Program



- 1% Medicare FFS penalty for bottom quartile of IPPS hospitals based on 6 risk-standardized measures (CMS composite of 10 claims-based PSIs, 5 NHSN HAIs)
- Right: Many meaningful outcome measures from diverse sources, forcing hospital attention to safety while balancing risk; attribution is essentially undeniable
- Wrong: Two-bin design stabilizes total penalty but doesn't reward improvement or recognize within-bin variation, sensitive to few events and unpredictable thresholds, disfavors teaching and safety net hospitals (2/3 of measures don't have patient-level risk adjustment), favors underreporting, little evidence of impact using exogenous data

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Is there a better approach for payment models?

Recognize attribution challenges for physician-focused models:

- MD/DOs work in teams with other MD/DO, RNs, MAs, therapists, techs
- MD/DOs don't choose their team members in many settings
- MD/DOs may split time across multiple teams
- Harm events are rare, have many causes (see RCA, FMEA), many risk factors, and may manifest after measured episode ("Swiss cheese")

Focus on linked outcomes (or intermediate outcomes) and processes that complement and balance each other… for example:

- Severe hypo and hyperglycemic episodes in hospitals
- Handwashing & HAIs
- Fall prevention (improving mobility) & injurious falls
- Diagnostic process timeliness and diagnostic outcomes

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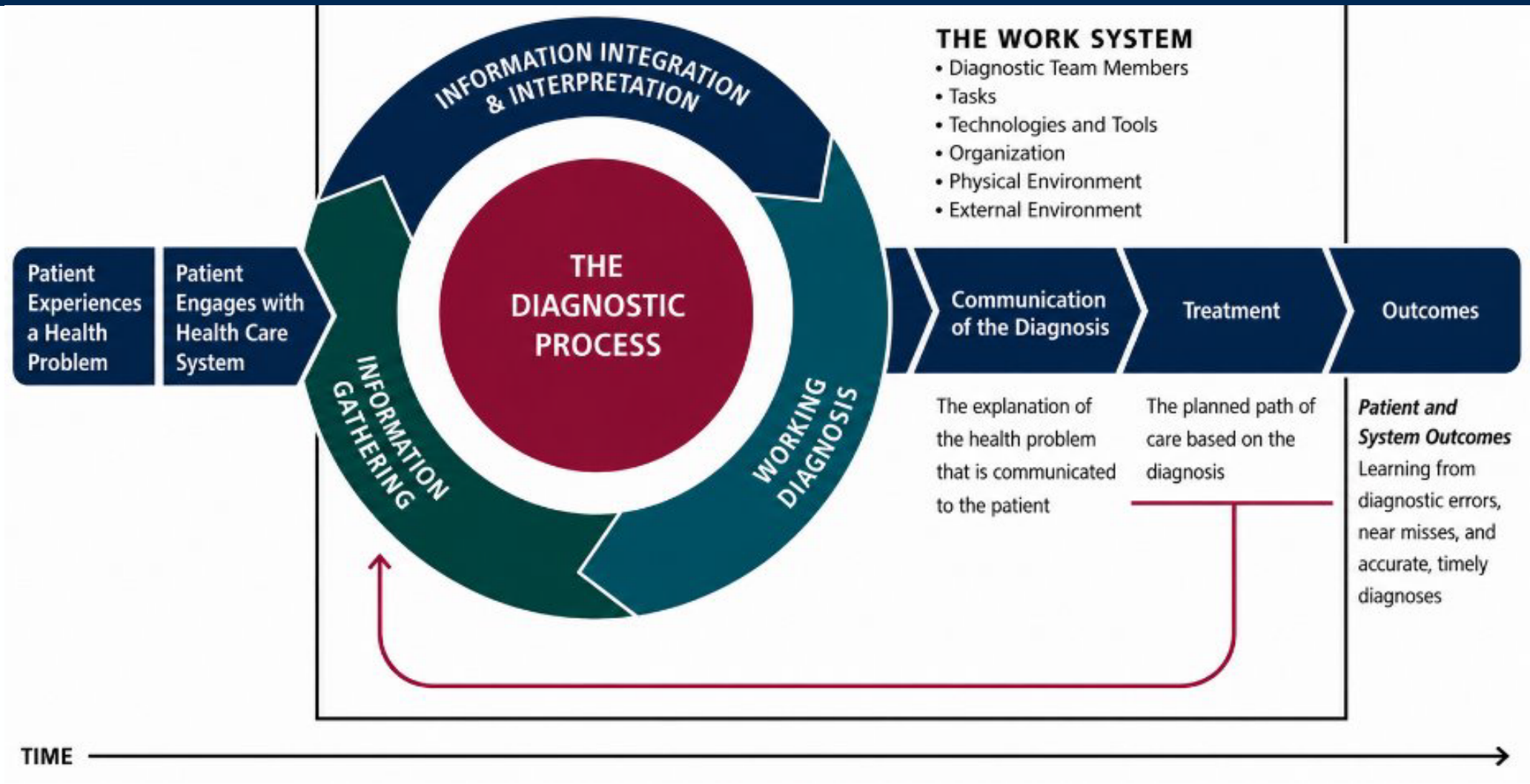
CMS Hospital Harms (electronic clinical quality measures)

Hospital Harm eCQM	Measure Type	Measure Description
Severe Hypoglycemia	Proportion	Inpatient hospitalizations for patients 18+ who were administered at least one hypoglycemic medication during the encounter and who suffer the harm of a severe hypoglycemic event during the encounter.
Severe Hyperglycemia	Ratio	Inpatient hospital days for patients 18+ with a hyperglycemic event (harm) per the total qualifying inpatient hospital days for that encounter.
Opioid-Related Adverse Events	Proportion	Inpatient hospitalizations for patients 18+ who have been administered an opioid medication outside of the operating room and are subsequently administered an opioid antagonist outside of the operating room within 12 hours, an indication of an opioid-related adverse event.
Acute Kidney Injury	Proportion Risk Adjusted	Inpatient hospitalizations for patients 18+ who have an acute kidney injury (stage 2 or greater) that occurred during the encounter. Acute kidney injury stage 2 or greater is defined as a substantial increase in serum creatinine value, or by the initiation of kidney dialysis (continuous renal replacement therapy, hemodialysis or peritoneal dialysis).
Pressure Injury	Proportion	Inpatient hospitalization for patients 18+ who suffer the harm of developing a new stage 2, stage 3, stage 4, deep tissue, or unstageable pressure injury.
Falls with Injury	Ratio Risk Adjusted	Inpatient hospitalizations where at least one fall with a major or moderate injury occurs among the total qualifying inpatient hospital days for patients 18+ .
Postoperative Respiratory Failure	Proportion Risk Adjusted	Elective inpatient hospitalizations for patients 18+ without an obstetrical condition who have a procedure resulting in postoperative respiratory failure.
Anticoagulant-Related Major Bleeding	Proportion	Inpatient hospitalizations for patients 18+ who were administered at least one anticoagulant medication within the first 24 hours of admission and had a subsequent bleeding event during the encounter.
Postoperative Venous Thromboembolism	Proportion	Inpatient hospitalizations for patients 18+ who have at least one surgical procedure during the encounter, and who suffer the harm of a postoperative venous thromboembolism (VTE) during the encounter or within 30 days after the first surgical procedure.

Diagnostic process model



NASEM. 2015. Improving diagnosis in health care. Washington, DC: The National Academies Press.

AHRQ's approach to diagnostic excellence (stay tuned)

Timely Follow-up After: Abnormal Breast Cancer Screening

- Timely imaging or biopsy after abnormal mammogram

Positive Colorectal Cancer Screening

- Timely colonoscopy after positive stool-based test

Abnormal Lung Cancer Screening

- Timely interval CT or diagnostic evaluation after abnormal screening

Late-Stage Diagnosis

- Proportion lung cancer diagnosed at a late stage
- Proportion colorectal cancer diagnosed at a late stage

New Cancer Diagnosis Following Acute Presentation

- Lung cancer dx at or within 30 days of an ED visit or unplanned admission
- Colorectal cancer diagnosis at or within 30 days of an ED visit or unplanned admission

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Takeaways – proceed cautiously and deliberately

- Payment models do NOT have a strong track record for improving patient safety (intrinsic vs. extrinsic motivation)
- Transparency is essential but can proceed with or without financial rewards and penalties
- Accountability and actionability must be linked at entity level (e.g., hospitals, SNFs, integrated health systems)
- Build on foundations of professionalism, continuous quality improvement, culture of safety, learning organizations
- Align with what's important to patients, families, purchasers
- Expected unintended consequences (underreporting, risk avoidance, undertesting, overtesting)

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AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Briefing on AHRQ Patient Safety Measurement Activities

CDR Karen Chaves

Director of the Division of Qualtiy Measurement and Improvement
Center for Quality Improvement and Patient Safety

