Diagnostic Errors and Patient Safety

Michael L. Rinke, MD, PhD Patrick W. Brady, MD, MSc Kathleen E. Walsh, MD, MS Trisha L. Marshall, MD, MSc Prashant Mahajan, MD, MPH, MBA APA QI Conference, April 28th, 2023









Evaluation Link

Diagnostic Errors and Patient Safety



https://associationresearch.lim equery.com/267328?lang=en









Disclosures

- Dr. Rinke was supported by AHRQ grants R01HS023608: Reducing Diagnostic Errors in Primary Care Pediatrics; R01HS24432: Comprehensive Pediatric Hypertension Diagnosis and Management; and 1K12HS 026396 The Center of Excellence in Promoting LHS Operations and Research at Einstein/Montefiore (EXPLORE)
- Dr. Brady is supported by NHLBI U01HL143475: Preparing for a Hybrid Trial of pulse oximetry de-implementation in stable infants with bronchiolitis, and AHRQ R18HS026644: Ambulatory Pediatric Patient Safety Learning Lab
- Dr. Marshall is supported by the DxQI grant from the Society to Improve Diagnosis in Medicine and the Gordon and Betty Moore Foundation
- Dr. Walsh consults for Sanofi and is currently supported by R18HS026644, R18 HS027401, PCORI DI-2018C3-14566, R18HS029346









Objectives

Participants will be able to:

- 1. Describe magnitude of diagnostic error and harm in pediatrics
- 2. Utilize existing tools and frameworks to identify diagnostic error incidence at their institution
- 3. Develop a set of potential interventions to reduce diagnostic error and harm via research and implementation science methodology









Outline

- Diagnostic error definitions and epidemiology
- Small group work on designing a study to better understand diagnostic error
- Strategies and interventions to reduce diagnostic error and error-related harm
- Small group work on designing a study to reduce diagnostic errors
- Wrap up and Q&A









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Introductions: Round Robin

- We want to get to know you! Please briefly share your:
 - Name
 - Institution
 - Specialty
 - Roles as related to QI and Implementation Science
 - Experience with diagnostic error QI or research









Diagnosis

The most critical of a physician's skills

"It is every doctor's measure of his abilities; it is the most important ingredient in his professional self image"

(Croskerry, A Universal Model of Diagnostic Reasoning, Academic Medicine, Vol. 84, No.8, August 2009; Nulund, SB.

How We Die: Reflection on Life's Final Chapter. New York, NY: Alfred A Knofp;1994)

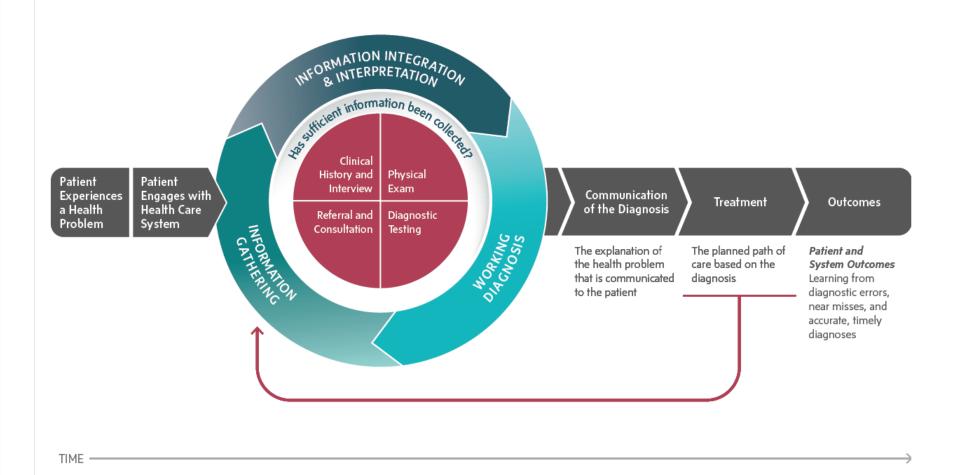








The Diagnostic Process











What is a diagnostic error?

- a) A diagnosis that is unintentionally delayed (sufficient information was available earlier)
- b) A diagnosis that is wrong (another diagnosis was made before the correct one)
- c) A missed diagnosis (no diagnosis was ever made)
- d) All of the above





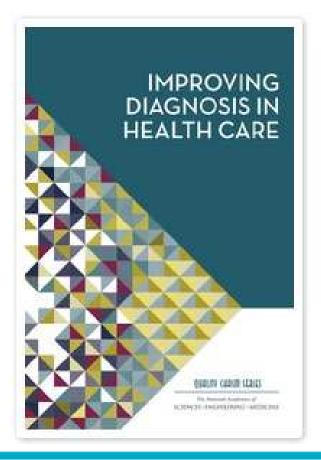




Diagnostic Error Defined

Diagnostic error is 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.











Diagnostic Error Defined

"<u>Missed opportunities</u> to make a correct or timely diagnosis based on the available evidence, regardless of patient harm."

