Diagnostic Error: A *Patient Safety Imperative*

Rebecca Jones, MBA, BSN, RN, CPHRM, CPPS
Director of Innovation & Strategic Partnerships, PA Patient Safety Authority
Director, PA Patient Safety Authority Center of Excellence for Improving Diagnosis

Timothy J. Mosher, MD
Physician Advisor to the PA Patient Safety Authority Center of Excellence for Improving Diagnosis
Chair, Department of Radiology Penn State Health

Patient Safety Authority

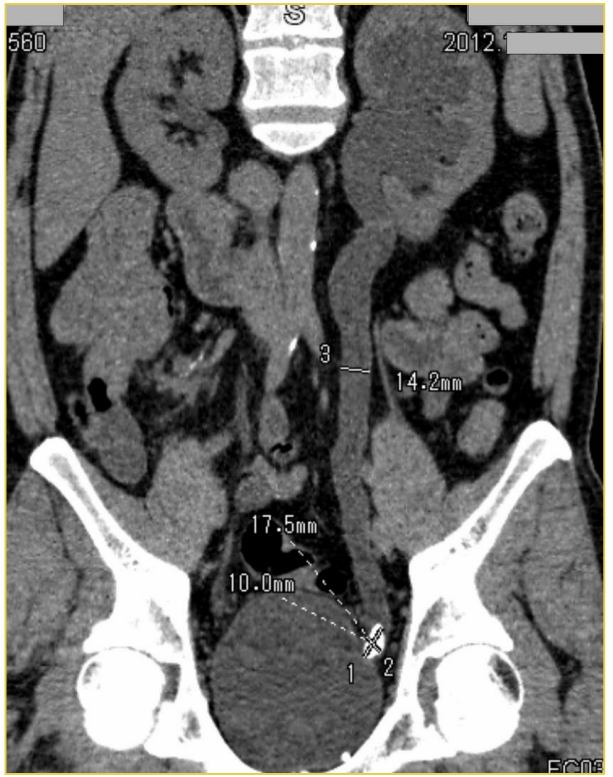
Learning Objectives

- Develop a working definition of the term “diagnostic error”
- Identify system and cognitive factors that contribute to risk for diagnostic error
- Describe areas of opportunity to improve the diagnostic process
- Identify the key objectives of the Pennsylvania Patient Safety Authority’s Center of Excellence for Improving Diagnosis

Disclosure: Tim Mosher

- Paid Advisor to the Pennsylvania Patient Safety Authority Center of Excellence for Improving Diagnosis
- Unpaid Penn State Health representative to Coalition to Improve Diagnosis
- Unpaid Member of the Board of Directors of the Society to Improve Diagnosis in Medicine

A Patient Story . . .



What is your story?

Understanding Error and Improvement in Diagnosis

To Err is Human: Building a Safer Health System – IOM 1999

Crossing the Quality Chasm: A New Health System for the 21st Century – IOM 2001

- Estimated that between 44,000 and 98,000 patients die in hospitals each year as a result of medical error that could have been prevented
- ~17% of medical errors are attributable to diagnostic errors
- Estimates are that 40,000 to 80,000 hospital deaths annually result from diagnostic error based on extrapolation of autopsy studies indicating 10% - 20% of undiagnosed disease as a cause of death

(Leape)

The Challenge of Reducing Diagnostic Error

- The heavy focus of the IOM report on process errors with system based solutions diverts attention and resources from diagnostic error
- Difficult to define and measure
- Much diagnosis occurs in the outpatient setting with a fragmented delivery system
- Multifactorial sources: system and cognitive causes
- Long interval between diagnostic error and adverse outcome
- No business model for reducing diagnostic error - primarily provider driven with lack of an accountable entity with resources to make system improvements

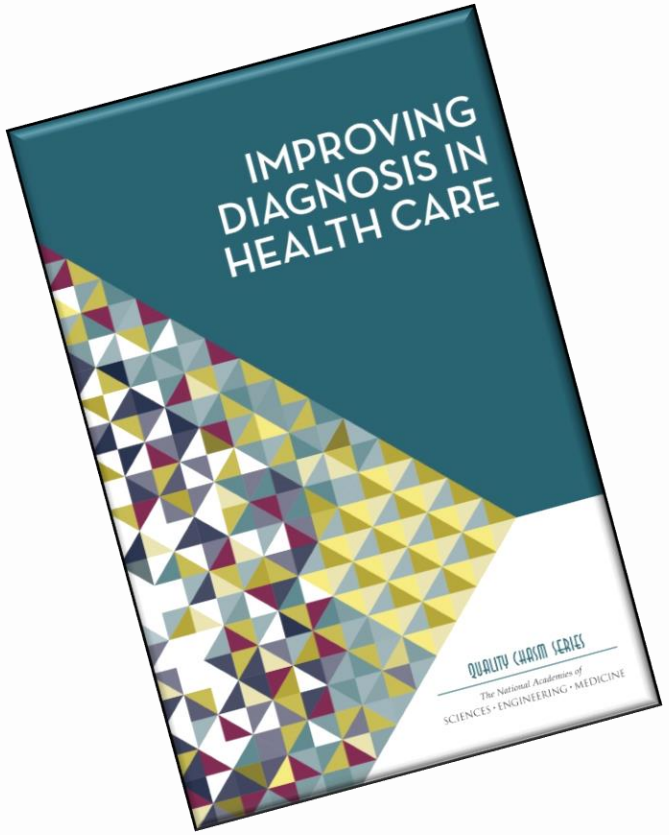
(Wachter)


MALPRACTICE & ERRORS

By Robert M. Wachter

Why Diagnostic Errors Don't Get Any Respect—And What Can Be Done About Them

Improving Diagnosis in Health Care

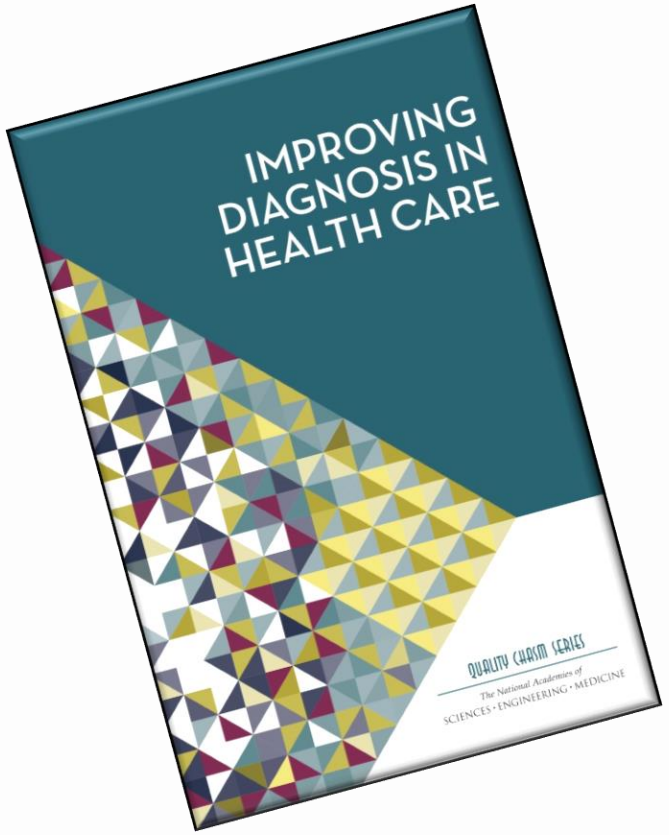


"Diagnosis -- and, in particular, the occurrence of diagnostic errors -- has been largely unappreciated in efforts to improve the quality and safety of health care. The result of this inattention is significant: the committee concluded *that most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences."*

The National Academies of
SCIENCES · ENGINEERING · MEDICINE

(NAM)

NAM Working Definition of Diagnostic Error



The committee defines diagnostic error as "the failure to

(a) establish an accurate and timely explanation of the patient's health problem(s) or

(b) communicate that explanation to the patient."

The National Academies of
SCIENCES · ENGINEERING · MEDICINE

(NAM)

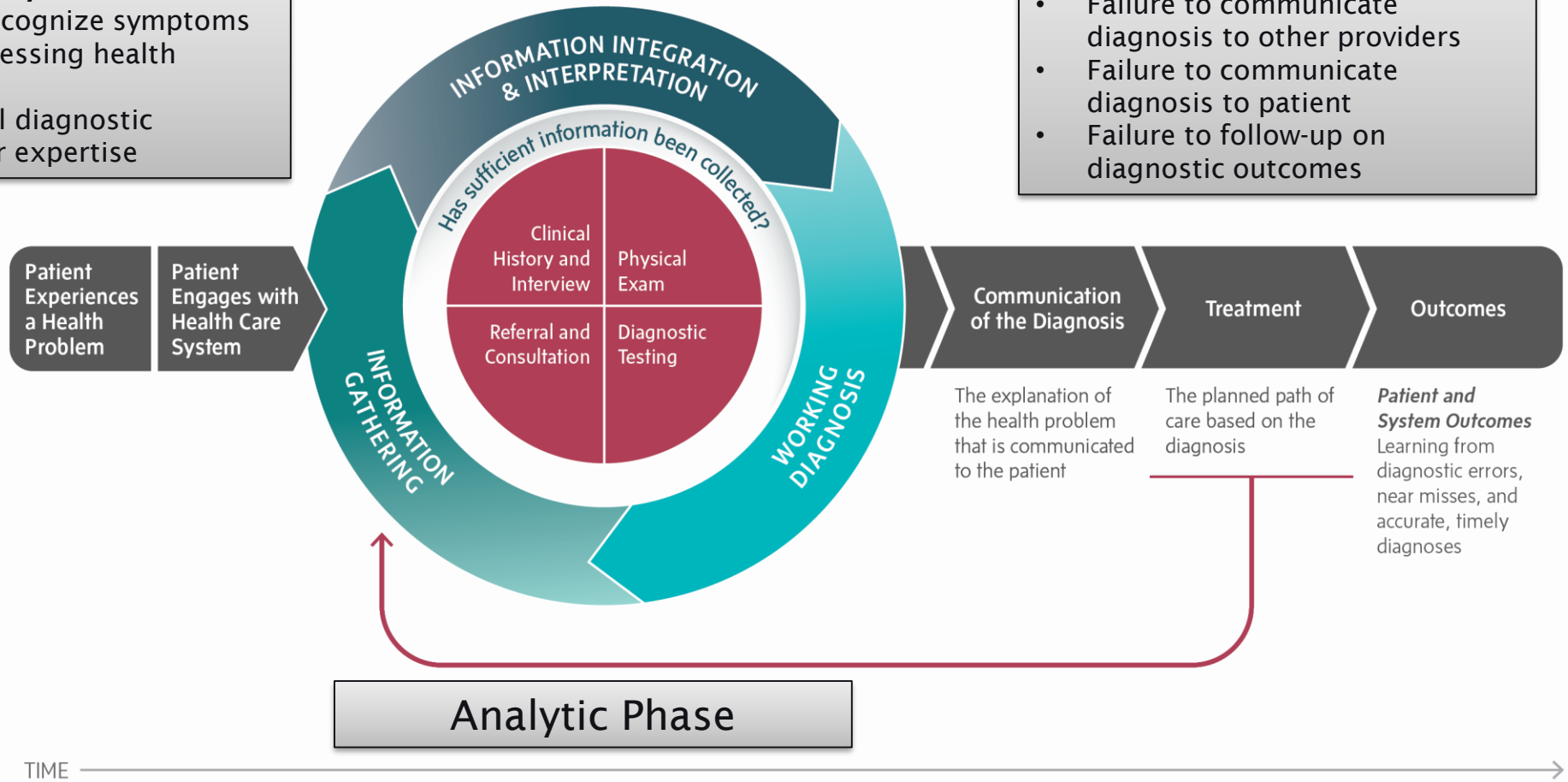
The Diagnostic Process

Pre- Analytic Phase

- Failure to recognize symptoms
- Delay in accessing health system
- Lack of local diagnostic resources or expertise