Physician-focused Payment-Model Technical Advisory Committee (PTAC) Meeting

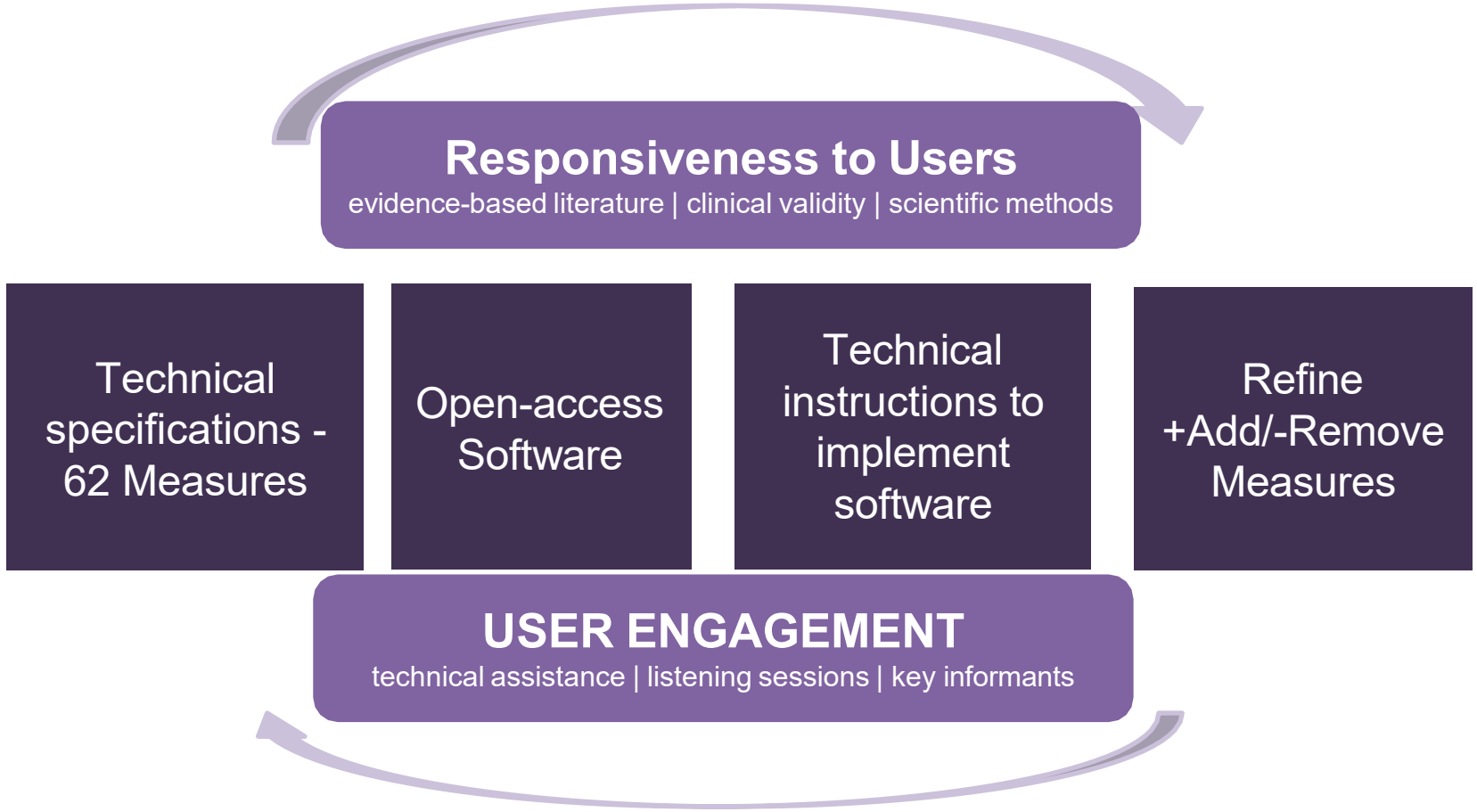
June 15, 2026

Overview

- AHRQ Quality Indicators Program
- Patient Safety Indicators (PSI) Gap Analysis - December 2025
- Current activites on diagnostic excellence, maternal health, outpatient surgery

AHRQ Quality Indicators Program

Mission: produce *scientifically* sound measures & software for healthcare users to identify *potential* quality of care improvements.

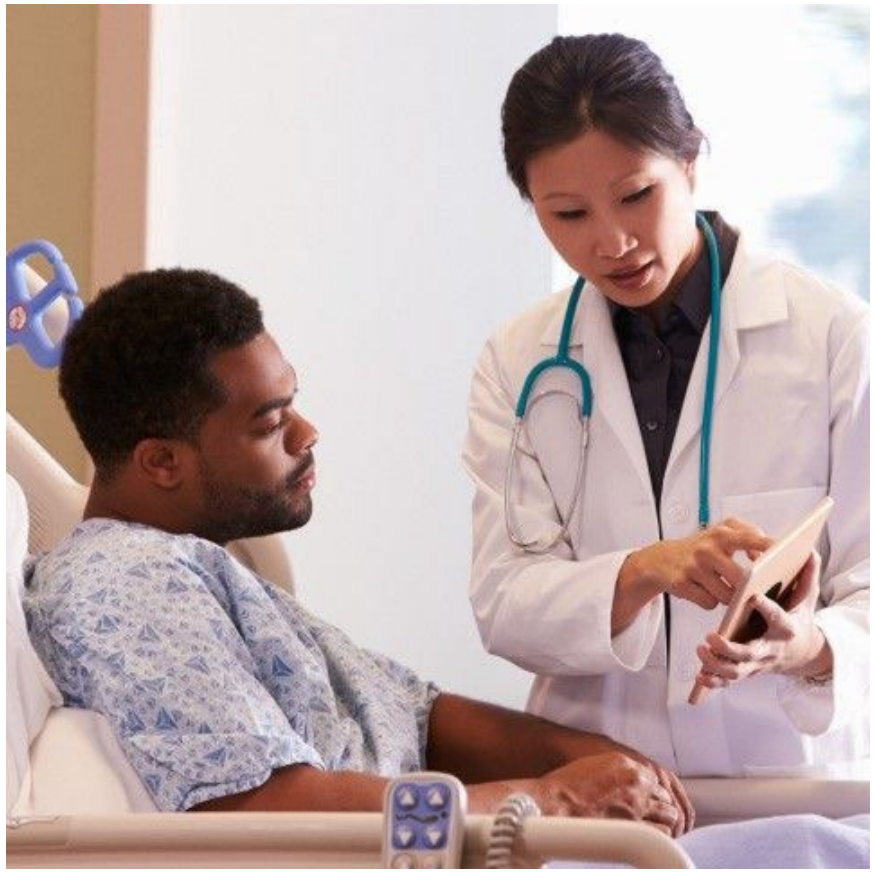


AHRQ Patient Safety Indicators

Broad use for quality improvement purposes

	Quality Improvement			Performance measurements			Research
	Identify	Prioritize	Guiding QI Work	Benchmark	Public Reporting	Payment Setting	Tools & Research
Hospitals & Health Systems including ACOs	●	●	●	●	●	●	●
Health/Hospital Associations	●	●	●	●	●		●
Health Plans				●	●	●	
3rd Party Vendors (QI/data/other)	●	●	●	●			●
State/Local Health Departments	●	●	●	●	●		
Federal Agencies					●	●	●
Federal Health Systems	●	●	●	●	●		●