Advancing the science of measurement of diagnostic errors in healthcare: the Safer Dx framework

Hardeep Singh,¹ Dean F Sittig²

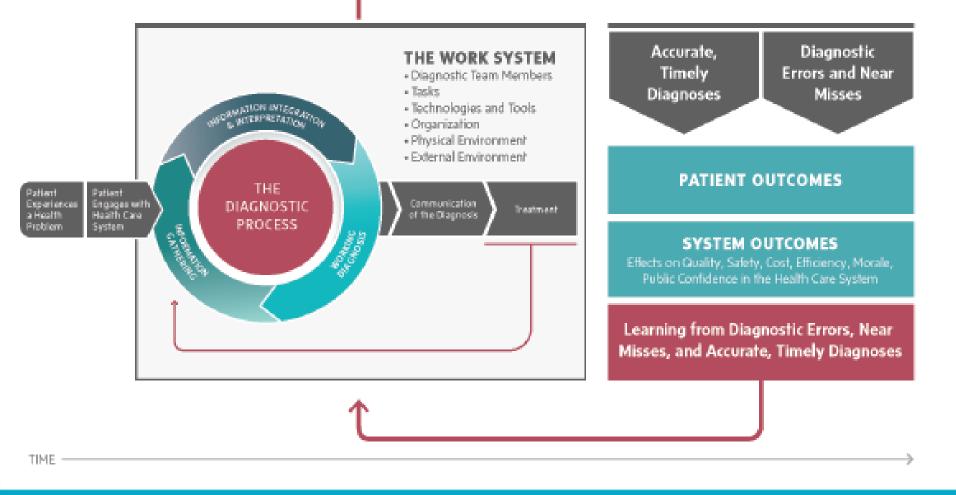








OUTCOMES











Concept of Safety II

- Safety is result of adaptations to a changing system
- Harm occurs when inappropriate adaptations are taken to an ever-changing environment
 - Clinical example: consultation or peer-to-peer feedback for unusual exam, involve cognitive uncertainty
 - Systems example: study resilience in teams in early Covid pandemic

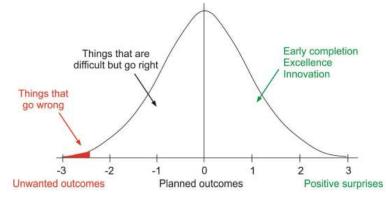
Ken Catchpole, Myrtede Alfred. Industrial Conceptualization of Health Care Versus the Naturalistic Decision-Making Paradigm: Work as Imagined Versus Work as Done. Journal of Cognitive Engineering and Decision Making 2018

John W. Ambrose. A Qualitative Protocol to Examine Resilience Culture in Health care Teams during COVID-19. Healthcare 2021



Safety I and Safety II

- <u>Safety I</u>. "a state where as few things as possible go wrong"
- <u>Safety II</u>. "assumes everyday performance variability provides adaptations needed to respond to varying conditions, and is the reason why things go right"
- <u>Resilience</u>. Ability to adjust functioning prior to, during, or following acute changes and disturbances to perform well in both anticipated and unanticipated conditions



Hollnagel E, Wears RL, Braithwaite J. From Safety I to Safety II: A White Paper. 2015. Hollnagel E. Resilience Engineering in Practice. Taylor & Francis Group; 2011:362





Diagnostic Error and Safety-II: a Preview

- In 2022, Congress authorized ~\$50M funding to support AHRQ's dx error research.
- 10 Centers: to develop systems, measures, and new technology solutions.
- Re-Engineering Patient and Family Communications to Improve Dx Safety Resilience. CCHMC (Brady, Marshall), CHOP, BCH (PI: Walsh, Landrigan)

https://www.ahrq.gov/patient-safety/diagnostic-excellence-grants/index.html





What is the incidence of diagnostic error?

- Diagnostic errors affect more than 12 million Americans each year and may seriously harm one-third of these patients
- 40,000-80,000 people die each year from diagnostic failures in U.S. hospitals alone
- By some estimates, the diagnosis a patient receives is incorrect up to 10-15% of the time
- Less is known in pediatrics though one survey found 54% of pediatricians report making an error once or twice per month

1.Leape LL. Counting deaths due to medical errors. JAMA. 2002;288(19):2404-5. 2.Singh H, et al. The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. BMJ Qual Saf. 2014. 3.Singh H,et al . Types and origins of diagnostic errors in primary care settings. JAMA Intern Med. 2013;173(6):418-25. 4. Singh H et al. Pediatrics 2010



Methods for Identifying Diagnostic Errors

- Incident reporting
- Stakeholder Interviews
- Chart review
- Trigger tools
- Lawsuit claims
- Patient and family report









Incident reporting











Electronic Triggers

ORIGINAL RESEARCH

Use of e-triggers to identify diagnostic errors in the paediatric ED

Daniel Lam ⁽¹⁾, ¹ Fidelity Dominguez, ² Jan Leonard, ³ Alexandria Wiersma, ³ Joseph A Grubenhoff ⁽¹⁾, ³









E-triggers in the Pediatric ED

- <u>Population</u>: Patients 0-22 years admitted at a single pediatric hospital over a 2-year period
- <u>E-trigger</u>: Unplanned admission to the hospital within 14 days following an ED visit.
 - Events underwent manual screening to compare index ED visit diagnoses and hospital discharge diagnoses to identify cases for further review