Post- Analytic Phase

- Failure to communicate diagnosis to other providers
- Failure to communicate diagnosis to patient
- Failure to follow-up on diagnostic outcomes

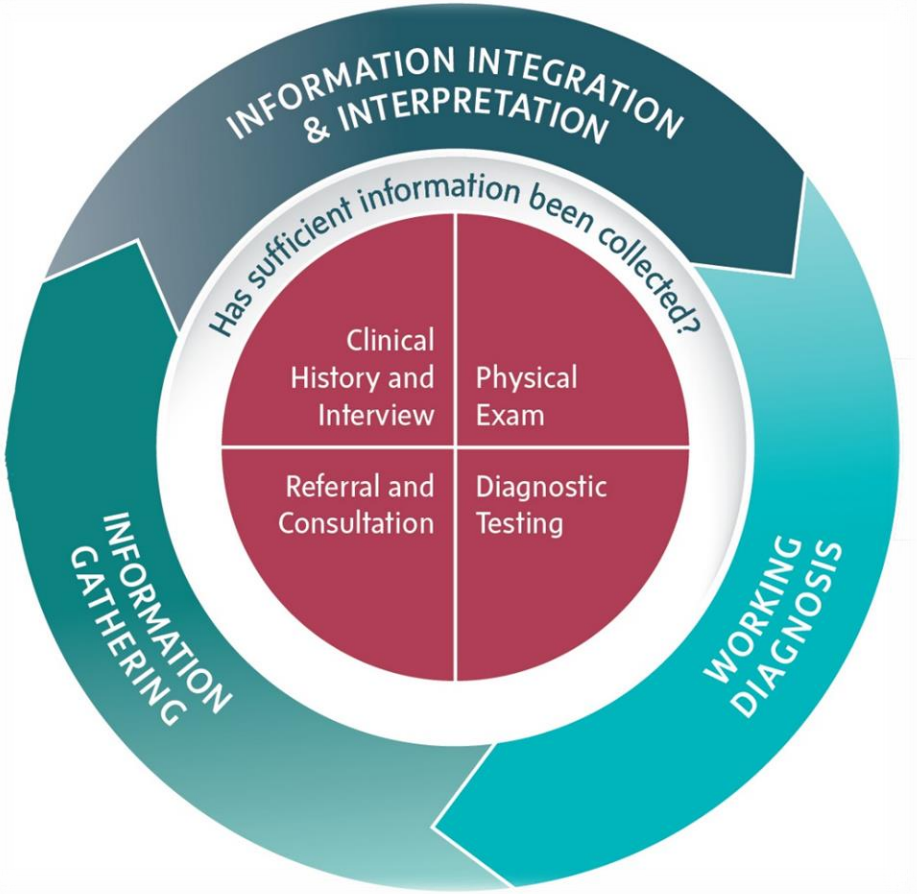


(NAM)

Failure Points in the Analytic Phase

Review of 583 cases

History Taking: 10%
Physical Exam 10%
Diagnostic Testing 44%
Referral and Consultation: 3%
Integration and Assessment 32%



(Schiff et al.)

Failure Modes in Diagnosis

"No-fault" errors

- Lack of symptoms
- Very atypical symptoms
- Symptoms mimicking a very common condition

Can never be eradicated

System errors

- Prior records unavailable
- Lack of necessary equipment
- Expertise not available
- Poor communication
- Failure to follow-up on abnormal results

Can be reduced but must be continuously monitored over time

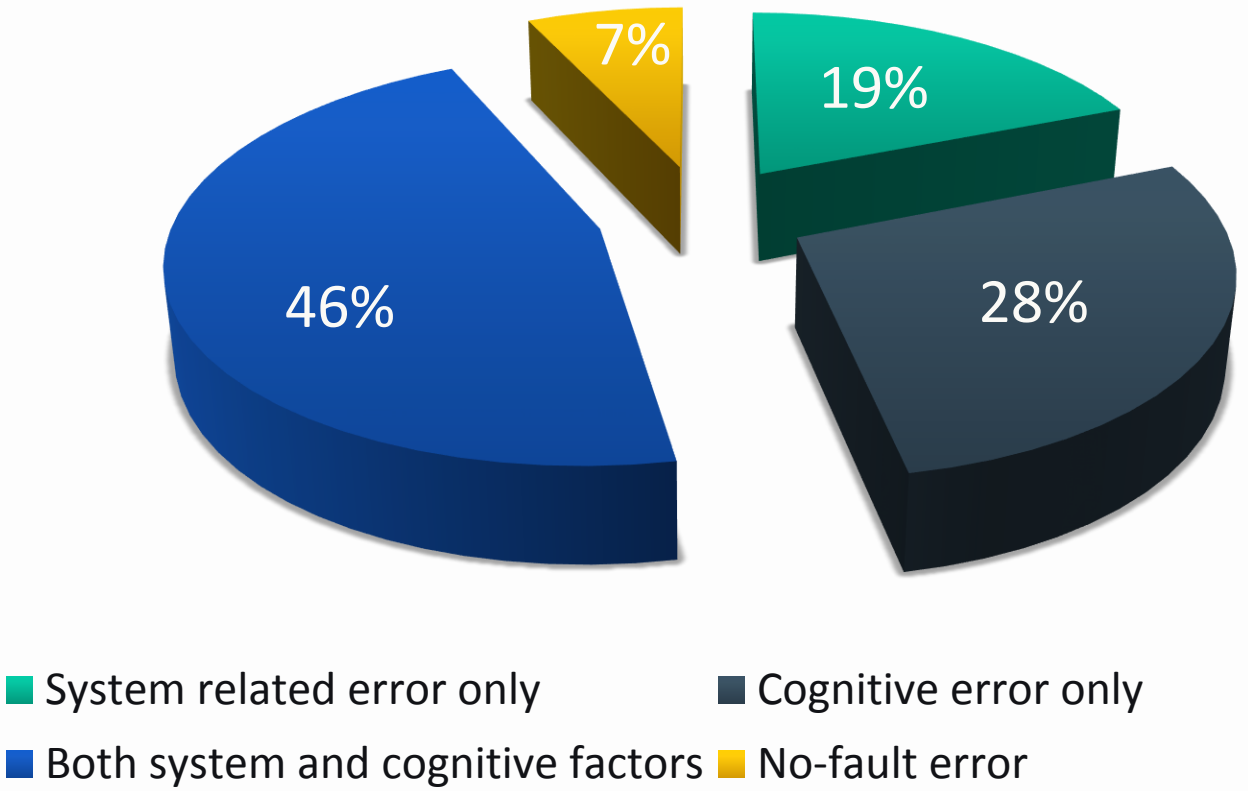
Cognitive errors

- Knowledge deficit
- Failure to perceive
- Failure to identify
- Flawed synthesis
- Flawed interpretation of results

Difficult to reduce

(Graber et al., 2002)

Diagnostic Error in Internal Medicine



(Graber et al., 2005)

Failure Modes in the Diagnostic Process

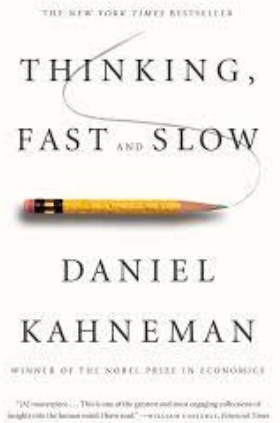
System modes

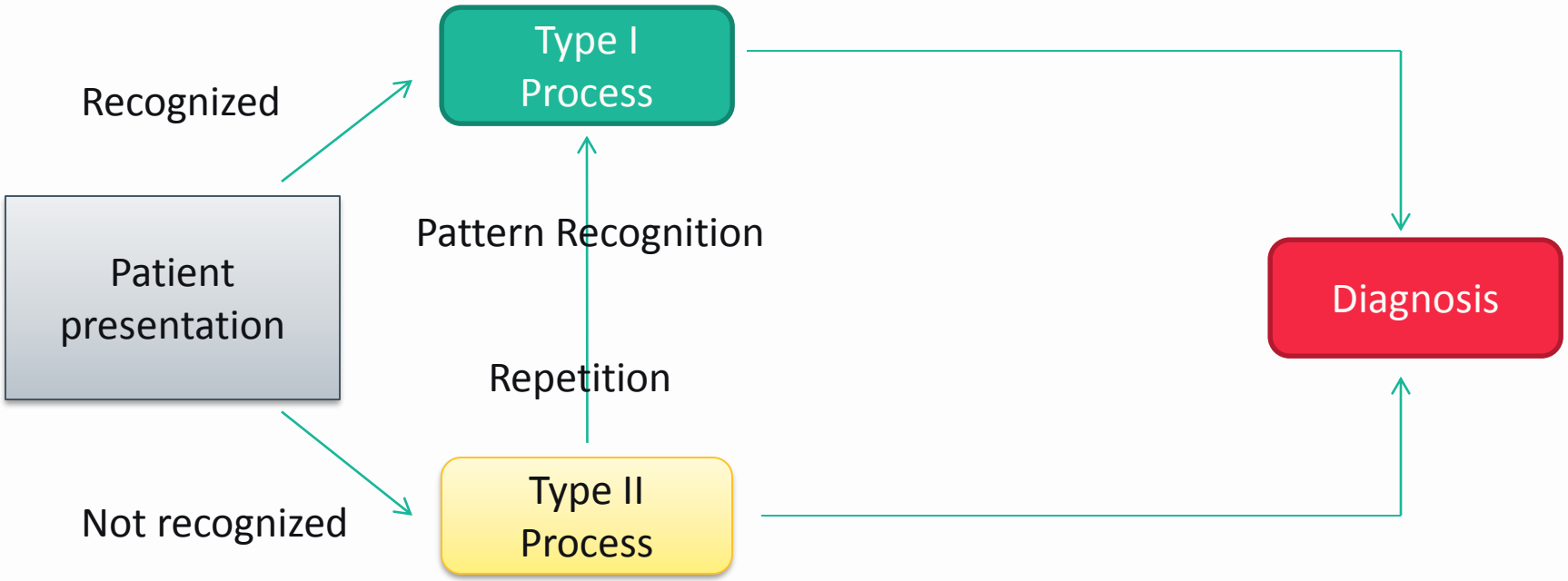
- Multiple slices of Swiss cheese in a predefined order

Person modes (Cognitive Errors)

- Few slices of Swiss cheese with holes that appear depending on different conditions