Patient Safety Indicators Gap Analysis

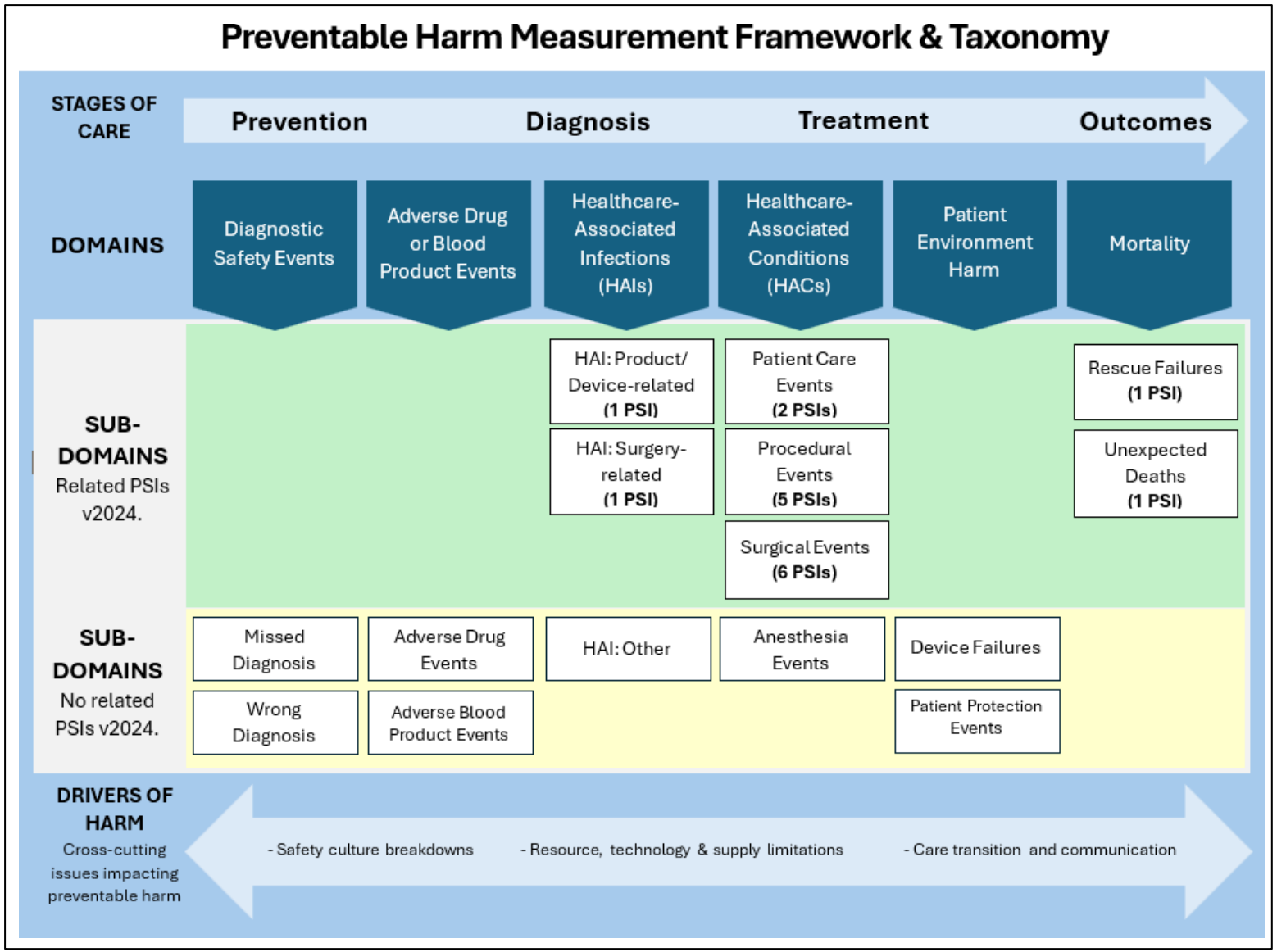


https://qualityindicators.ahrq.gov/resources/webinars

Key Themes

- Address overlap across measures
  (PSIs, CDC's NHSN, CMS's electronic clinical quality measures (eCQMs), NCQA's HEDIS ambulatory quality metrics, and patient experience surveys)
- Administrative burden of measurement
- Consider measuring access to care more broadly
- Expand PSIs to other settings (free-standing EDs, urgent care facilities)
- Measures on patient-reported harm and incorporating patient perspectives into measurement

Guiding Framework: CMS Meaningful Measures 2.0



Considerations

- **Settings**: Ambulatory, Home Health, Hospice, Hospital Inpatient, Psychiatric Facility, Rehabilitation Facility, Skilled Nursing Facility/Nursing Home
- **Populations**: Infant, Child, Young Adult, Adult, Older Adults
- **Priority Areas**: Health Information Technology (HIT), Artificial Intelligence (AI), Telehealth, Radiology, Failure to Rescue, Care Transitions, Maternal, Behavioral Health
- **Federal and Other Safety Reporting Programs**:
  - CMS, NHSN
  - Reportable Adverse Events (California),9 Quality in Healthcare Program Adverse Event Reporting (Connecticut),10 Sentinel Event Registry (Nevada),11 and Patient Safety Reporting System (Pennsylvania)12

Conditions Discussed

1. Diagnostic safety events
2. Adverse Drug or Blood Products Events
3. Healthcare Associated Infections (HAIs)
4. Healthcare Associated Conditions (HACs)
5. Mortality

1. Diagnostic Safety Events

Measurement Opportunities:

- Missed lab, imaging, or other test results that lead to delayed or missed diagnoses
- Inappropriate follow-up care
- Late-stage diagnosis

2. Adverse Drug Events

Measurement Opportunities:

- Frequency of medication errors
- Few measurement opportunities in literature
- Challenges in defining what constitutes adverse drug events

3. Healthcare-Associated Infections (HAIs)

Measurement Opportunities:

- Existing PSIs (PSI 07, PSI 13, new MHI measures)
- Potential to measure common HAIs, such as C. diff, ventilator- and non-ventilator- associated pneumonia, hospital-onset bacteremia and fungemia, catheter-associated urinary tract infections, or SSIs among cardiovascular and colorectal surgeries
- NHSN tracking and measuring HAIs

4. Healthcare-Associated Conditions (HACs)

Measurement Opportunities:

- Existing PSIs in the inpatient setting (PSI 03, PSI 05, PSI 06, PSI 09, PSI 10, PSI 11, PSI 12, PSI 14, PSI 15, PSI 17, PSI 19)
- Potential to expand to outpatient setting (e.g., falls, ulcers, anesthesia)
- Potential for measure of advanced tools to prevent HACs

5. Mortality

Measurement Opportunities:

- Existing PSIs (PSI 02, PSI 04)
- Examine preventable death in non-acute care settings
- Population-level measures of preventable deaths, such as mortality due to chronic diseases among younger populations
- Potential to leverage novel data sources, such as those within vital sign monitoring systems and AI tools

Recommendations

1. *Review existing PSIs to eliminate overlap with other federal safety measures, such as those from the CDC, which will help streamline reporting and reduce provider burden.*

2. *Expand PSIs to Ambulatory Surgery Centers (ASCs) and develop measures for perioperative care in this setting, as increasingly complex procedures are being performed in ASCs.*

3. *Broaden maternal and neonatal safety measures to care settings beyond the hospital, such as birthing centers, and develop perinatal safety indicators to better quantify preventable harms for these populations.*

4. *Continue efforts to identify data sources for measures of preventable harm from diagnostic errors, including in behavioral health.*

Current Activities

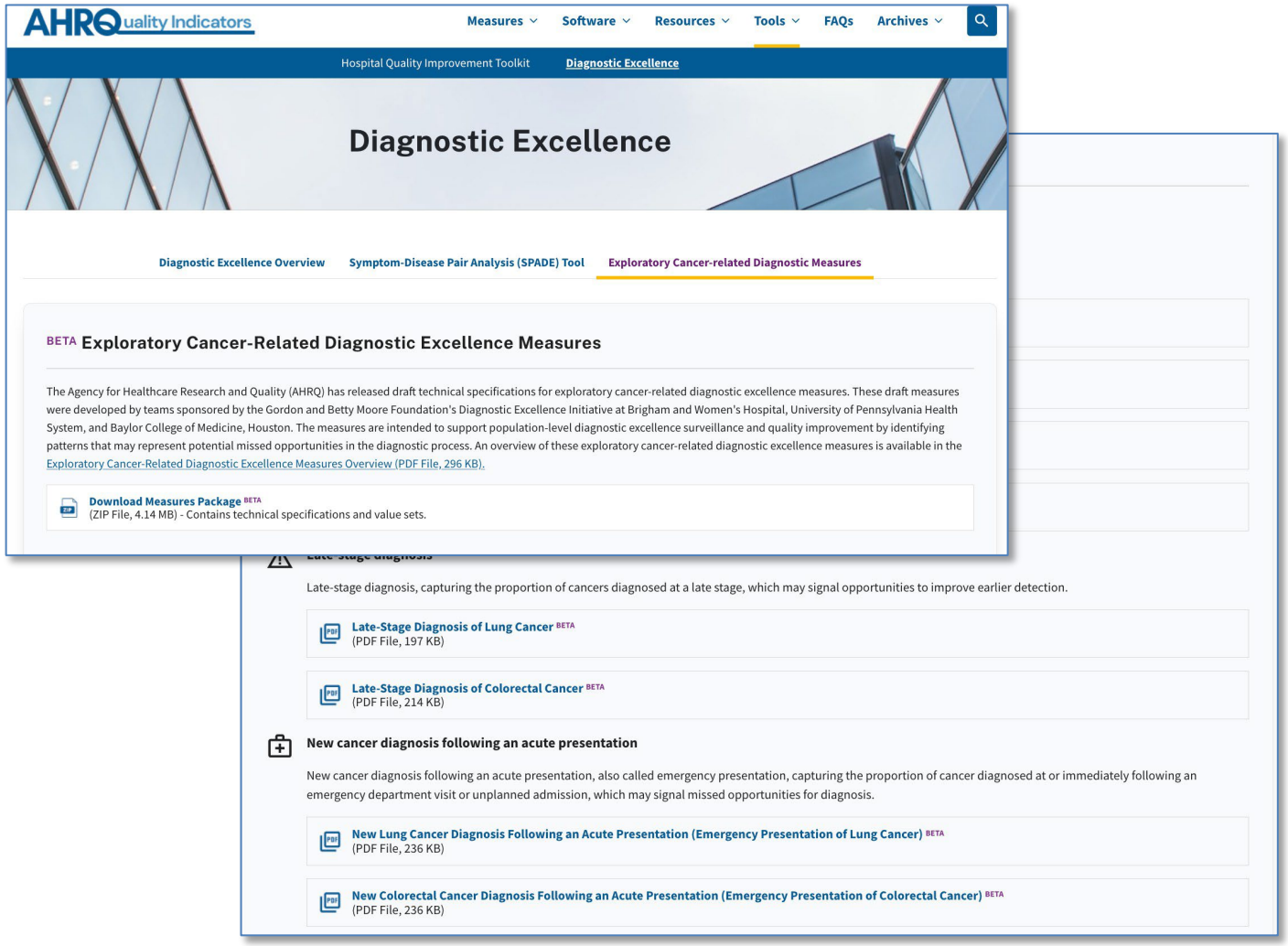
- AHRQ Quality Indicators focus on broad use for quality improvement purposes and are not designed for accountability