E-triggers in the Pediatric ED

<u>Results</u>

- 1915 admission identified with e-trigger
- 453 admissions underwent in-depth review using the SaferDx following initial screening
- 92 cases were classified as likely diagnostic errors
 - 0.4% of all hospital admissions
 - 4.8% of admissions identified by e-trigger









The Diagnostic Error Index: A Quality Improvement Initiative to Identify and Measure Diagnostic Errors

Michael F. Perry, MD^{1,2}, Jennifer E. Melvin, MD^{2,3}, Rena T. Kasick, MD^{1,2}, Kelly E. Kersey, BS, CPHQ⁴, Daniel J. Scherzer, MD^{2,3}, Manmohan K. Kamboj, MD^{2,5}, Robert J. Gajarski, MD^{2,6}, Garey H. Noritz, MD^{2,7}, Ryan S. Bode, MD^{1,2}, Kimberly J. Novak, PharmD⁸, Berkeley L. Bennett, MD^{2,3}, Ivor D. Hill, MD^{2,9}, Jeffrey M. Hoffman, MD^{2,10}, and Richard E. McClead, MD²

- QI team developed standardized event review process to identify and confirm DxE from:
 - Class 1 autopsy findings
 - Root cause analyses
 - Electronic voluntary reporting system
 - M&M conferences
 - Abdominal pain EHR trigger tool
- Data fed back into QI initiative with education and focused interventions









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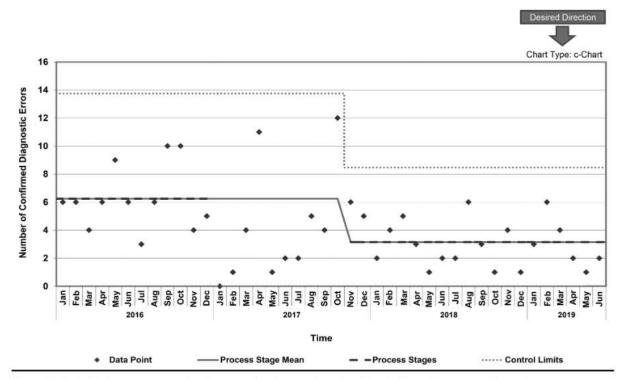


Figure 3. Statistical process control c-chart revealing the number of confirmed diagnosis errors each month.









Diagnostic Errors in Pediatric EDs



Diagnostic uncertainty High decision density High cognitive load High levels of activity Provider inexperience Interruptions, distractions Shift work, changes Compromised teamwork Poor feedback



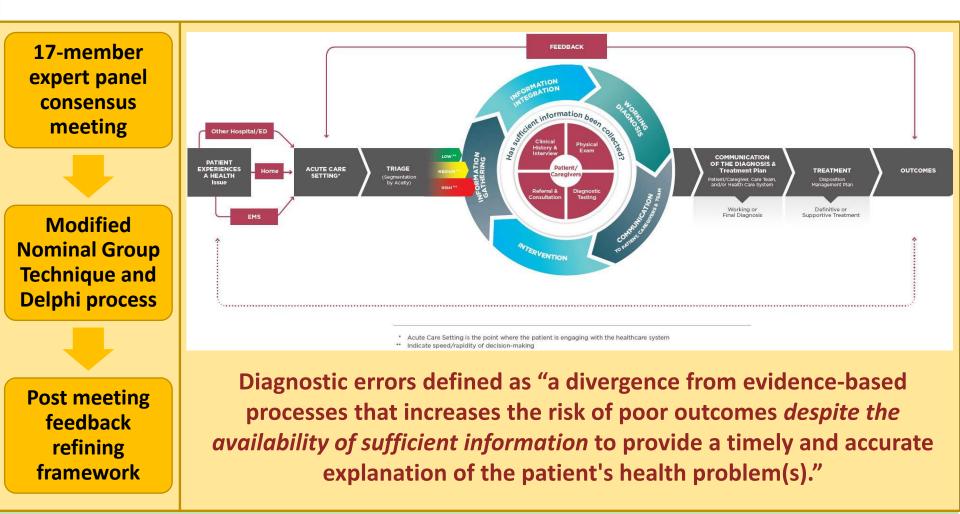








Diagnostic Process in the Emergency Department: An Adaptation of NASEM Framework



Mahajan et al. An Operational Framework to Study Diagnostic Errors in Emergency Departments: Findings from a Consensus Panel. *J Patient Saf.* Nov 2019.

Diagnostic Errors in Pediatric EDs

DE GRUYTER

Diagnosis 2020; aop

Prashant Mahajan*, Chih-Wen Pai, Karen S. Cosby, Cynthia J. Mollen, Kathy N. Shaw, James M. Chamberlain, Robert El-Kareh, Richard M. Ruddy, Elizabeth R. Alpern, Helene M. Epstein, Traber D. Giardina, Mark L. Graber, Laura N. Medford-Davis, Richard P. Medlin, Divvy K. Upadhyay, Sarah J. Parker and Hardeep Singh

Identifying trigger concepts to screen emergency department visits for diagnostic errors





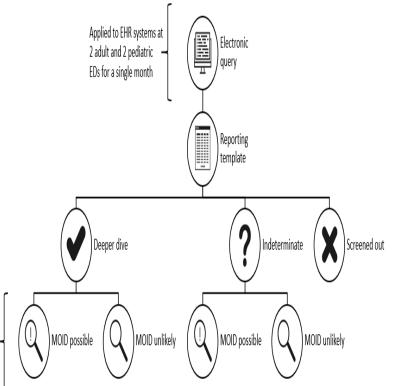




Diagnostic Errors in Pediatric EDs

Table 3: E-Trigger and non-EHR based signal concepts recommended by expert panel.