Dual Process Theory

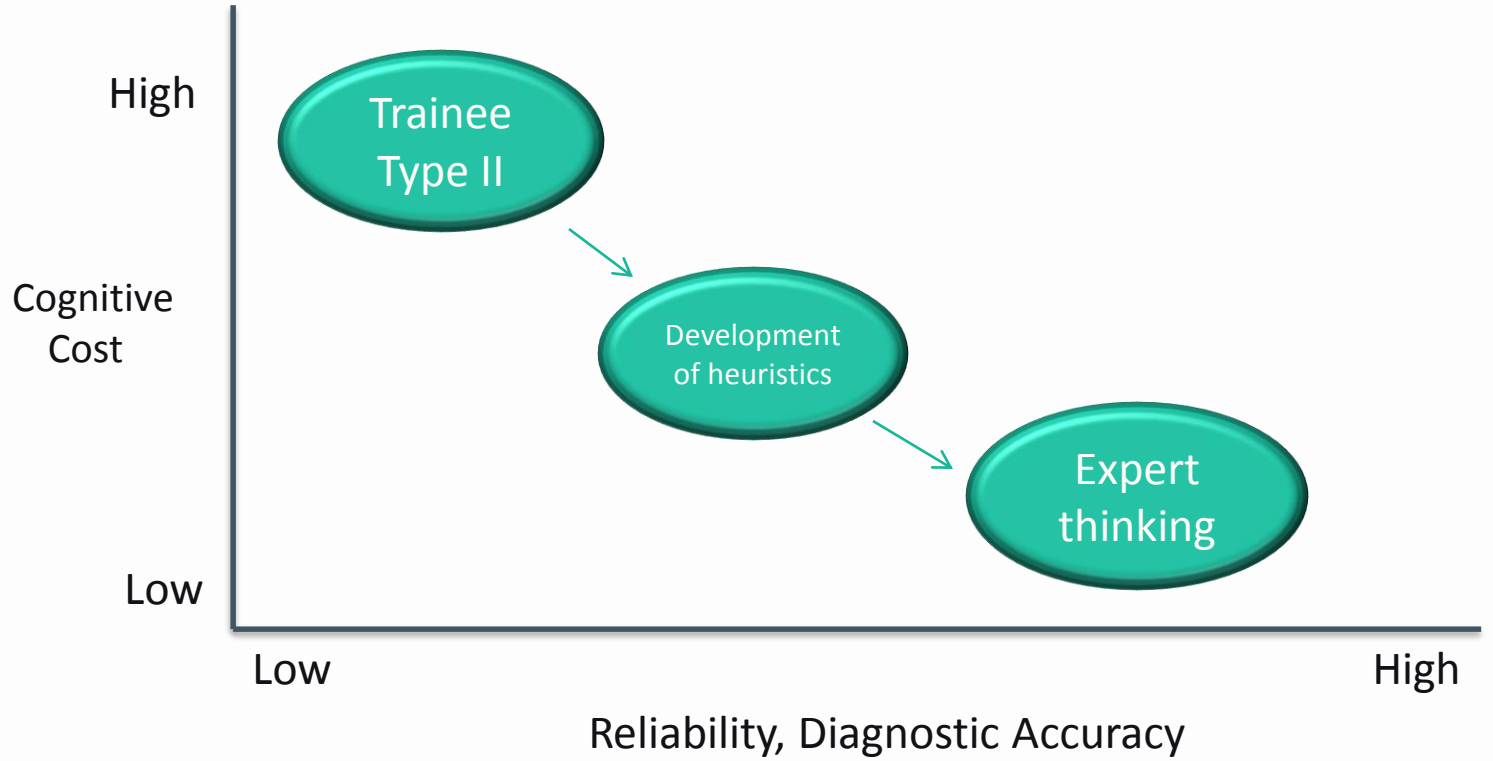




(Crosskerry)

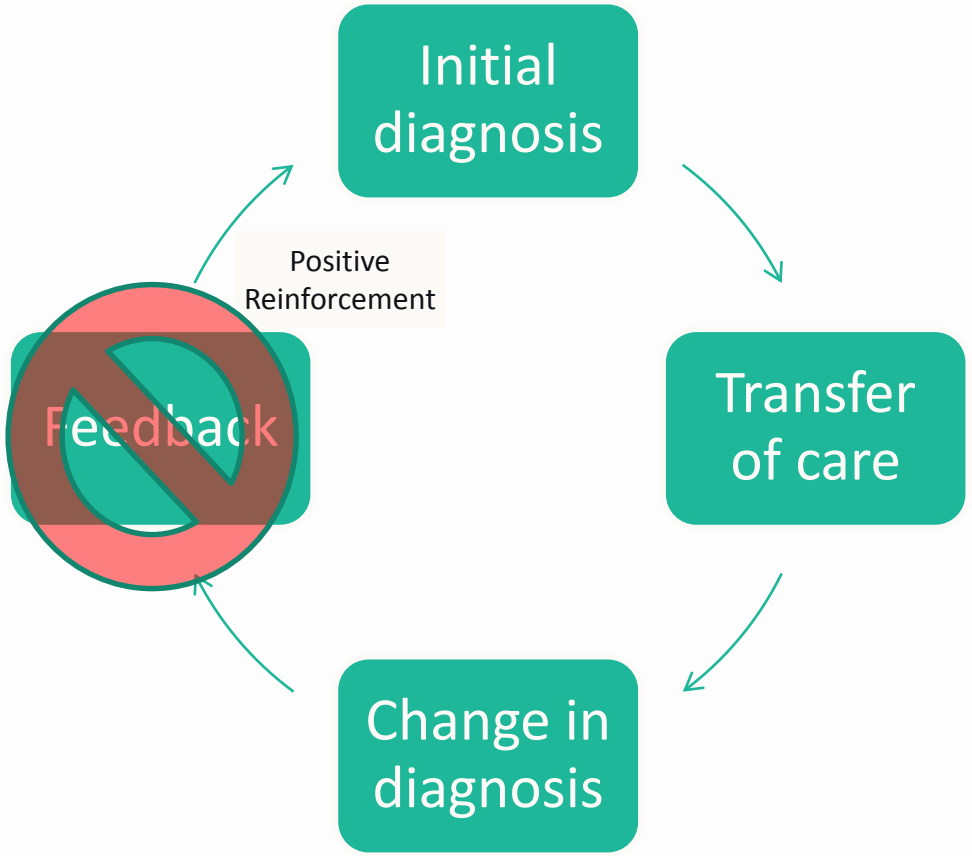
Wrong Diagnosis: Over-reliance on Heuristics

Relationship Between Cost and Reliability in Decision Making

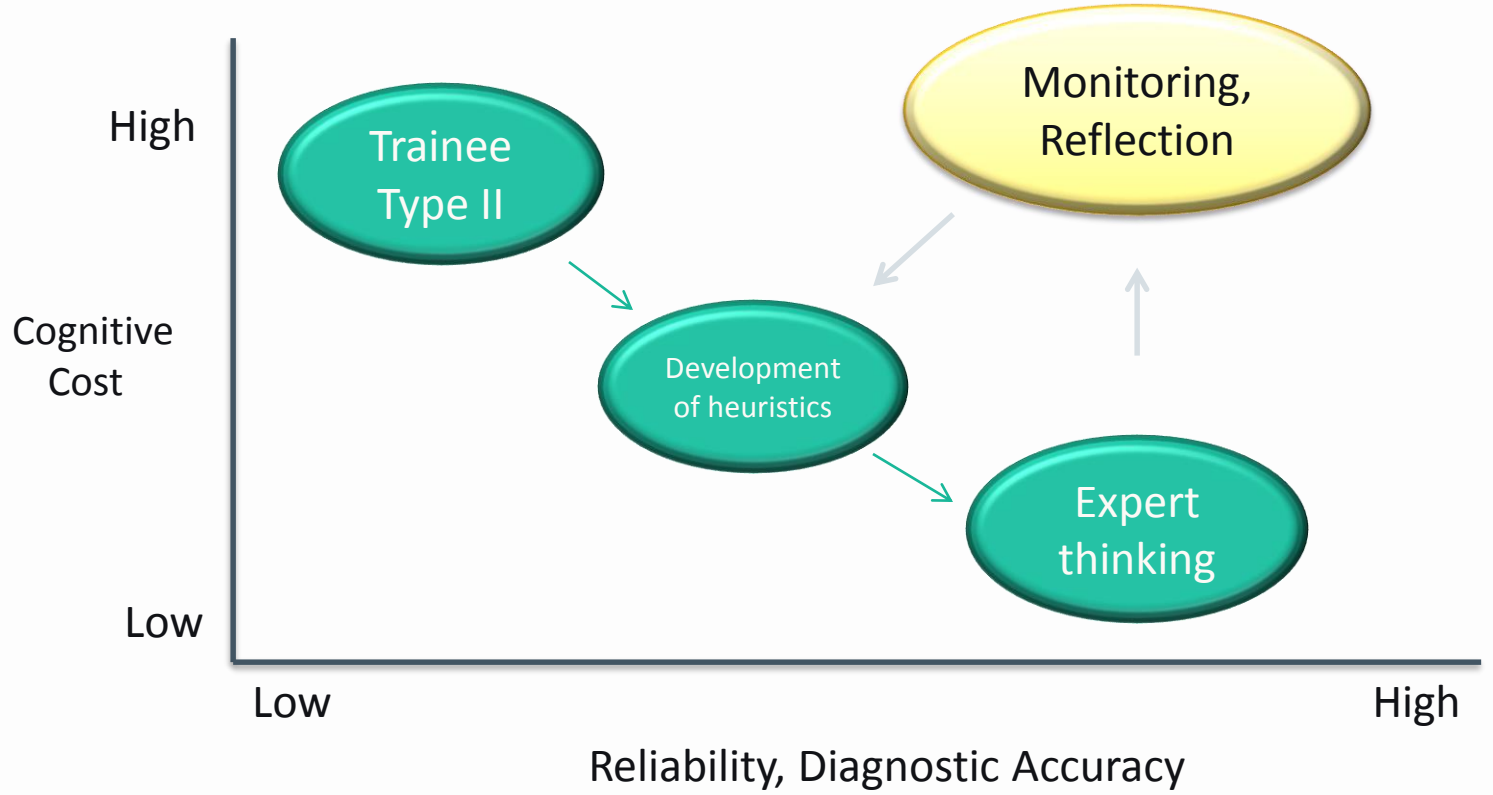


(Graber, 2009)