- Work underway or planned:
  - Diagnostic excellence measures of cancer-related conditions
  - Maternal health – postpartum cardiomyopathy, behavior health
  - Outpatient surgery - potentially preventable complications analogous to inpatient postoperative complications measured by PSIs

SUPPLEMENTAL SLIDES

Where to Find the Cancer-Related Measure Specifications

AHRQ QI Website: https://qualityindicators.ahrq.gov/tools/diagnostic_excellence#Cancer-Tab



Scan the QR code to access resources

AHRQ Role:
Diagnostic Excellence Measurement

Address gap in diagnostic excellence measurement with a *population-level* lens:

1. Starter set of **standardized measures** to support population-level diagnostic safety surveillance
2. Measures **accessible and applicable across users**, especially those with limited access to clinical data sources
3. **National reference for developing a baseline benchmark** of population-level diagnostic safety surveillance
4. **Foster healthcare quality improvement** around diagnostic excellence

Cancer-Related Diagnostic Excellence Measures

- New AHRQ diagnostic excellence indicators under development for cancer care pathways
- Targets timely follow-up after abnormal cancer screening results
- Includes measures for potentially delayed diagnosis
- Applies electronic health record (EHR) data for indicator calculation
- Aims to support health systems in identifying **diagnostic delays** and **improvement opportunities**
- Intended for **quality improvement and research**, not for accountability or benchmarking

Exploratory Measures - Cancer-Related Diagnostic Excellence

- **Timely Follow-up After Screening**
  - **Abnormal Breast Cancer Screening**
    - Timely imaging or biopsy after abnormal mammogram
  - **Positive Colorectal Cancer Screening**
    - Timely colonoscopy after positive stool-based test
  - **Negative Lung Cancer Screening**
    - Timely repeat chest CT after negative screening
  - **Abnormal Lung Cancer Screening**
    - Timely interval CT or diagnostic evaluation after abnormal screening

Where to Find MHI Resources

VISIT →
qualityindicators.ahrq.gov → /tools/maternal_health_indicators
AHRQ Quality Indicators Website · MHI module homepage

Resources available

Technical specs
ICD-10-CM/PCS for each MHI

Software documentation
Reference manuals for AHRQ Quality Indicators software

Measure definitions
Numerator, denominator, code lists

User guides
Getting started and applied examples

Scan to visit →

Purpose and Background

1

WHY THIS MATTERS

- Maternal health outcomes are a critical public health concern

2

PERSISTENT CHALLENGES IN HEALTHCARE MEASUREMENT

01	02	03
Severe maternal morbidity (SMM)	Maternal mortality	Maternal behavioral health

3

THE GAP

✓ MHI fills gaps in standardized, claims-based measures

MHI Module at a Glance

INTENDED USE

- Surveillance
- Quality Improvement
- Research

INTENDED USERS

- State / Local Health Agencies
- Health Systems & Hospitals
- Researchers

CLINICAL DOMAINS

- **Severe Maternal Morbidity (SMM)**
- **In-Hospital Mortality**
- **Maternal Mental & Behavioral Health**

TIME WINDOWS

- **Delivery Hospitalization**
- **Delivery → 42 Days**
- **Postpartum Days 1–42**

DATA SOURCES

- **Inpatient Discharge Data**
- **ED + Inpatient Discharge**

OUTPUTS & RISK ADJUSTMENT

Outputs
Area-level results
Stratified results

Risk Adjustment
No risk adjustment currently available

Preliminary plans
Hospital outpatient surgical complications

Problem: ***Selected procedures in PSI denominator cohorts have declined consistent with migration to hospital outpatient settings.*** *Example: THA/TKA*

2026 aim: ***Explore whether PSI-related concepts are clinically meaningful, feasible to specify, and feasible to test in outpatient procedure cohorts linked to follow-up ED and inpatient events***

Exploratory work:

- Near-term goal is to assess concepts, definitions, and feasibility rather than present finalized measures.

Targeted scope:

- Focus on a small set of high-priority procedure groups already represented in PSI logic.
- Develop candidate CPT code definitions for outpatient testing.

Testing frame:

Begin with hospital-owned outpatient encounters.
Use linked outpatient/inpatient/ED HCUP data to assess follow-up ED and inpatient events where feasible.

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THE UNIVERSITY OF UTAH

Measuring Patient Safety In Value Based Care: The PSO Perspective

David Classen MD MS
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Senior Advisor PascalMetrics PSO

ERRORS & ADVERSE EVENTS

By David C. Classen, Roger Resar, Frances Griffin, Frank Federico, Terri Frankel, Nancy Kimmel, John C. Whittington, Allan Frankel, Andrew Seger, and Brent C. James

'Global Trigger Tool' Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured

DOI: 10.1377/hlthaff.2011.0190
HEALTH AFFAIRS 30,
NO. 4 (2011): –
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The People-to-People Health
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ABSTRACT Identification and measurement of adverse medical events is central to patient safety, forming a foundation for accountability, prioritizing problems to work on, generating ideas for safer care, and testing which interventions work. We compared three methods to detect adverse events in hospitalized patients, using the same patient sample set from three leading hospitals. We found that the adverse event detection methods commonly used to track patient safety in the United States today—voluntary reporting and the Agency for Healthcare Research and Quality's Patient Safety Indicators—fared very poorly compared to other methods and missed 90 percent of the adverse events. The Institute for Healthcare Improvement's Global Trigger Tool found at least ten times more confirmed, serious events than these other methods. Overall, adverse events occurred in one-third of hospital admissions. Reliance on voluntary reporting and the Patient Safety Indicators could produce misleading conclusions about the current safety of care in the US health care system and misdirect efforts to improve patient safety.

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Terri Frankel is a director at the Institute for Healthcare Improvement.

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EXHIBIT 4

Adverse Event Detection, By Severity Level And Hospital

	IHI Global Trigger Tool	AHRQ Patient Safety Indicators	Hospital voluntary reporting system
SEVERITY LEVEL			
E	204	23	0
F	124	7	2
G	8	1	2
H	14	0	0
I	4	4	0
Total	354	35	4
HOSPITAL			
Hospital A	161	13	0
Hospital B	92	13	3
Hospital C	101	9	1
Total	354	35	4

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The Foundation: Automated GTT the "First Step" to Real-time Patient Safety…

IDEAS AND OPINIONS — Annals of Internal Medicine

Measuring Patient Safety in Real Time: An Essential Method for Effectively Improving the Safety of Care

David C. Classen, MD, MS; Frances A. Griffin, RRT, MPA; and Donald M. Berwick, MD, MPP

The continuing evidence of preventable deaths due to medical error has led to recent calls to improve measurement of safety in hospitals. This need can be adequately addressed by harnessing health information technology. Electronic health records (EHRs), which have been broadly adopted, offer the opportunity for measurement of all-cause harm in hospitalized and ambulatory patients and real-time mitigation to reduce it. Yet, the recent Institute of Medicine (IOM) report, "Health IT and Patient Safety," which recommends this method, notes that this opportunity has generally not been taken (1).

Widespread preventable injury to hospitalized patients persists more than 15 years after the IOM report, "To Err is Human," brought it to international attention. In fact, medical error was recently cited as the third leading cause of death in U.S. hospitalized patients (2). This magnitude of harm will likely persist until it is measured effectively and consistently by every hospital, as many have called for. Among the barriers to measurement of harm are the lack of standard definitions for it, the perceived burden of data collection, and the limitations of current ways of estimating the true incidence of harm. All of these barriers can be lowered with better methods to measure harm through the use of EHRs.

Studies estimating the amount of patient harm from medical error have historically relied on retrospective review of medical records, particularly paper records. The Harvard Medical Practice Study (3), on which the IOM based many of its estimates, involved detailed, manual retrospective review of more than 30 000 medical records. Most hospitals do not have sufficient resources to conduct this type of intensive review; they rely instead on data collected for other purposes, such as administrative billing data.

The Harvard approach remained the most commonly cited method for review of all-cause harm until the 2011 publication of a study that performed expedited retrospective review by searching for triggers typically associated with the most frequent and harmful adverse events. This method allows for detection and measurement of adverse events or all-cause harm with lower resource intensity through the use of sampling and has been shown to identify more than 90% of harm in hospitalized patients. Other indicators based on billing data capture less than 10% of actual harm, and voluntary reporting finds less than 5% (4).

In 2010, the Office of Inspector General of the U.S. Department of Health and Human Services evaluated 5 methods for measuring the rate of adverse events in hospitalized Medicare beneficiaries and determined that a trigger review method was the most effective (5), subsequently using it to conduct a study that was reported to Congress (6). A trigger method has been used by thousands of hospitals worldwide to measure all-cause harm and is recommended by the World Health Organization and in national initiatives to improve safety in the United Kingdom, Norway, and other nations. However, this manual method is limited due to resource requirements and its retrospective nature. It does not allow for real-time prevention or rapid amelioration of safety problems.

A recent survey by the U.S. Office of the National Coordinator found that more than 96% of U.S. hospitals have implemented an EHR system (7). However, most hospitals do not use the EHR to directly measure patient harm. Instead, measurement is more often based on electronic voluntary reporting systems and automated coding of medical records at discharge. One clinical area—infection prevention surveillance—has harnessed the power of EHRs to improve detection of safety problems. Electronic surveillance for infections has enabled practitioners to monitor all hospitalized patients efficiently and to improve detection through automated identification of laboratory diagnostics, such as positive blood culture results. This approach has greatly enhanced detection and identification of serious infections, such as central line–associated bloodstream infections, and the measurement of these has accelerated efforts to reduce such harm.