Data source	Trigger/Signal concepts	Applied to E
e-triggers	Unscheduled return to ED resulting in hospital admission	2 adult and EDs for a sir
	Death following ED visit Care escalation following transfer to floor from ED High risk conditions based on symptom-disease dyads Return visits with new therapeutic interventions ^a	
	Change of service during admission from the ED	
Non-EHR based signals ^a	Cases discussed in morbidity and mortality conference Cases from risk management/safety office Cases referred to division chief/medical director Cases from provider feedback and patient complaints Radiology misread cases and/or laboratory call backs	Assessed using the Safer Dx Instrument



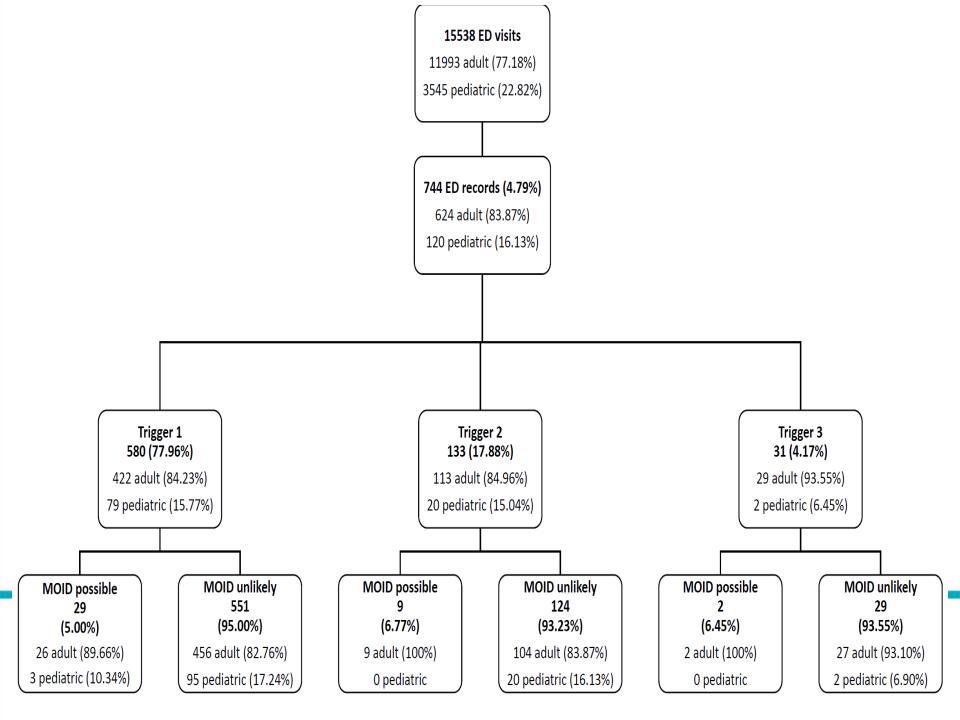












Lawsuit Claims





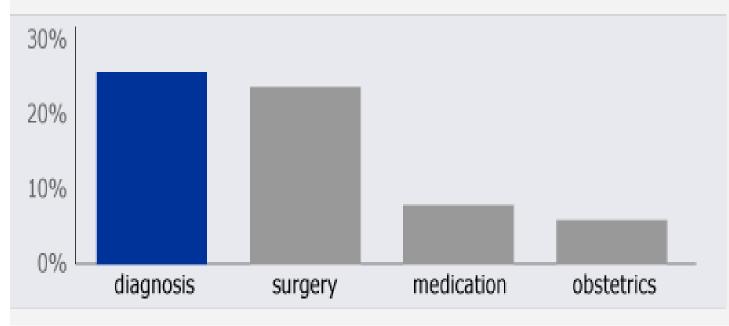






CRICO/RMF Database

64% of claims come from these four high-risk areas. percentage of all claims asserted 2002-2006, N=1,164 claims











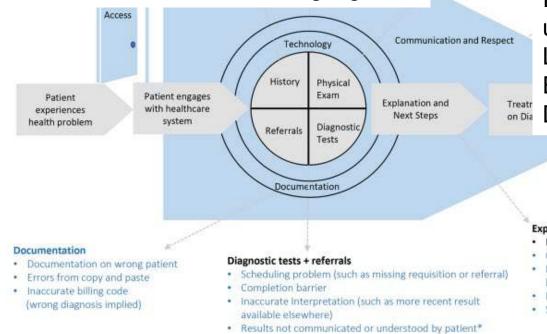
Patient- and family-reported outcomes

Patient engagement throughout the diagnostic process (from Access to Outcomes)

Access to care & diagnostic process:

Unaddressed social determinants of health

Lack of access to health info Lack of education about warning signs



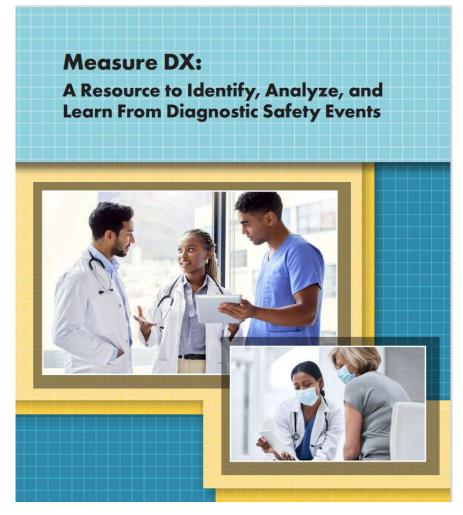
Communication & respect:

Physical Exam Patient feels unheard Misalignment b/patient & clinician about symptoms or visit events Inadequate communication about uncertainty Lack of transparency Experience of disrespect Discomfort speaking up

Explanation and next steps (NAM: "Communication of the Diagnosis")

- Diagnosis not communicated or understood by patient*
- Correct diagnosis made by a different provider
- Disagreement between clinicians about diagnosis or next steps leading to confusing/conflicting information
- Plan does not match patient understanding or priorities
- Something important missing from next steps

Bell S et al. Filling a gap in safety metrics: development of a patient-centred framework to identify and categorise patient-reported breakdowns related to the diagnostic process in ambulatory care. BMJ Q&S 2022



 Measure Dx: A Resource To Identify, Analyze, and Learn From Diagnostic Safety Events (ahrq.gov)









Measure Dx Guide

- Part I Outlines approach to engaging the necessary organizational leaders in diagnostic safety work
- Part II Self-assessment checklist to gauge readiness to begin and choosing measurement strategies which match local organizational resources









Measure Dx Guide

- Part III Describes strategies to measure diagnostic error leveraging different data sources, including how to leverage existing organizational data
 - Other strategies include event reporting from clinicians and staff, patient-reported data, and enhanced EHR chart review
- Part IV Provides recommendations for systematic review of cases and how to translate findings into learning and improvement









Small Group Work

- Challenge: Design a study to better understand the epidemiology of diagnostic error
- Break out groups of 4-5 people
- Briefly introduce yourselves
- Discuss as group for <u>15 minutes</u> and develop <u>1</u>
 <u>idea</u> to share with larger group









Small group report out

- Each group report out on their idea for study on diagnostic error epidemiology
- Other groups: share what you like and opportunities for improvement









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5 Minute Stretch Break









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Reducing Diagnostic Error: Strategies and Interventions

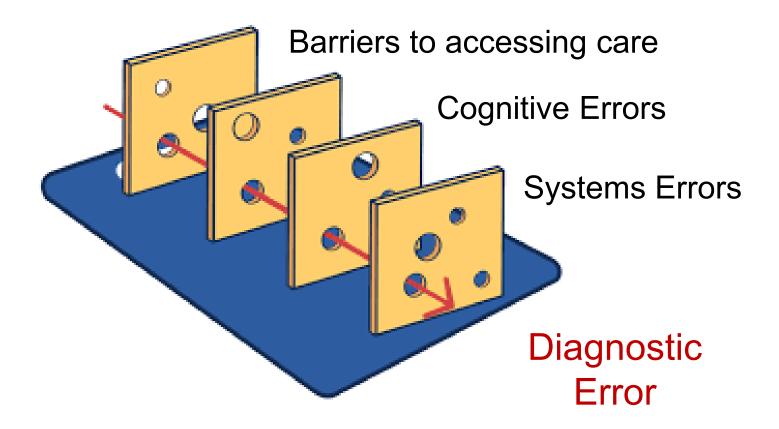








Diagnostic Errors are Multifactorial











The Field of Diagnostic Error

Cognitive errors

- Inadequate knowledge
- Data gathering
- Data interpretation

System errors

- Technical failures
- Organizational issues

(Graber, Diagnostic Error in Internal Medicine, Arch Intern Med/Vol 165, July 11, 2005)









- No-fault errors
 - Atypical, silent
 - New disease
 - Lack of cooperation

Reducing Cognitive Errors

Improve cognition

- Learn to avoid cognitive biases
- Improve diagnostic reasoning skills

Diagnostic calibration

Regular feedback on diagnostic errors









Sample CDRs

- Availability bias: Particular diagnosis is considered more likely because it is easily recalled
- Representativeness bias: "If it looks like a duck, it walks like a duck, it must be a duck"
- Anchoring Bias: Too much reliance on one piece of information
- Confirmation bias: Clinicians seek information to confirm their initial impression, weigh evidence favoring our diagnosis more heavily
- **Premature diagnostic closure:** Reaching a diagnosis and failing to assimilate additional data that contradicts it









Diagnostic Calibration

- Clinicians often receive little, or no, feedback on the outcome of their diagnostic decisionmaking (open-loop system)
- Closing the loop may help clinicians avoid similar errors in the future









Closing the Loop

- Structured feedback to residents focused on overnight admissions
- Diagnostic changes noted in 43.7% of admissions
 - 29% (or 12.7% of overall admissions) had major diagnostic changes

Improving Resident Feedback on Diagnostic Reasoning after Handovers: The LOOP Project