Incomplete Feedback Loop and Overconfidence



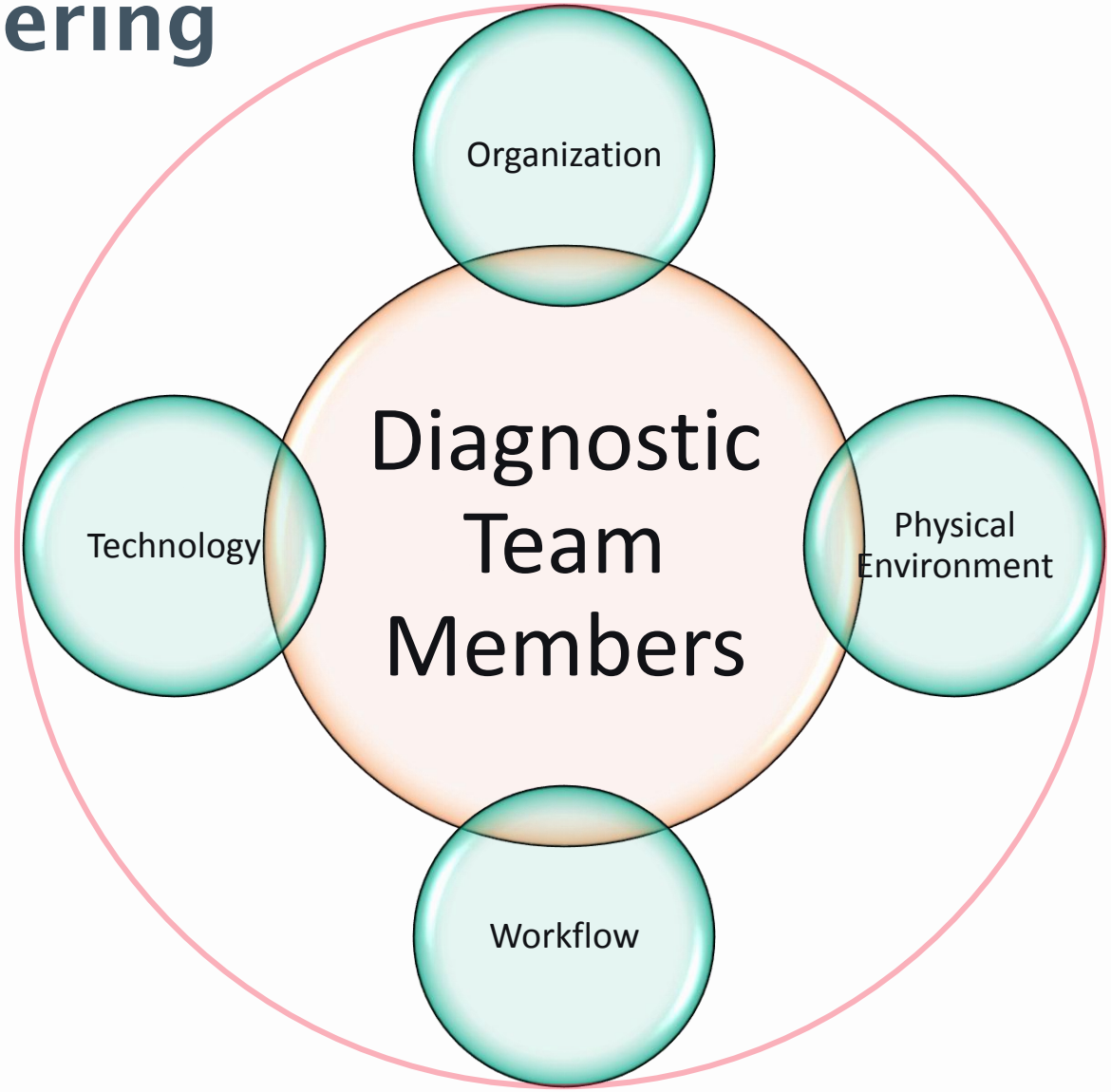
Relationship Between Cost and Reliability in Decision Making



(Graber, 2009)

Human Factors Engineering

- System factors modulate the risk of cognitive errors
- To reduce the risk of cognitive error we must modify the system



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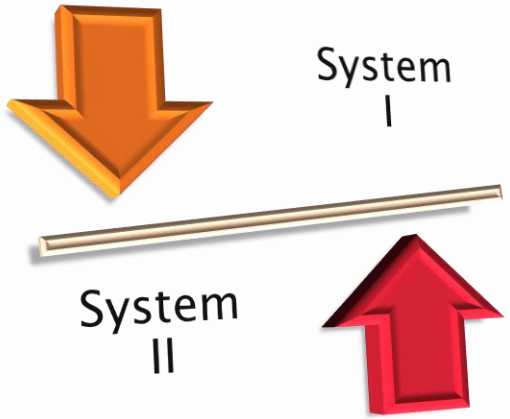
Human Factors Engineering

Can we design technology interfaces that monitor our activity and predict when we are at increased risk of diagnostic error?



External Factors that Impact Diagnostic Error in Radiology

Fatigue

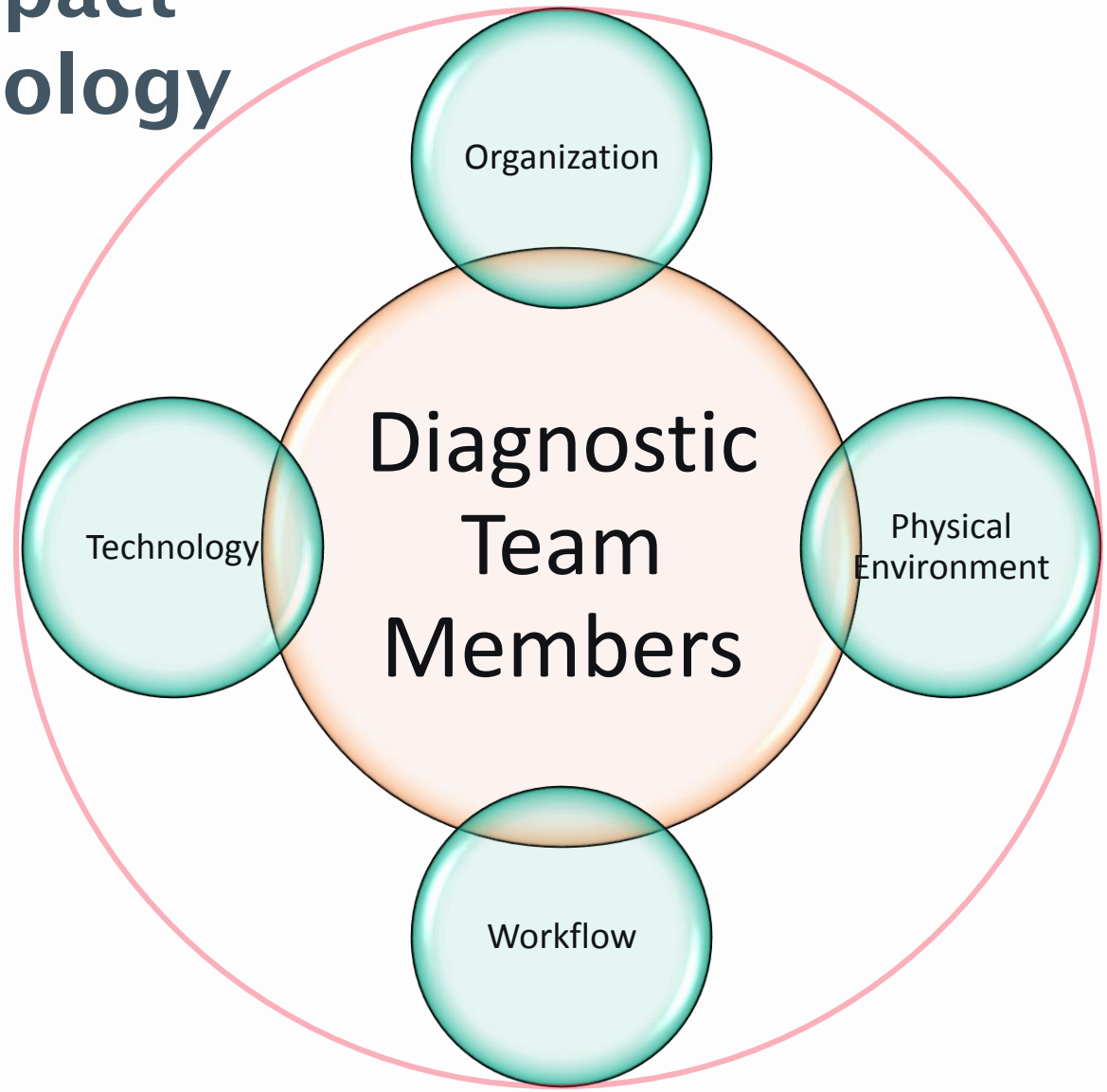
- High cognitive load drains the ability to engage System II processing
- Need to allow recovery time – building reserve

Priming

- Impact of radiology history on search pattern
- Prevalence impacts sensitivity/specificity of reads

Environmental

- Distractors/Interruptions
- Ambient conditions



(NAM)

Improving the Diagnostic Process: *A Patient Safety Imperative*

Rebecca Jones, MBA, BSN, RN, CPHRM, CPPS
Director, Innovation and Strategic Partnerships
Director, PSA Center of Excellence for Improving Diagnosis

Disclosure: Rebecca Jones

- PA Patient Safety Authority representative to Coalition to Improve Diagnosis
- Unpaid Member of the Advisory Council of the Coalition to Improve Diagnosis
- Unpaid Chair of the Practice Improvement Committee of the Society to Improve Diagnosis in Medicine (SIDM)

Improving the Diagnostic Process

- Effective teamwork
- Reliable diagnostic process
- Engaged patients and family members
- Optimized cognitive performance
- Robust learning systems

(HRET)

Effective Teamwork

- Diagnostic team members
  - Patients and families
  - Radiologists
  - Pathologists
  - Nurses
  - Allied health professionals
  - Medical librarians
  - And many more . .
- Culture of safety
- Communication skills (e.g., TeamSTEPPS)
- Bedside huddles

(HRET)

Reliable Diagnostic Process

- Optimized structures
  - Surveillance tools (e.g., Kaiser Permanente SureNet program)
  - Early warning systems
- Clinical operations and flow of information
  - Forcing functions and alerts (use wisely)
  - Processes for closing the loop on test results
- Accessible specialists
  - Electronic or telemedicine consults

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Reliable Diagnostic Process: Project Failsafe

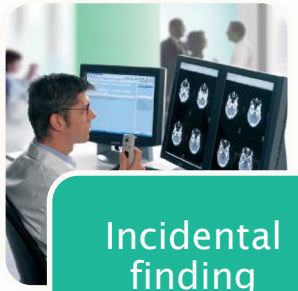
Reducing the harm from mismanaged incidental findings

- Incidental Finding: A test result unrelated to the patient's presenting condition that is of uncertain clinical significance requiring either additional diagnostic testing or serial monitoring to determine risk to patient.

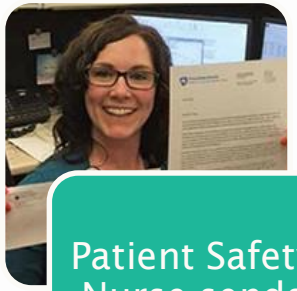
PennState Health
Milton S. Hershey Medical Center

Project Failsafe Workflow

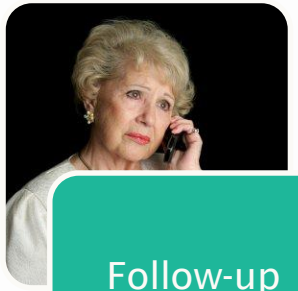
Radiologist Identifies incidental finding



Incidental finding entered into electronic data base



Patient Safety Nurse sends failsafe letter to patient



Follow-up phone call to patient

PennState Health
Milton S. Hershey Medical Center

Improving Reliability of Tracking Report Discrepancy on Overnight Trauma Patients

PennState Health
Milton S. Hershey Medical Center

Problem to be Fixed

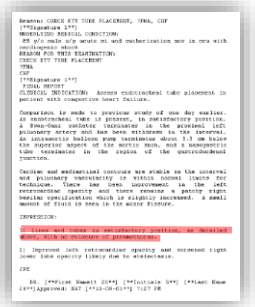
- Current tracking of diagnostic discrepancy:
  - Self reported – default mode requires attending to enter discrepancy
  - Significance of discrepancy on patient care not evaluated
  - No follow-up to determine the impact of the discrepancy on patient care
- Wide variability in published discrepancy of overnight resident reports ranging from 1% to 9%

(Cooper et al.; Huntley et al.)