Research and development on the automation of all-cause harm detection using the infection prevention surveillance model is well under way and was initially based on work at Kaiser Permanente, which has automated detection using data from its EHR system and almost all of the triggers from the Institute for Healthcare Improvement Global Trigger Tool (8). Other leading health systems using data from their EHRs have expanded on this work, such as Adventist Health System, Baylor Scott & White Health, Dignity Health, Providence Health & Services, and Cook Children's Health Care System. These organizations have demonstrated the ability to measure all causes of harm in real time in the whole inpatient population, allowing for more robust measurement and actionable intervention to reduce or mitigate harm. Surveillance for harm in the electronic record using the leading commercial EHR vendors' products can be affordable, sustainable, and actionable. It not only provides a full-hospital population approach to patient safety but also can help to predict which patients might experience harm and when, supporting prevention before harm occurs (9).

Nearly 20 years have elapsed since the landmark IOM report on patient safety without sustainable, mea-

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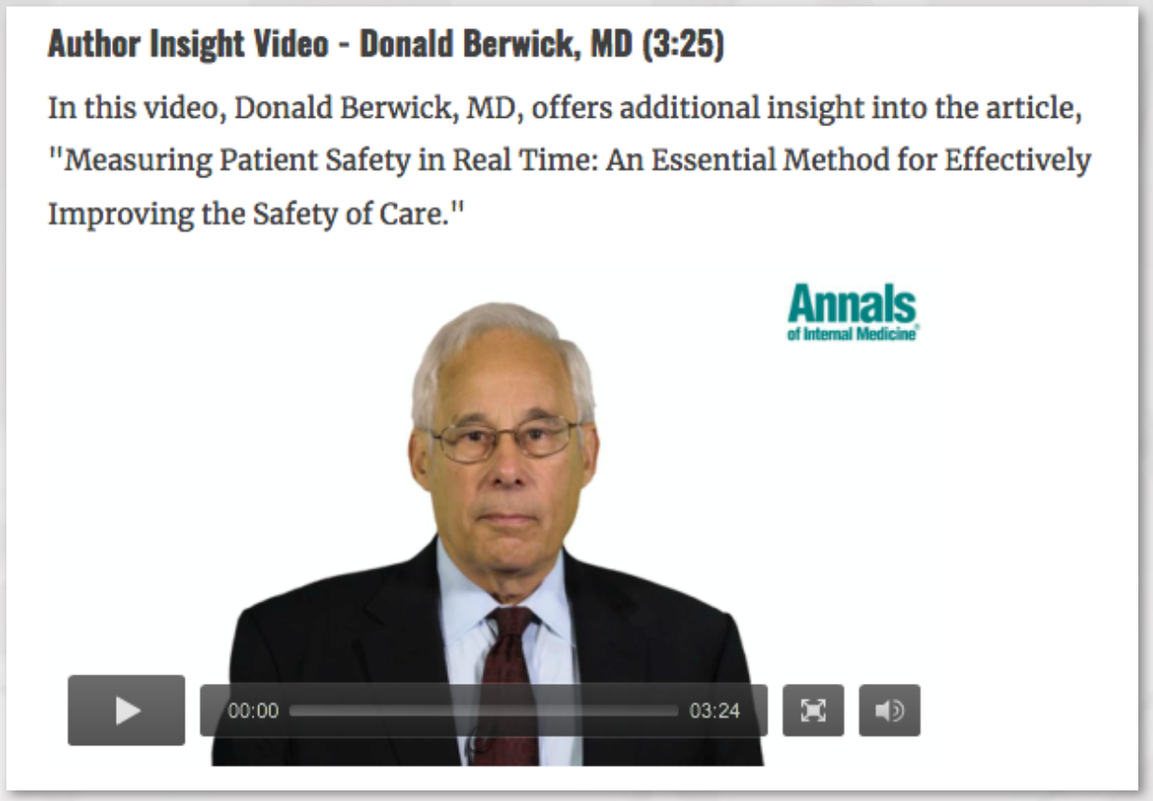

Don Berwick – "Using the EHR for Safety" via pascalmetrics.com

"We've made progress…in particles of care…but we've not made healthcare systematically [safe]…and we won't, we can't, until we take stock of safety levels in organizations systematically."

-- *Dr. Don Berwick*

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New CMS Harms Measures (Automated Triggers) – eCQMs

Opioid-Related Adverse Events

Hypoglycemia

Hyperglycemia

Pressure Injury

Acute Kidney Injury

Anticoagulation -Related Major Bleeding

Falls with Injury

Postoperative Venous Thromboembolism

Postoperative Respiratory Failure

QUALITY OF CARE

By David Classen, Michael Li, Suzanne Miller, and Drew Ladner

An Electronic Health Record–Based Real-Time Analytics Program For Patient Safety Surveillance And Improvement

ABSTRACT **Twenty years after publication of the report *To Err Is Human*, studies demonstrate persisting high levels of patient harm. Most patient safety measurement remains highly retrospective, relying on voluntary reporting and post discharge administrative coding. Progress has been limited by the lack of advances in measurement accuracy, detection sensitivity, and timely actionability. The broad adoption of electronic health records (EHRs) offers a significant opportunity to leverage digital information to improve safety measurement and management using real-time data. We developed a novel method to extract safety indicators from EHRs to identify harm and its precursors by implementing a patient safety active management system (PSAM) in hospitals within a national Patient Safety Organization (PSO). The PSAM generated validated adverse event outcomes and leveraged EHR data to develop a real-time safety predictive model. This study describes the PSAM's pilot at two large community hospitals in 2014–17. We found that the PSAM could detect harm in real time, at higher rates than current levels are detected, and that such harm could be predicted. In addition to outlining future opportunities and challenges with this EHR-enabled PSAM approach, we discuss implications and next steps for policy and practice.**

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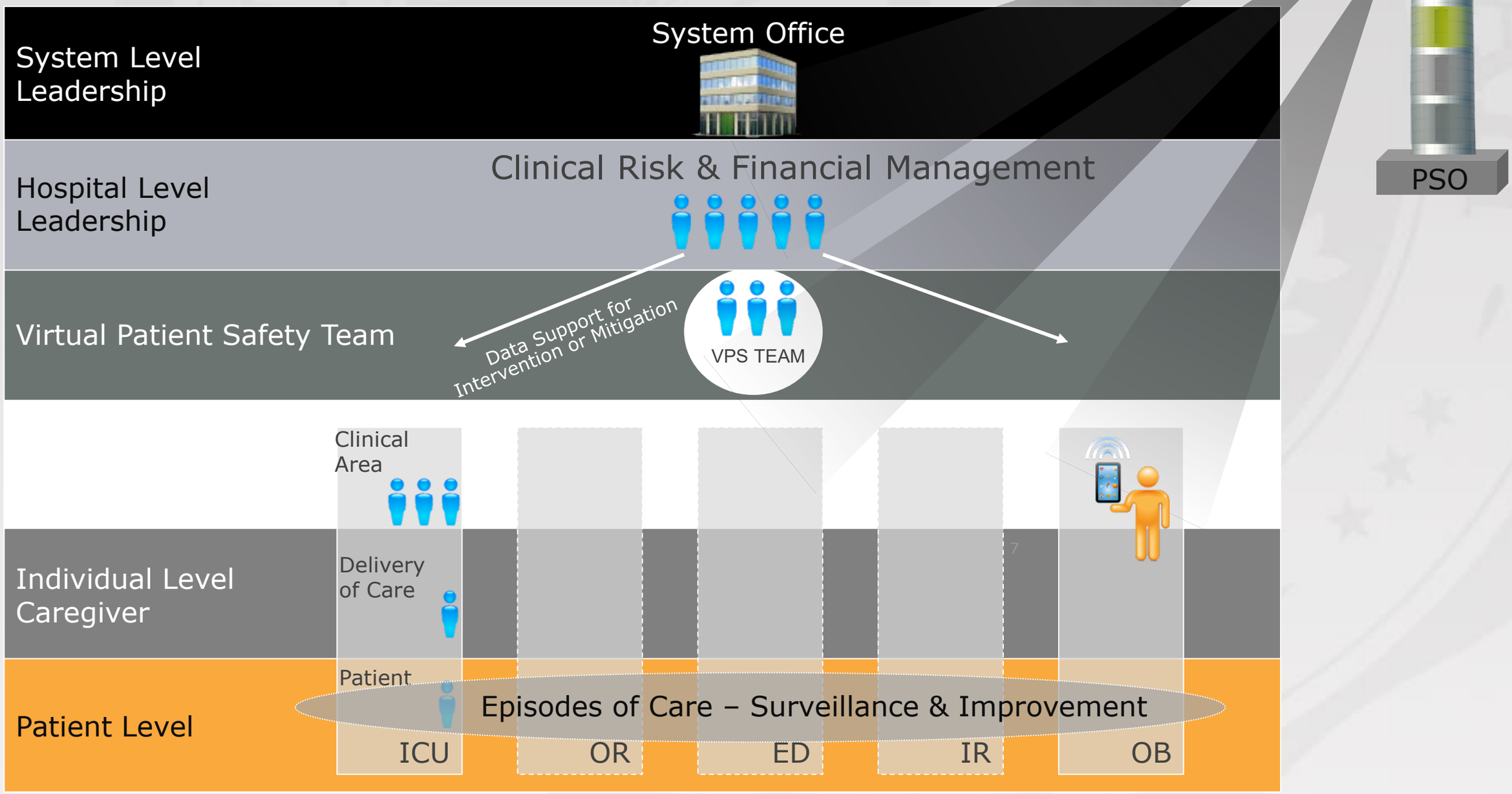
PATIENT SAFETY & RISK IMPROVEMENT USING REAL-TIME DATA