J. Hosp. Med. 2019 October;14(10):622-625. Published online first August 21, 2019 I 10.12788/jhm.3262

By: Kathleen P Lane, MD ☑, Catherine Chia, MD, Juan N Lessing, MD, Julia Limes, MD, Benji Mathews, MD, Julie Schaefer, MD, L Barry Seltz, MD, Grant Turner, MD, Brittany Wheeler, MD, David Wooldridge, MD, Andrew PJ Olson, MD









Systems Approaches to Reducing Diagnostic Errors

- Top Recommendations from the NAM:
 - Facilitate more effective teamwork in the diagnostic process
 - Ensure that health information technologies support the diagnostic process
 - Develop approaches to identify, learn from, and reduce diagnostic errors and near misses
 - Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance



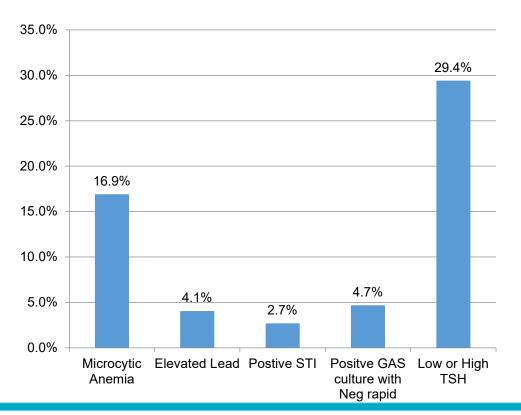






Project RedDE! Reducing Diagnostic Errors in Primary Care Pediatrics

- 55% of pediatric patients with elevated blood pressure were not acted upon by their pediatricians
- 62% of adolescents did not have mental health addressed at primary care visits
- 11% of actionable laboratory values were not acted upon without delay by their pediatricians











Project RedDE: Methodology:

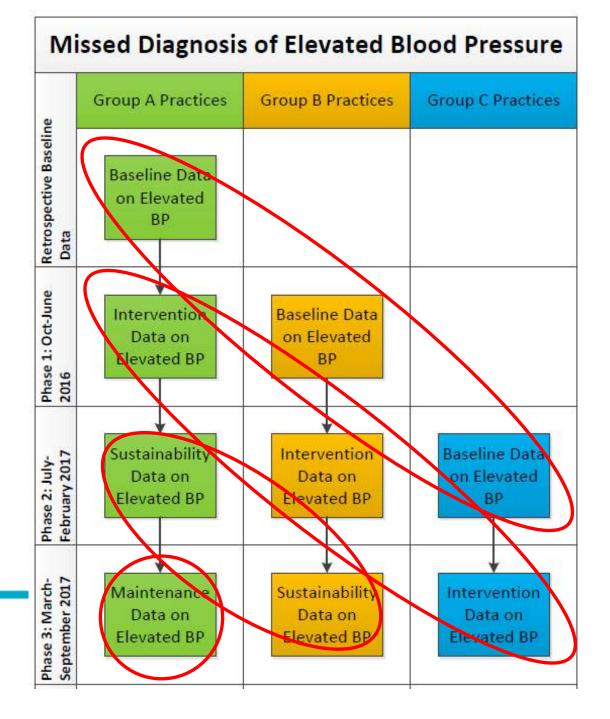
- Primary Care Pediatric Practices recruited from around the country in Wave 1 & Wave 2
- Participate in a randomized trial to investigate whether a quality improvement collaborative can reduce 3 diagnostic errors
- Each practice randomly assigned to collect retrospective baseline data on 1 error (February-June, and September 2015)
- Then intervene to reduce that error (October-June 2016)
- They also collect control data on 2nd error











Quality Improvement Collaborative Intervention

- All-teach, all-learn
 - Monthly video conferences, every 8 months day long video conference
- Mini-RCAs monthly on diagnostic error
 - Focus on Failures
- Change packages of tools and resources
- Practices receive QI coaches
- Practices enter data on web-based portal and get regular data feedback with complete transparency
- Email listserves for reminders and questions









Results:

Intervention vs. Control

Outcome	Ν	%	RD (95% CI)	Р
Documentation of Diagnosis of <u>Depression</u>	7508	10.5% vs. 6.6%	3.9% (2.4%, 5.3%)	<0.0001
Appropriate action taken and documented for <u>EBP</u>	3783	75.4% vs. 58.9%	16.5% (12.8%, 20.1%)	<0.0001
Documentation of appropriate action for abnormal <u>Lab</u> <u>results</u>	2663	93.9% vs. 92.9%	0.9% (-1.1%, 3.0%)	0.370
The Children's Hospital at Montefiore	Where th	Boston Children's Hospital		ncinnati Children's Inging the outcome together

Declaring Uncertainty: Using Quality Improvement Methods to Change the Conversation of Diagnosis