Workflow: Overnight Trauma Patients 10pm – 7am

Resident preliminary report

Final report



Version Compare
Nuance Power scribe 360

FINAL ATTENDING REPORT: Small left apical pneumothorax. Discrepancy discussed with Dr. Smith at 9:24 am . . .

Filter version for trauma patients

Discrepancy scored by clinical impact

Clinically important discrepancies are tracked

Evaluate for Patient Harm

24 hours

30 Days

60 Days

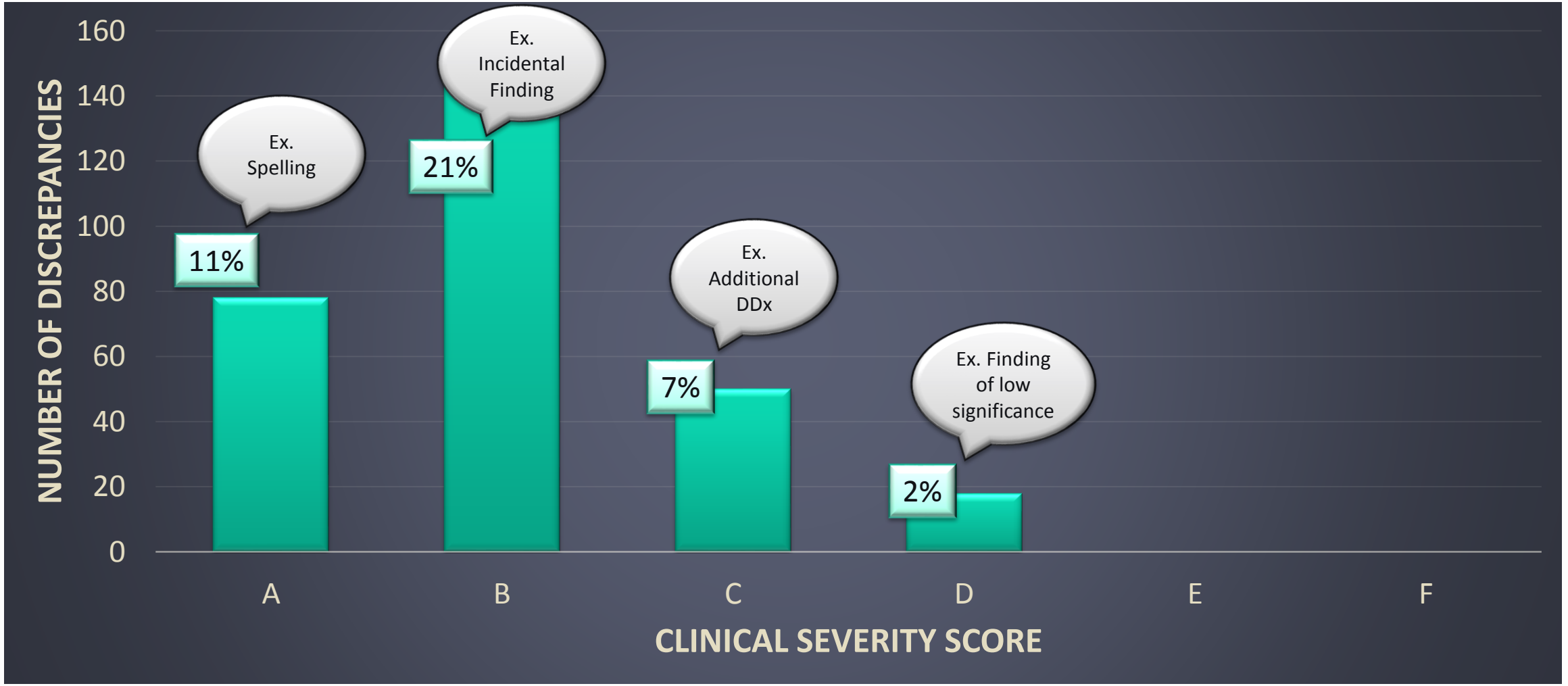
Scoring of Clinical Significance	
A	No substantive change (ex. editorial/spelling/grammatical change in report)
B	Minor change of no clinical significance (ex. Addition of fracture nomenclature, trauma grading scale to an otherwise accurate report, addition of incidental findings not directly related to acute patient management)
C	Minor change of doubtful clinical significance (ex. change in wording that may be interpreted as a change in level of diagnostic confidence, addition of diagnosis in the impression that is appropriately described in the body of the report, recommendation for additional non-emergent studies that may alter diagnosis)
D	Major change of low clinical significance (Finding related to patient's acute condition that alters patient care but would not have changed overnight clinical management)
E	Major change of high clinical significance (Clinically significant finding related to patient's acute condition that would have changed overnight clinical management)
F	Patient harm (Clinically significant finding related to patient's trauma that led to patient harm because of delay in diagnosis or inappropriate treatment based on a wrong interpretation by a radiology resident) Harm assessed at 24 hours, 30 days, 60 days

Scores of D, E or F are tracked

Pilot Testing

- Pilot period March 23 to September 21, 2018
- 184 trauma patients examined during overnight hours
- 723 reports (CT and CR)

Report Discrepancies by Clinical Score



Example of Score D findings

- Bladder rupture – patient was going to OR for suspected bowel injury
- Fractured teeth – seen on physical exam
- Overcall – acute sacral fracture
- T3 spinous process fracture
- Opacity in LLL upgraded to possible aspiration

Scalability

- Initial manual technology: 7 hours/week to complete report
- Current semi automated process: 9–10 minutes/week

Engage Patients and Family Members

- Tools and education for patients and family members
  - Patient's Toolkit for Diagnosis
  - Teachback
- Ensure patients and family members understand their health condition and treatment (diagnosis, discharge instructions, etc.)
- Patient and family advisory committees
- Encourage patients and family members to speak up and share feedback
  - Processes and systems
  - Environment
  - Rapid response system
- Ensure access to health records (test results, notes, etc.)

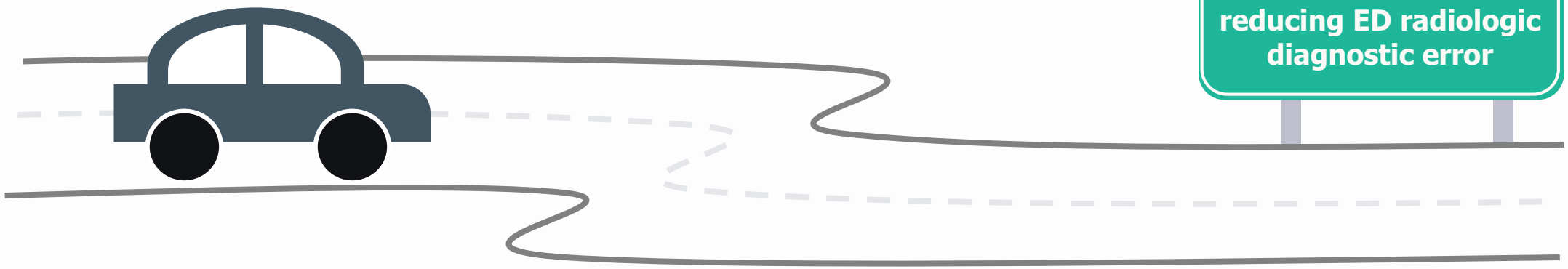
(HRET)

HAP HIIN Collaborative

HOSPITAL IMPROVEMENT INNOVATION NETWORK (HIIN)

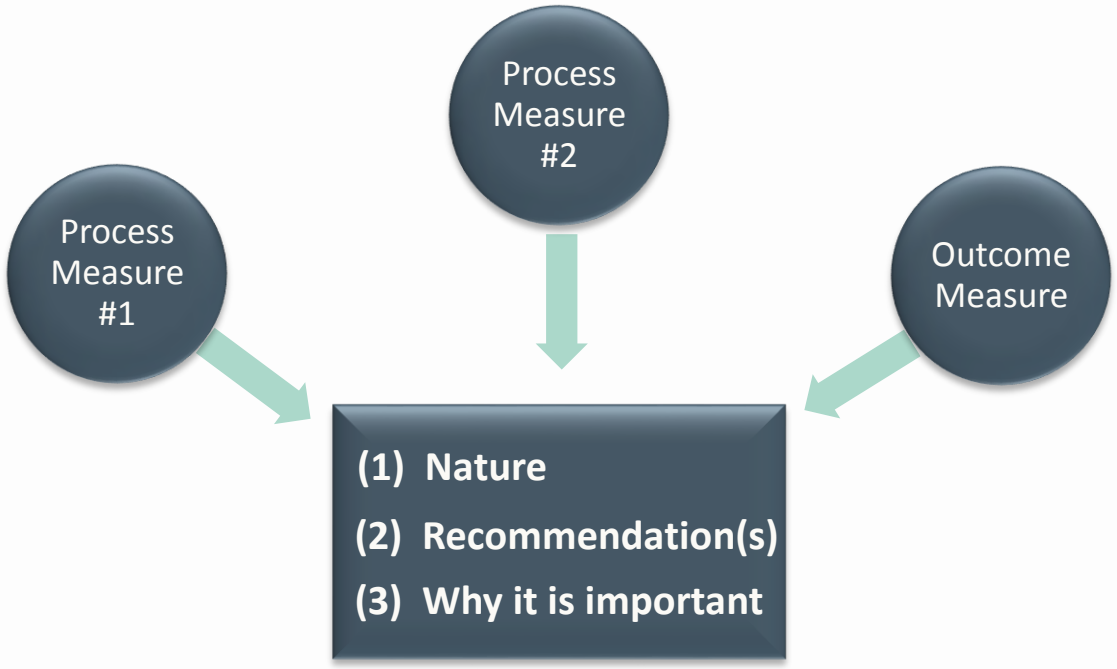
Diagnostic Error

PENNSYLVANIA HOSPITAL COLLABORATIVE



Patient-Centered Measures

Process Measure #1	Number of patients fully informed verbally about the incidental finding/ Number of patients with an incidental finding
Process Measure #2	Number of patients provided with complete printed materials about the incidental finding/ Number of patients with an incidental finding
Outcome Measure	Number of patients who demonstrated a full understanding of the incidental finding/ Number of patients with an incidental finding



Optimized Cognitive Performance

- Clinical decision support
- Clinical reasoning education (e.g., University of Pittsburgh program)
- Reflective practice
  - Diagnostic timeout
  - Forum for debriefing and discussion

(HRET)

Robust Learning Systems

- Identify failures in the diagnostic process
  - Modified DEER Taxonomy
  - Root cause analysis – fishbone diagram
- Feedback on diagnostic performance
  - Processes for feedback between clinicians
  - Diagnostic performance score
- Continuous learning
  - Awareness
  - Medical/Healthcare professional education