Healthcare Provider



The PSO shares data across units, hospitals, and health systems, and enables health systems to identify and reduce harm in a culture of safety – given that this method finds 10x the level of harm as compared to event reporting

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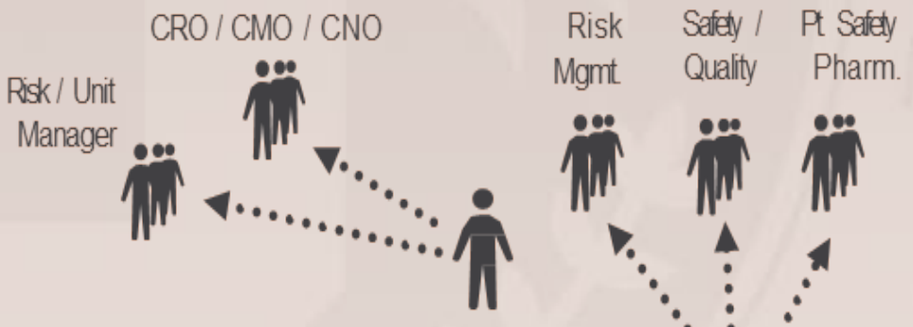
Automated Triggers High-Level Workflow

Hospital

Real-time Data Streaming

Real-time EHR, as well as Admin/Billing, and Litigation Data

Intervention and Improvement



PSO

Triggers & Algorithms Fire

Data Analytics Library and Data Sets

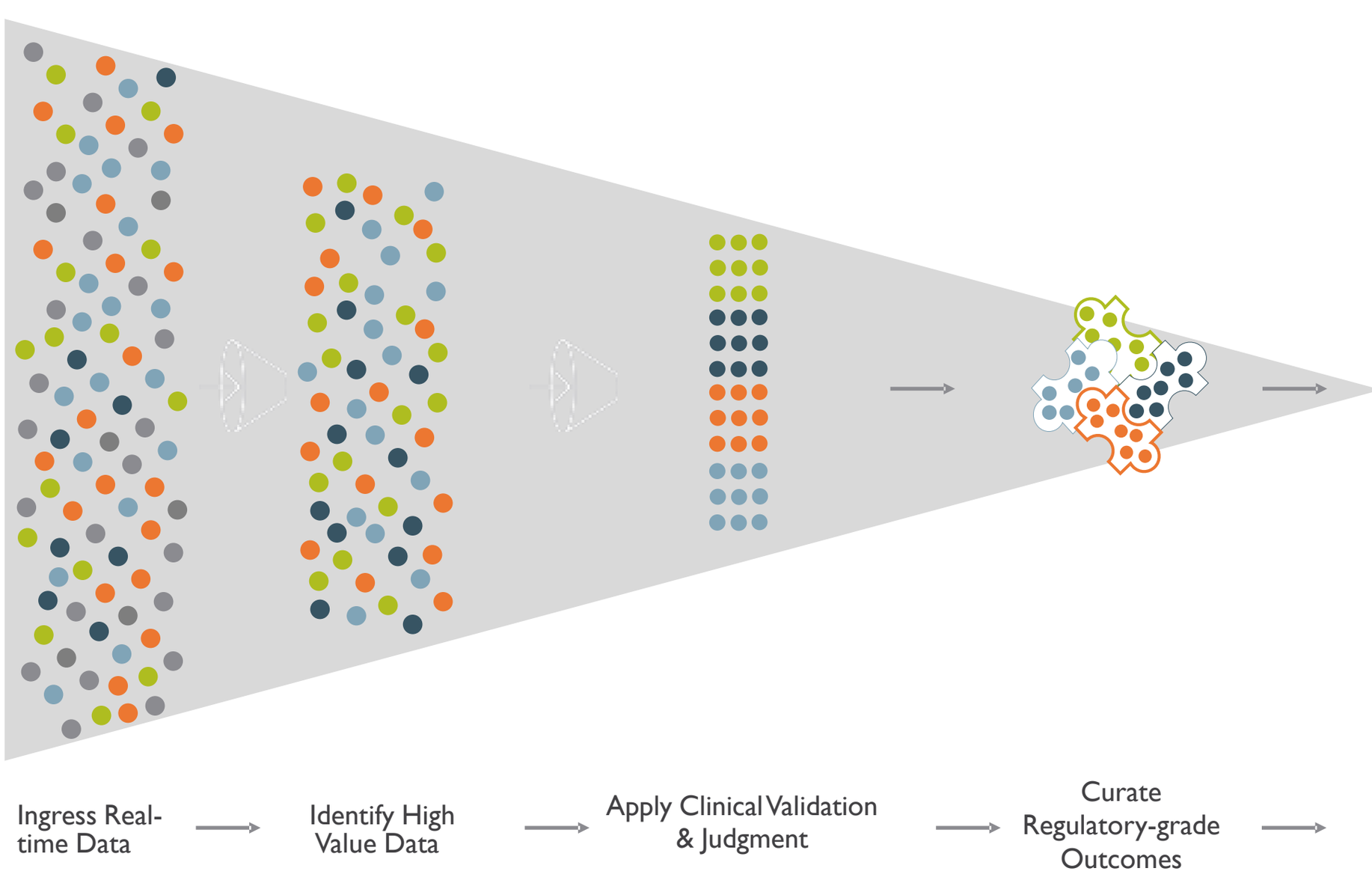
Outcomes Data

Patients to Monitor, Measure & Manage

Expert Safety Review & Validation

Patient Safety Organization (PSO) Protection

Foundational Role: EHR-based Safety Outcomes "Engine"



Ingress Real-time Data → Identify High Value Data → Apply Clinical Validation & Judgment → Curate Regulatory-grade Outcomes →

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Developing and Evaluating an Automated All-Cause Harm Trigger System

Christine Sammer, DrPH, RN; Susanne Miller, RN, MS; Cason Jones, MLS, MHA; Antoinette Nelson, RN, BSN, MSHSA; Paul Garrett, MD; David Classen, MD, MS; David Stockwell, MD