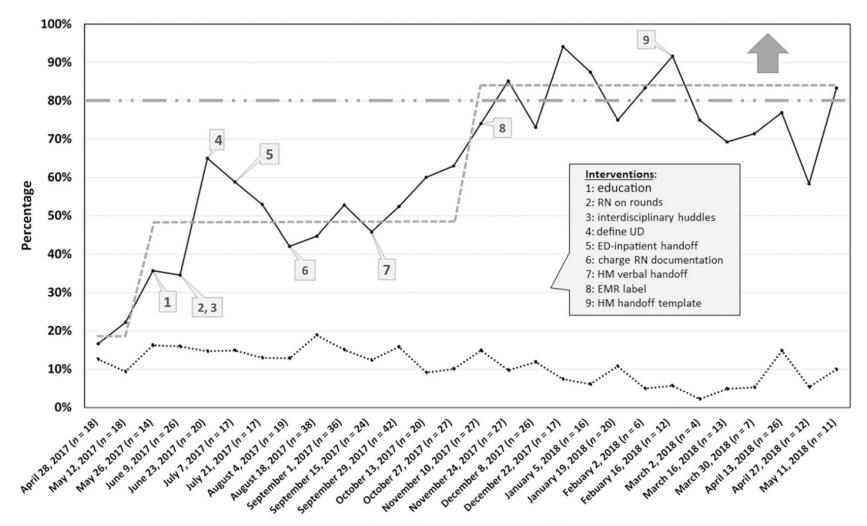
Anna J. Ipsaro, MD, MBE,^a Shivani J. Patel, DO, MEd, MS,^{ab} Dane C. Warner, MD, MPH,^{ab} Trisha L. Marshall, MD,^{ab} Steven T. Chan, MD,^{b,c,†} Katherine Rohrmeier, MSN, APRN-CNP,^d Deborah Richardson, BSN, RN, CPN,^d Amanda Kammer, BSN, RN, CNML,^d Emily Luksic, BSN, RN, CPN,^d Kathleen D. Bell, MS,^e Philip A. Hagedorn, MD, MBI^{a,b,tg}

SMART Aim: Increase the percentage on patients form whom the charge nurse and clinician agree that the diagnosis is uncertain from 19% to 80% within 6 months









Every 2 Weeks, Starting on Date Listed







Declaring Uncertainty

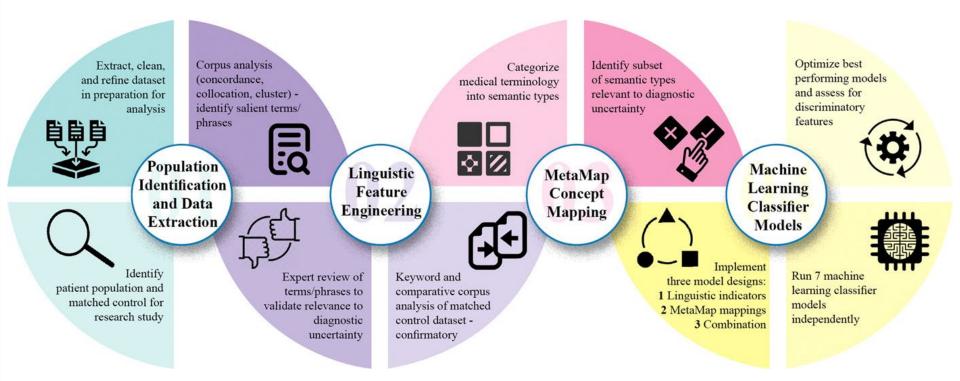
- Create shared situation awareness of patients admitted to the pediatric hospital medicine service with uncertain diagnoses
- Resulted in the creation of a novel uncertain diagnosis (UD) label within the electronic health record







Leveraging QI data for new knowledge generation





Example from UD patient and matched control

Control Documentation

The most likely diagnosis is acute gastroenteritis of viral etiology. Other differential diagnoses for consideration include bacterial gastroenteritis or a parasite infection although less likely at this time since symptoms have seemed to resolve rather quickly. If diarrhea increases in frequency or blood is seen, would consider sending stool studies at that time. Will continue on MIVF's until she is able to tolerate oral intake without emesis

UD Case Documentation

Unclear diagnosis at this time, but differential would include post-viral gastroparesis/ileus, although severe intermittent abdominal pain would not be consistent with that diagnosis. Could have intermittent intussusception or volvulus, with lead point of an enlarged lymph node in the setting of recent viral gastroenteritis. Renal colic is a possibility with the description of "writhing" in pain, but pain is not localized to the back or flanks and no blood or other abnormality seen on UA. Biliary colic could be considered, although would be unusual in her age range and without association with food. Appendicitis remains on the differential, as was not visualized on ultrasound, but exam findings not consistent with that diagnosis.

Legend: Linguistic Indicators Diagnosis or Syndrome Semantic Type Other MetaMap Semantic Types



Linguistic Indicators of Diagnostic Uncertainty

Term	Corpus	Frequency	Odds Ratio (95% Confidence Interval)	
Uncertain	Case	12%	19.88 (11.52-	
	Control	0.7%	34.31)	
Broad	Case	5%	12.12 (6.12-23.99)	
	Control	0.5%		
Differential	Case	31%	5.48 (4.38-6.84)	
	Control	8%		
Unclear	Case	18%	5.25 (3.95-6.97)	
	Control	4%		
Etiolog*	Case	29%	4.81 (3.84-6.01)	
	Control	8%		
Abdominal/Abdominal	Case	41%	4.49 (3.70-5.45)	
pain	Control	13.5%		



Small Group Work

- Challenge: Design a clinical research or QI study reduce diagnostic errors
- Break out same groups of 4-5 people
- Discuss as group for <u>15 minutes</u> and develop <u>1</u>
 <u>idea</u> to share with larger group