DIAGNOSTIC PROCESS STEP	FAILURE POINT
1. Access/ Presentation	A. Failure or delay in patient seeking care
	B. Failure or denial of access to care
2. History	A. Failure or delay in providing or eliciting a piece of history data
	B. Inaccurate or misinterpreted piece of history data
	C. Suboptimal weighing of a piece of history data
	D. Failure or delay in acting on or following-up on a piece of history data
3. Physical Examination/ Assessment	A. Failure to perform a physical examination or assessment
	B. Inaccurate or missed physical examination or assessment finding
	C. Suboptimal weighing of a physical examination or assessment finding
	D. Failure or delay in acting on or following-up on a physical examination or assessment finding
4. Testing (Laboratory/ Radiology/ Other)	A. Failure or delay in ordering needed test(s)
	B. Failure or delay in performing needed test(s)
	C. Suboptimal test sequencing
	D. Wrong test(s) ordered
	E. Test(s) ordered the wrong way
	F. Identification failure (e.g., sample mix-up, mislabeled specimen, or test performed on the wrong patient)
	G. Technical or processing error (equipment problem, poor processing of specimen/test, or skill issue)
	H. Specimen delivery problem (e.g., specimen never sent, delayed delivery, or lost specimen)
	I. Misread or misinterpreted test(s)
	J. Failure or delay in transmitting or communicating test result to healthcare provider
	K. Failure or delay in acting on or following-up on test result (including results not communicated to the patient)
5. Hypothesis Generation	A. Failure or delay in considering correct diagnosis
	B. Suboptimal weighing or prioritizing
	C. Too much weight given to lower probability or priority diagnosis
6. Referral/ Consultation	A. Failure or delay in ordering a referral or consult
	B. Failure or delay in obtaining or scheduling an ordered referral or consult
	C. Failure or delay in communicating consultation findings
7. Monitoring/ Follow-Up	A. Failure or delay in monitoring (e.g., failure to routinely check vital signs, failure to apply monitor, technical issue)
	B. Inaccurate or missed physiologic monitoring finding (e.g., misinterpreted fetal monitor strip)
	C. Failure or delay in recognizing urgency of condition or complication
	D. Failure or delay in communicating findings among healthcare team members
	E. Failure to refer the patient to appropriate setting or for appropriate monitoring
	F. Failure or delay in timely following-up with or rechecking the patient

*Source: Adapted from Schiff GD, Kim S, Abrams R, Cosby K, Lambert B, Elstein AS, Hasler S, Krosnjar N, Odwazny R, Wisniewski MF, McNutt RA. Diagnosing diagnosis errors: lessons from a multi-institutional collaborative project. In: Henriksen K, Battles JB, Marks ES, et al, editor(s). Advances in patient safety: from research to implementation. Vol. 2, concepts and methodology. Rockville (MD): Agency for Healthcare Research and Quality; 2005 Feb. p. 255-78.

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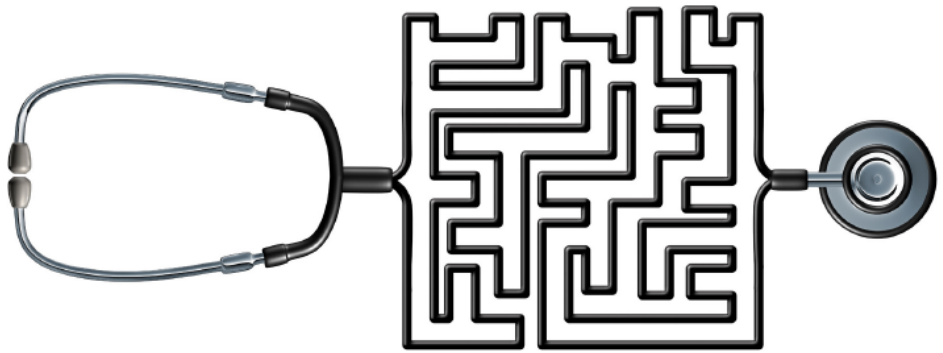
(HRET)

Identifying and Learning from Failures in the Diagnostic Process: PSA/PA-PSRS Exemplar

Review/
Analysis



Identifying and Learning from Events Involving Diagnostic Error: It's a Process

Rebecca Jones, MBA, BSN, RN, CPHRM, CPPS & **Mary C. Magee**, MSN, RN, CPHQ, CPPS

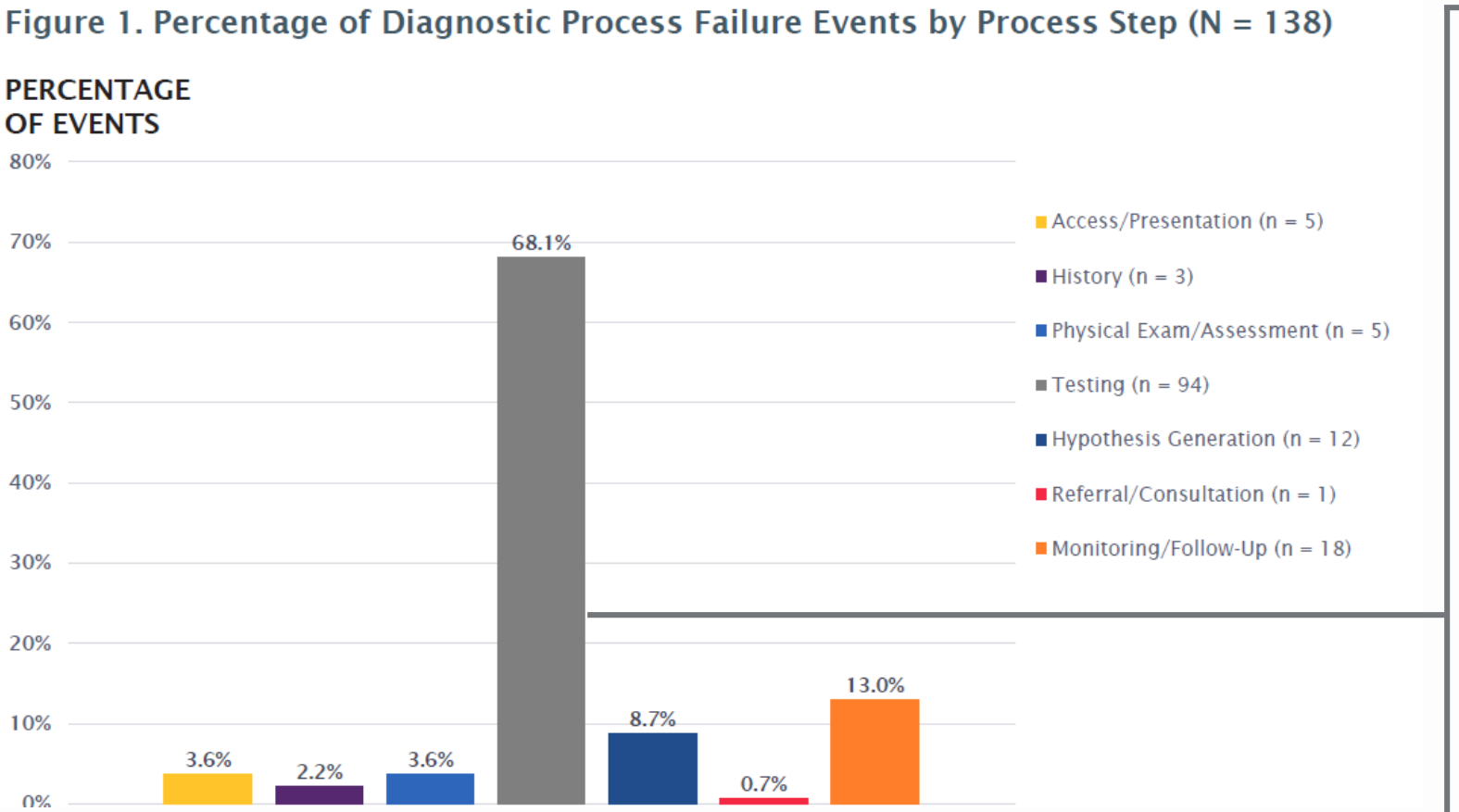
Abstract: Diagnosis involves a complex system with many team members and numerous interdependent steps, all of which can make it challenging to identify and learn from failures in the process. The Pennsylvania Patient Safety Authority sought to explore this by analyzing events involving patient harm. We queried the Pennsylvania Patient Safety Reporting System for Serious Events likely to involve diagnostic error or the diagnostic process reported during calendar year 2016. The query yielded **1,212** reports, from which we identified **138** diagnostic process failure events. We modified the **diagnostic error evaluation and research** (**DEER**) taxonomy and classified events according to process step and failure point. In the event reports, failure points in testing were involved most frequently (**68.1%**, n = 94 of **138**) and the surgical/procedural care area predominated (**21.0%**, n = 29 of **138**). Although the monitoring/follow-up process step accounted for just **13.0%** of all events, it represented nearly half of those that resulted in death. Healthcare facilities can act now by using the modified DEER taxonomy to classify events from various sources, identify vulnerabilities in the diagnostic process, and prioritize areas of opportunity for learning and improvement. *Pa Patient Saf Advis 2018 Oct 31;15[Suppl 1]:3-15.*

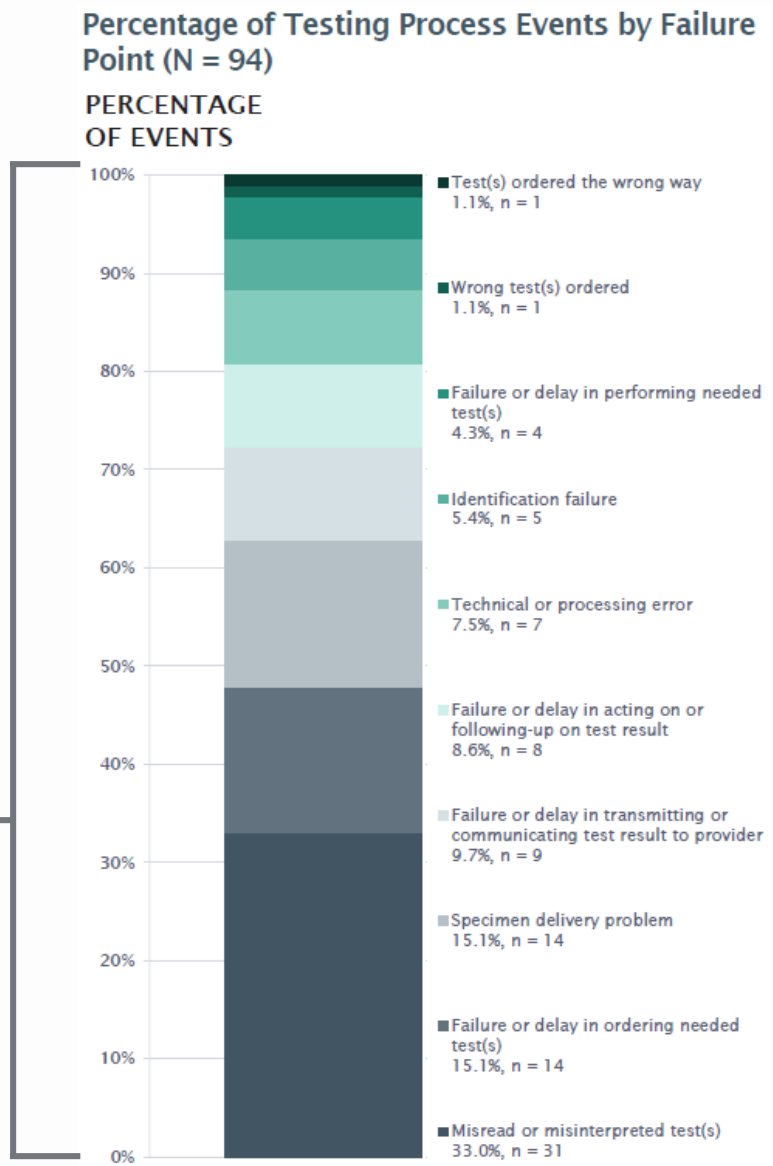
*PA-PSRS is a secure, web-based reporting system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error Act (Act 13 of 2002).[18]

‡A "Serious Event" is an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient.[18]

(Jones and Magee)

PA-PSRS Event Analysis





Note: Serious Events reported through the Pennsylvania Patient Safety Reporting System, January 1, 2016, through December 31, 2016.