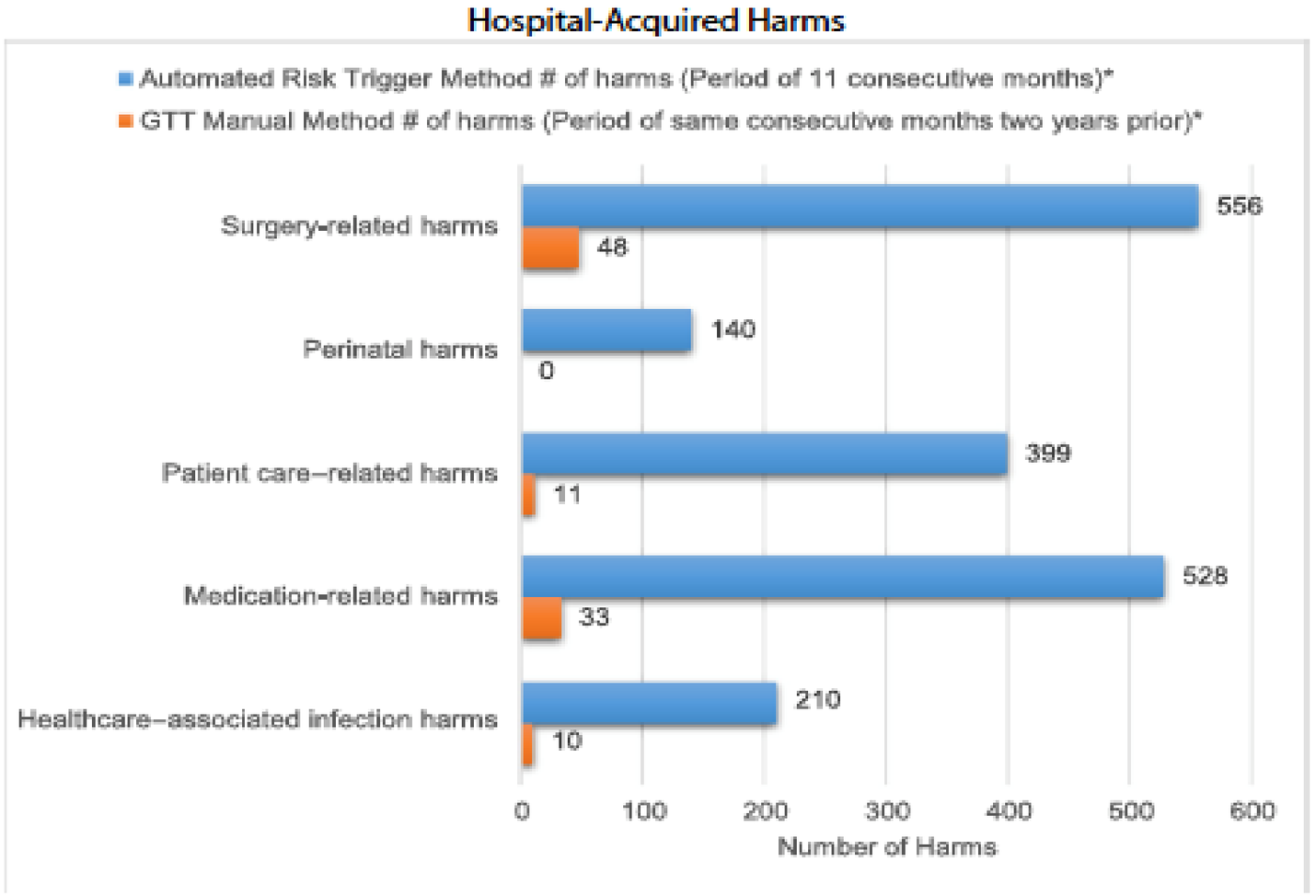

Figure 2: The automated risk trigger process captured significantly more hospital-acquired harms in all five harm categories than the Global Trigger Tool (GTT) manual method for similar time periods. *Data format complies with non-identification standard of the Patient Safety and Quality Improvement Act of 2005.

Results, Identification: EHR-based vs. Industry Standard, i.e., Voluntary Event Reporting (VER)

Illustrative Example: 1 Hospital with Strong Culture Over 7 Years

3,740

Adverse events ID'd with EHR-based method

147

# of those adverse events ID'd with Standard VER

CLINICAL EFFECTIVENESS COMPARISON: **25x**

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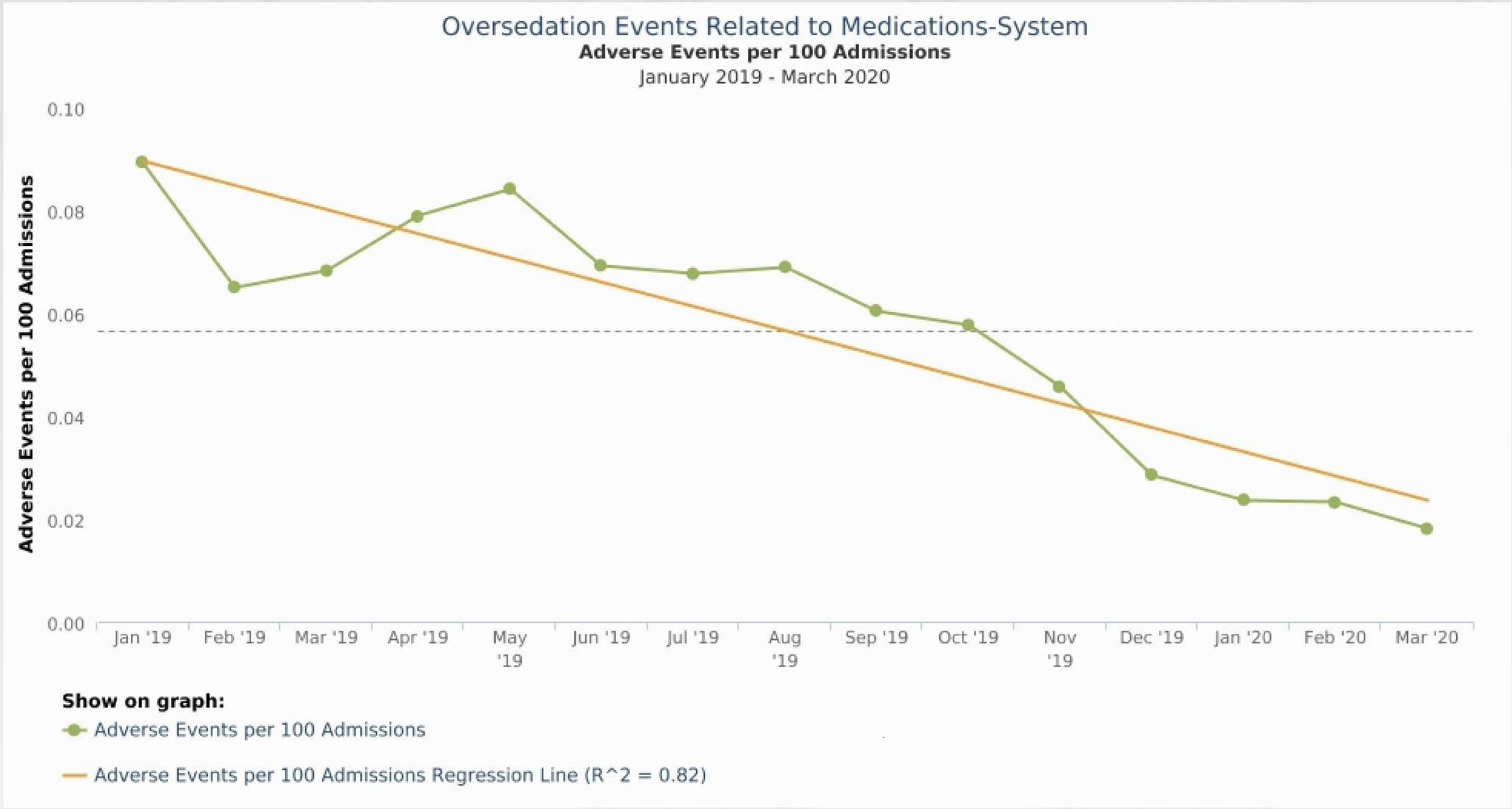
Results – Reduction: Specific Harm, System-wide



PASCALHEALTHBENCH richard.reyman@pascalmetrics.com

Risk Trigger Monitoring

Safety Dashboard | Monitoring | Worklist | Authenticate | Approve | Reports

Patient: Allen, Jonathan

Southwest Regional, Johnson Memorial Medical Center

Current Global Safety Risk: **HIGH 62**
As of: 8/5/2014 06:57

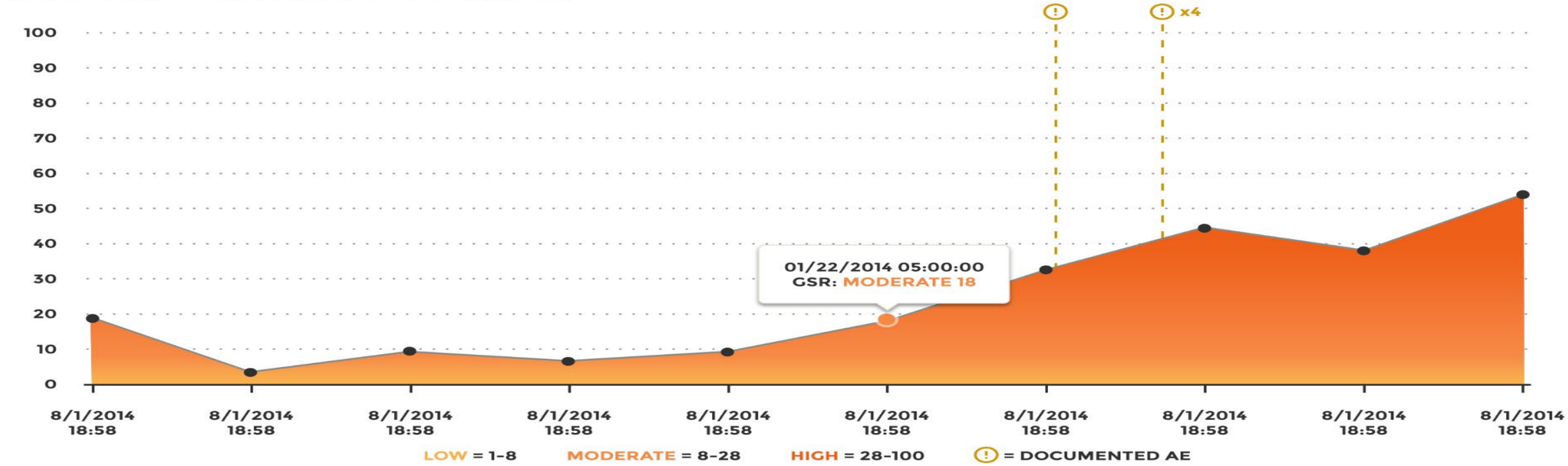
EMPI:	Gender:	Current Visit Date:	Current Unit:	Reason for Current Visit:
75643987	Male	11/14/2013 13:43	10 MCU-ORM	ABDOMINAL PAIN, LEUKOCYTOSIS, LEFT FOOT DIABETIC FOOT ULCER
MRN:	**Date of Birth (Age):**	**Discharge Date:**	**Current Location:**	
456321	14 April 1942 (71)	--	Room 302-Bed A	
Current Visit #:	**Weight:**	**Current Pt. Class:**	**Current Attending Physician:**	
8123456-9	8.5 kg	I	Rodriguez MD, Jonathan	

POSITIVE TRIGGERS - 1 | TRIGGER HISTORY | ALL DOCUMENTS | GLOBAL SAFETY RISK | SPECIFIC RISKS | AUDIT LOG

Below is a graph of the Patient's Global Safety Risk Score over time.
Click the "i" icon in the top right section of the page for more information.