Small group report out

- Each group report out on their idea for study on reducing diagnostic errors
 - Start with if you designed research study or QI project
- Other group(s): share what you like and opportunities for improvement









Take-homes

- Diagnostic error is common but poorly quantified, particularly in pediatrics
- Interventions to reduce diagnostic error draw upon a rich, decades-long line of research in cognitive psychology
- Yet very few have been applied and fewer still evaluated in healthcare









Resources for Diagnostic Error



SIDM

AHRQ Grant Announcements



SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

Patient Stories Programs & Projects Get Involved Coalition Resources Conferences

Medscape

Understanding **Diagnostic Error**

About

Medscape, in partnership with SIDM, developed a learning module for primary care physicians, emergency medicine physicians, radiologists, and nurses.



Patient's Toolkit

The Patient's Toolkit for Diagnosis is a resource created for patients, by patients. With this toolkit, patients can prepare for upcoming appointments, map symptoms, account for medications, and plan for next steps.

Download the Toolkit

Challenge

- Talk with your table about <u>1 step</u> you will take to move diagnostic error research or QI forward at your institution
 - Meet with Chief Safety Officer
 - Present at a research meeting
 - Ask colleagues about their last diagnostic error
 - Design a presentation for residents or fellows
 - Etc.









Thanks

QR code for brief eval:

Diagnostic Errors and Patient Safety



• Questions?

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Diagnostic Errors and Patient Safety



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Index slides







Reduce Cognitive Errors

Improve cognition

- Learn to avoid cognitive biases
- Improve diagnostic reasoning skills

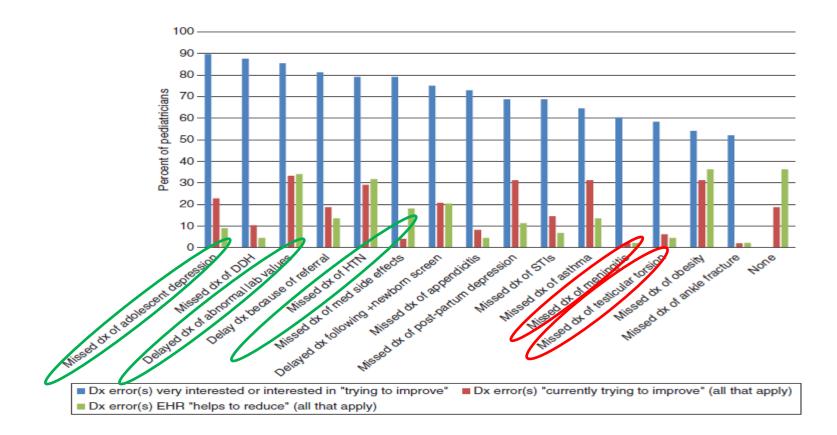
Adopt system solutions to cognitive errors

- Availability of experts
- Second opinions
- <u>Clinical guidelines</u>, clinical-decision support systems
- Project RedDE!









<u>Opportunity</u>: Involve research "subjects" in choosing the research topic







IOM Report Recommendations

- 1. Facilitate more effective teamwork in the diagnostic process among health care professionals, patients, and their families
- 2. Enhance health care professional education and training in the diagnostic process
 - 3. Ensure that health information technologies support patients and health care professionals in the diagnostic process
 - 4. Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice
- 5. Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance
 - 6. Develop a reporting environment and medical liability system that facilitates improved diagnosis by learning from diagnostic errors and near misses
 - 7. Design a payment and care delivery environment that supports the diagnostic process
 - 8. Provide dedicated funding for research on the diagnostic process and diagnostic errors







Metacognitive Training

- Force a complete differential diagnosis
 - Extra effort, more evidence
 - Detect incongruity, ambiguity, atypical instances
- "Crystal ball experience"
 - Examine flaws of original thought
 - Search for alternatives





Metacognition: Operational Definition

Monitor and manage one's own thinking

- Making plan <u>before</u> thinking episode
- Regulating thought *during* thinking episode
- Reflecting back <u>afterwards</u> to revise and plan future practices









Perkins & Grotzer, 1997

Time out

Surgical Pause





Metacognition and Medical Decision Making

- Step back from the immediate situation
- Check one's own diagnostic thinking
 - limitations & failings of memory
 - Possible biases (CDRs)
- See the problem in wider perspective







"Cognitive Autopsies"

- Conduct as soon as possible
- Be well-rested
- Find a secluded place, free of interruptions
- Start with the beginning of the day or shift
- Free-associate fully about the event-recall thoughts and feelings
- Pay attention to ambient conditions
- Write everything down
- Discuss with others and record their comments and observations
- Review cognitive biases

(Adapted from Croskerry, P., Advances in Patient Safety, Vol. 2., pp. 241-252.)







Other Tips for Reduction of Diagnostic Errors

- Promote a systematic approach to common problems.
- Use of algorithms or checklists
- Keep asking questions. What can I not explain?
- Acknowledge your feelings about a patient or family. Positive or negative feelings may bias your approach.
- Slow down. When individuals are rushed, more mistakes may occur.
- Be aware of the critical impact of fatigue and sleep on decision-making
- Admit your mistakes. This can lead to reflection and change in behavior.