(Jones and Magee)

PA-PSRS Event Analysis

Table 3. Diagnostic Process Failures in Serious Events by Harm Score (N = 138)

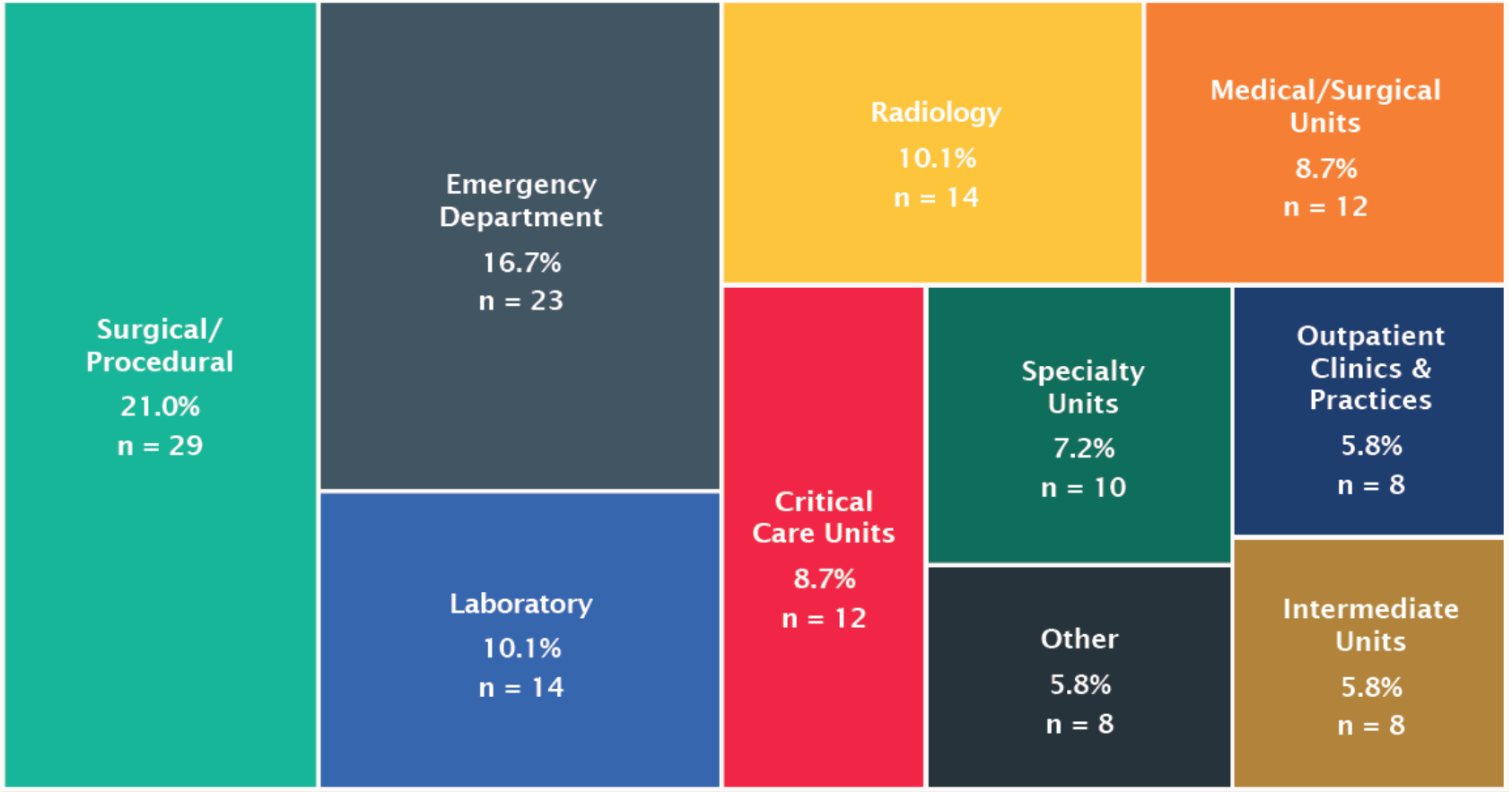
HARM SCORE	PERCENTAGE	NUMBER
E—An event occurred that contributed to or resulted in temporary harm and required treatment or intervention.	48.6	67
F—An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization.	24.6	34
G—An event occurred that contributed to or resulted in permanent harm.	12.3	17
H—An event occurred that resulted in a near-death event (e.g., required intensive care unit care or other intervention necessary to sustain life).	3.6	5
I—An event occurred that contributed to or resulted in death.	10.9	15

Note: Serious Events reported through the Pennsylvania Patient Safety Reporting System, January 1, 2016, through December 31, 2016.

(Jones and Magee)

PA-PSRS Event Analysis

Figure 2. Percentage of Diagnostic Process Failure Events by Care Area (N = 138)

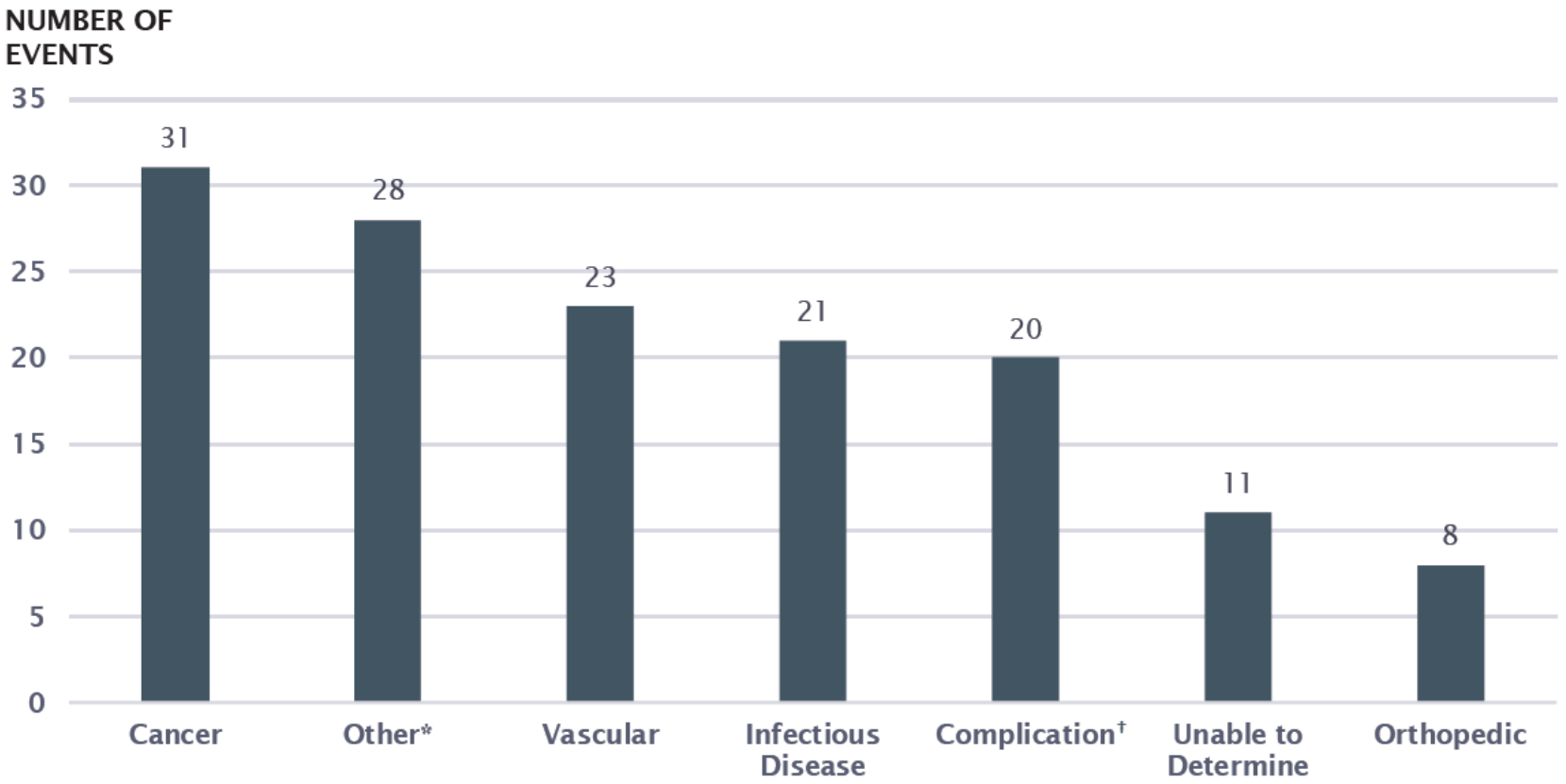


Note: Serious Events reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS), January 1, 2016, through December 31, 2016; only practices and clinics under a hospital license are mandated to report into PA-PSRS.

(Jones and Magee)

PA-PSRS Event Analysis

Figure 3. Number of Diagnostic Process Failure Events by Medical Condition (N = 138)



Note: Serious Events reported through the Pennsylvania Patient Safety Reporting System, January 1, 2016, through December 31, 2016; the conditions total more than the 138 diagnostic process failure events because some events described more than one condition.