Updated: 6/23/2014 06:52:30
BETA VERSION

The data shown here is NOT RELATED to the Positive Triggers tab.



The data elements in the table below contribute to this patient's cumulative safety risk, represented by the Global Safety Risk score.
They reflect parts of the patient's current clinical state as well as clinical information that occurred earlier in the hospitalization.

You can click each GSR score to see the data elements for that specific score

Currently Viewing: **01/22/2014 05:00:00 | GSR: MODERATE 18**

RANKING	DATA ELEMENT	VALUE	DATE/TIME
1	Hct	21.7%	01/07/2015 11:23:31
2	Number of surgies	2	01/06/2015 11:44:00
3	Hgb	6.9 g/dL	01/07/2015 11:23:31
4	WBC	20.9X10'3/microL	01/07/2015 11:23:31
5	Platelet	674.0x10'3/microL	01/06/2015 11:44:00
6	Platelet	674.0x10'3/microL	01/06/2015 11:44:00
7	Braden Total	16.0	12/28/2014 20:00:00

ROBERT WOOD JOHNSON PROJECT

Share real time EHR based electronic safety information with patients, families, and care givers across multiple IT platforms as part of their own integrated care across the continuum of care

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BWH BRIGHAM AND WOMEN'S HOSPITAL

PASCAL METRICS

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John Smith

Born: 1/1/1960

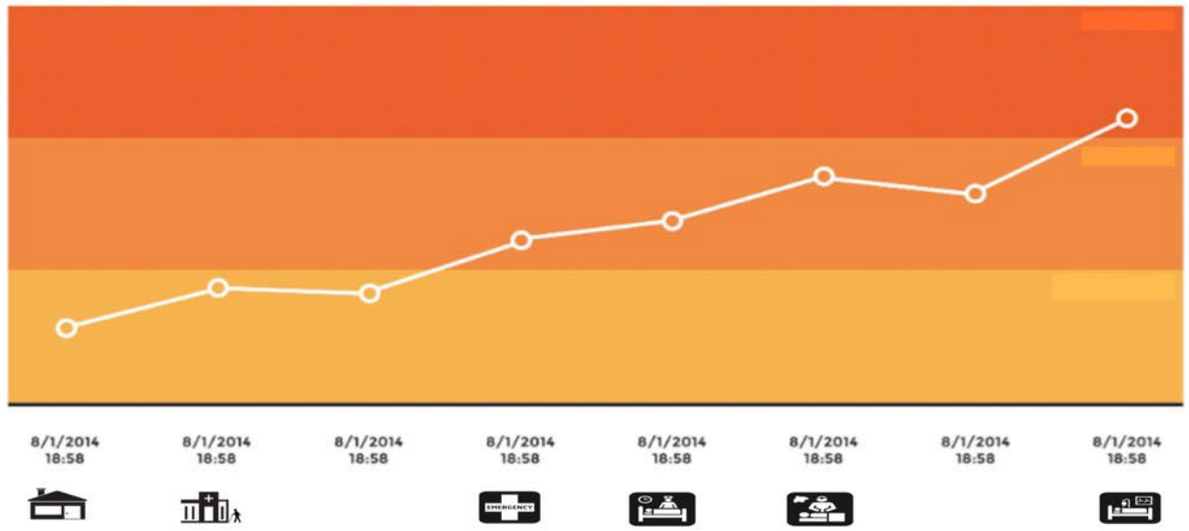
My Safety Advisor

Nurse Manager:

Jill Jones

Contact info

Overall Risk Score



1d **3d** 1wk 1mo all

My Safety Issues	Questions you should ask	Things you can do	More Information
Today			
You have tested positive for a bacteria in your urine	Why did this happen? What can I do to prevent this from happening again? What will you do to prevent this from happening again?	Talk to your doctor and nurses to make sure you understand why this happened and how this should be treated , and how it can be avoided in the future Make sure you understand the source of this infection and how it is being treated If you leave the hospital with a urinary catheter in place make sure you have detailed instructions for how to care for it	Medline Plus on Urine Culture
Yesterday			
Your stool has tested positive for a bacteria called C. difficile	Why did this happen? What can I do to prevent this from happening again? What will you do to prevent this from happening again *Make note of your question here...*	Always wash your hands and nails before eating and after using the restroom Make sure everyone who treats you in the hospital (doctors, nurses, therapists, etc.) Wash their hand before and after seeing you At home make sure all clothes are washed with soap and bleach	Medline Plus on C. Difficile

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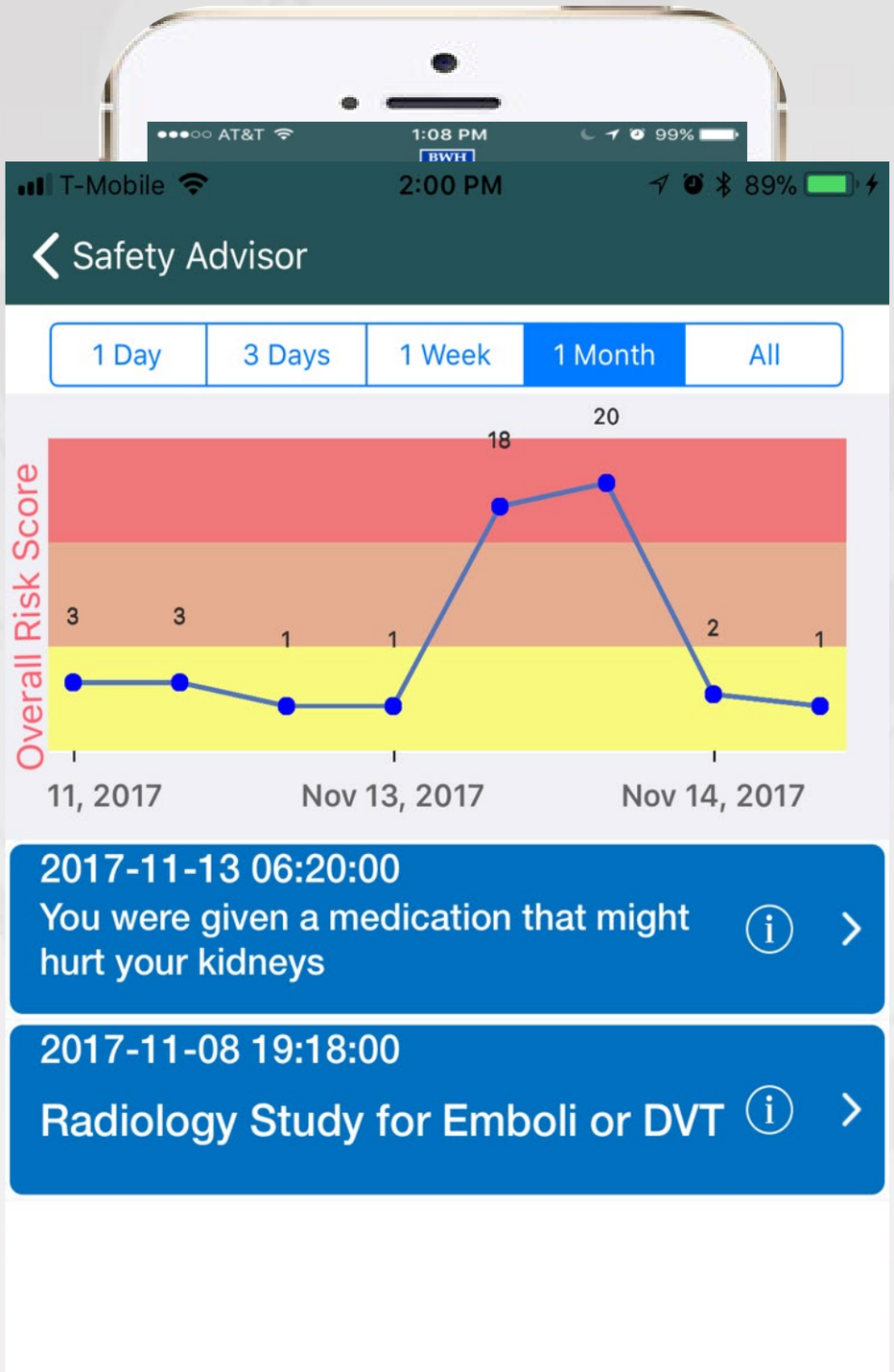
Real Time Safety Patient Mobile App



Clinical Trial Impact on Patient Outcomes

Primary Outcomes

- **Higher PAM Scores in E Dashboard User**
- **Lower 30-day readmission in High E users**
- **Lower 30-day mortality in High E users**

Secondary Outcomes

- **No Increase in Fear Response**
- **Very Good Patient Acceptance and Value**
- **Good Usability Scores**
- **Heavy use of iPhone and Family at Home Use**

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Patient Safety

10-15x
More serious harm identified than industry standard

25%
Consistent reduction in patient harm

3-5x
Annual ROI achieved by health systems

Risk

36 hours vs. 50 days
Time to identify potential risk & claims

1 week vs. 6 months
Time to complete internal investigation

ROI Drivers
Close documentation gaps
Reduce legal expenses
Reduce indemnity payouts
Reduce premiums

AI Integrated Patient Safety Business Case

Questions?