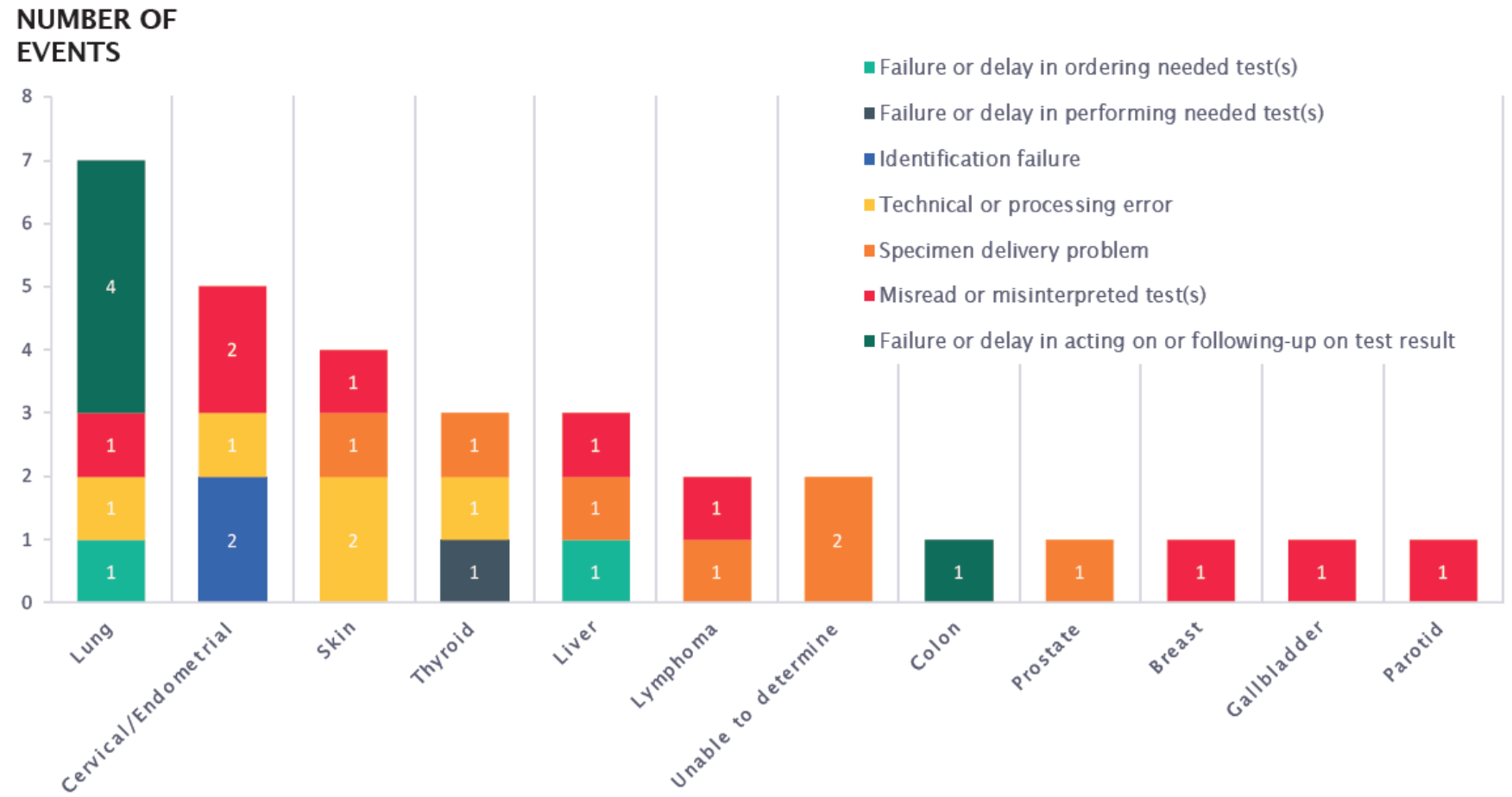
* Includes hypo- and hyperglycemia, subdural hematoma, ectopic pregnancy, and esophageal diverticula

† Includes retained surgical items missed on imaging, pneumothorax, perforation, and retroperitoneal bleeding

(Jones and Magee)

PA-PSRS Event Analysis

Figure 4. Number of Cancer-Related Events by Testing Process Failure Point (N = 31)



Note: Serious Events reported through the Pennsylvania Patient Safety Reporting System, January 1, 2016, through December 31, 2016.

(Jones and Magee)

Center of Excellence Core Team

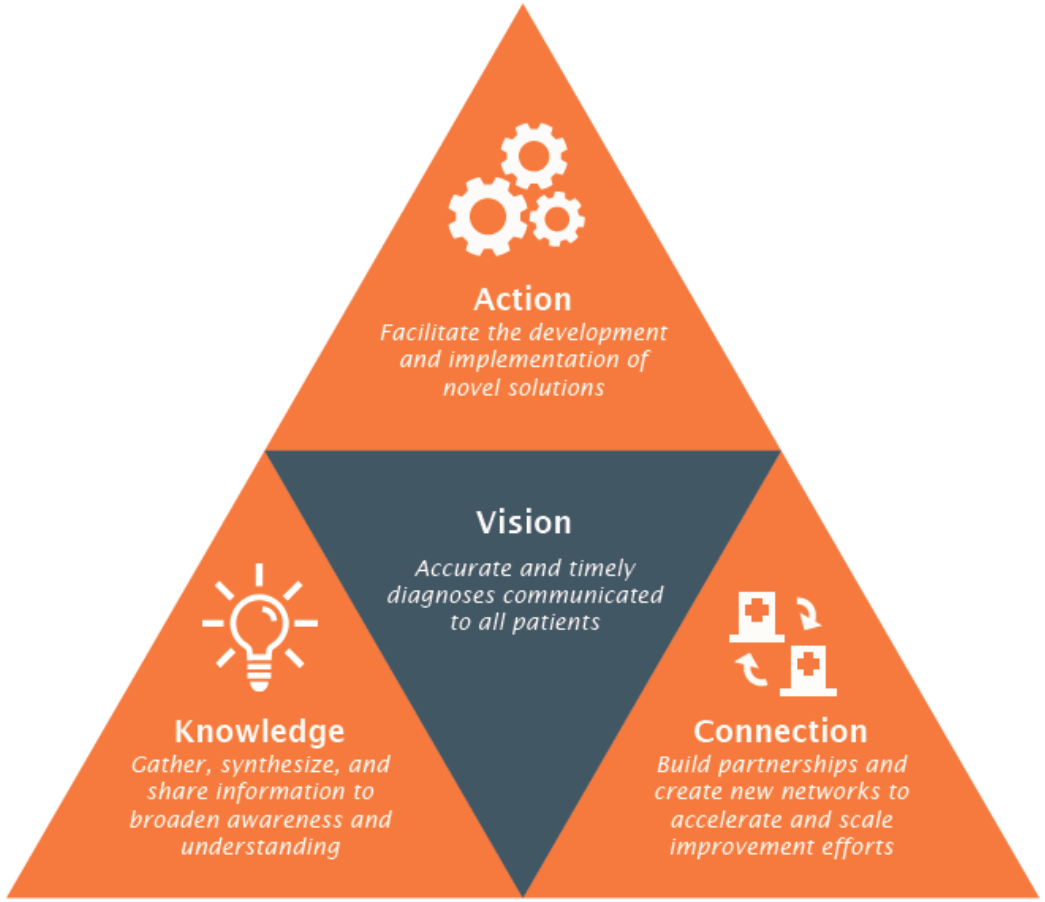






Center of Excellence *for Improving Diagnosis*

INSPIRING ACTION. SAVING LIVES.



PSA Center of Excellence *for Improving Diagnosis*

INSPIRING ACTION. SAVING LIVES.

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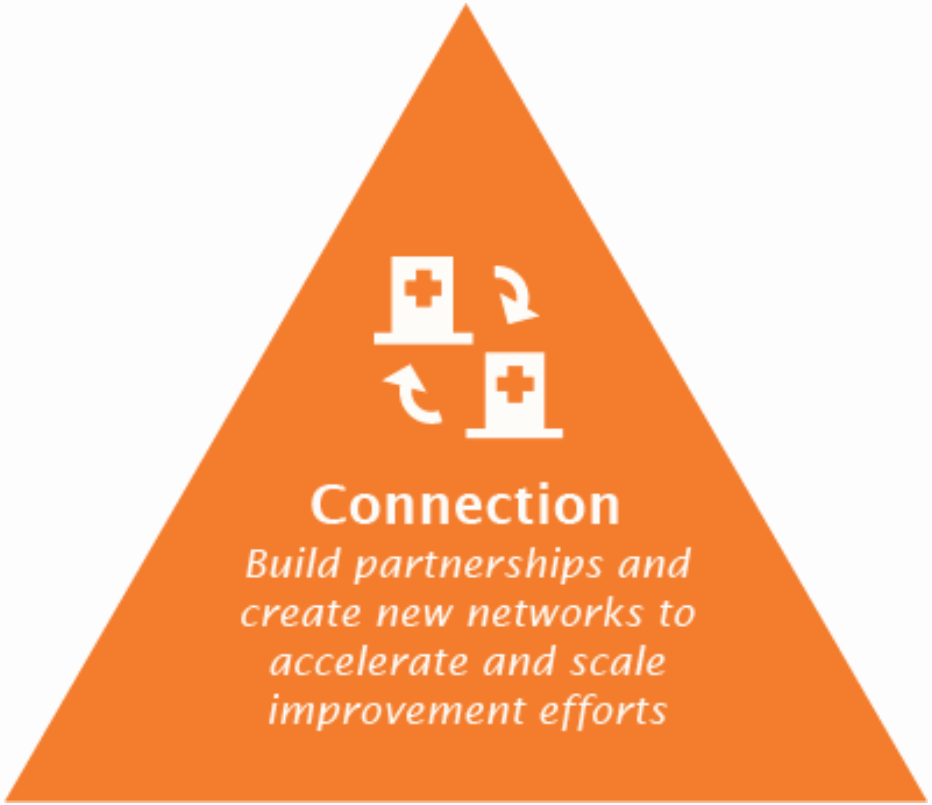

Center of Excellence
for Improving Diagnosis

INSPIRING ACTION. SAVING LIVES.

PA Center of Excellence *for Improving Diagnosis*

INSPIRING ACTION. SAVING LIVES.

- Disease or department specific measures related to improving diagnosis
- Projects designed to improve the diagnosis of cancer
- Projects designed to improve the diagnosis of vascular events
- Projects designed to improve the diagnosis of infections
- Method to collect and track events via internal event reporting system

Resources

- Improving Diagnosis in Health Care (IOM/NAM)
- Improving Diagnostic Quality and Safety (NQF)
- HRET Change Package
- Identifying and Learning from Patient Safety Events Involving Diagnosis
- SIDM
  - Patient's Toolkit for Diagnosis
  - Clinical Reasoning Toolkit
- The New Diagnostic Team
- Teachback (AHRQ)

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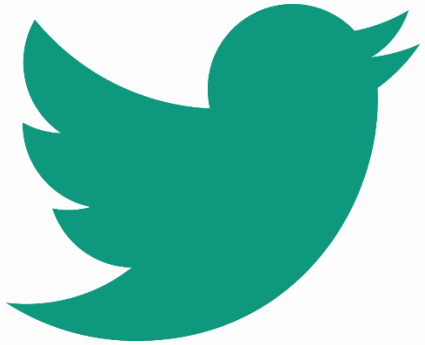
What questions do you have?

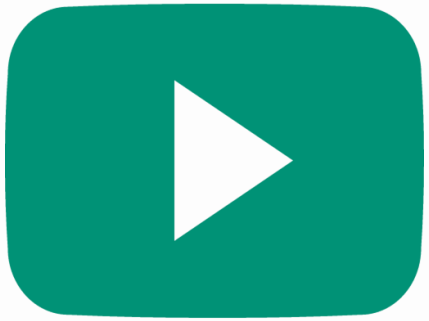
Thank You!

@PennsylvaniaPatientSafetyAuthority



@PAPatientSafety

Pennsylvania Patient Safety Authority



Pennsylvania Patient Safety Authority

PSA Patient Safety Authority