ROOT CAUSE ANALYSIS OF CASES INVOLVING DIAGNOSIS
A Handbook for Healthcare Organizations
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> "*Safety is an emergent property of systems; it does not reside in a person, device or department of an organization or system. Safety cannot be purchased or manufactured; it is not a feature that is separate from the other components of the system…The state of safety in any system is always dynamic; continuous systemic change insures that hazard and its management are constantly changing.*"   "*People continuously create safety.*"
>
> **Richard I Cook. How Complex Systems Fail (1)**

EXECUTIVE SUMMARY

Diagnostic errors comprise the largest threat to patient safety in healthcare today. Improving the quality and safety of diagnosis will require learning from cases of diagnostic error (Safety 1) and from cases where the diagnostic process works well (Safety 2).

Most healthcare organizations use root cause analysis (RCA) to study safety breakdowns, and there are many comprehensive resources already available on how to conduct these investigations, from IHI, ASHRM, The Joint Commission, and the VA. Unfortunately, none of these are suitable for analyzing cases of diagnostic error (or success); cases involving diagnosis require considering the cognitive aspects of medical decision-making, a critical area that is not adequately addressed by any of the existing manuals.

This RCA Handbook provides up-to-date and authoritative guidance on how the existing approaches to conducting an RCA can be modified to study cases involving diagnosis. There are several differences: In cases involving diagnosis, the investigation should begin immediately after the incident, the clinicians involved should be members of the RCA team, and the review must include consideration of how the clinical reasoning process went astray (or succeeded), in addition to using a human-factors perspective to consider the system-related contextual factors that might have played a role in the incident.

The Handbook presents detailed instructions for conducting RCA's of cases involving diagnosis:

- How to find cases of diagnostic error or success
- How to confirm that the case does indeed reflect a diagnostic error
- Whether a particular case should be peer reviewed, or go to RCA
- Who should be on the RCA team? Clinicians and patients should be involved
- How to map where in the diagnostic process problems were encountered
- Using fishbone diagrams to consider the 4 major domains relevant to most cases:
      The case, the patient, the clinicians, and the context of care
- How to evaluate the cognitive aspects of the decisions that were made by considering both the subconscious, intuitive aspects of clinical reasoning as well as the deliberate, conscious counterparts
- Guidance on selecting appropriate interventions

A collection of useful tools and resources is presented in the accompanying Appendix.

Although the factors that contribute to diagnostic errors are well established, healthcare organizations have been slow to address the problem in a meaningful way. The RCA Handbook represents a novel resource for any organizations seriously interested in improving the quality and safety of diagnosis for their patients.

INTRODUCTION

This Handbook is intended to be a resource for healthcare risk managers, patient safety leads and clinicians responsible for conducting root cause analyses (RCAs). Originally developed to improve the safety of commercial aviation, RCA has become the primary tool for reviewing adverse safety events in health care organizations today. The Joint Commission requires accredited hospitals and facilities to identify and address Sentinel Events, and they recommend using RCAs to do so (2, 3).

Several healthcare organizations have published comprehensive RCA manuals and guidance:

- **IHI**, **the Institute for Healthcare Improvement**, (4)

- **ASHRM, the American Society for Healthcare Risk Management** (5)

- **TJC, The Joint Commission**, (3) and the

- **VA, the Department of Veterans Affairs** (6).

The IHI's "RCA[2]" handbook, which is free and endorsed by over 20 of the nation's leading health care and patient safety organizations, is perhaps the most widely used approach to conducting RCAs in US health care organizations.

Why do I need another RCA model and handbook?

The various handbooks of healthcare-related RCAs listed above (we will refer to them as the system-focused RCAs) focus largely on the systems-related and organizational issues to be examined in a particular case. Even the ones that include the consideration of 'human factors' were not designed to consider the cognitive aspects of the clinical reasoning processes involved in deriving a medical diagnosis (7, 8), and as a result none of the current approaches to conducting RCAs are appropriate for considering cases involving diagnostic error. With the growing appreciation that diagnostic error is a leading cause of healthcare-related harm, new tools are needed to learn from cases where diagnosis failed, (the Safety 1 approach) and also from cases where the diagnostic process succeeded (Safety 2).

> The good news: Whatever systems-focused RCA model your institution may already use, it can easily be adapted to analyze diagnosis-related factors as well. This Handbook will build on the current systems-focused RCA models to include the added capability to analyze diagnosis-related cases, and use Safety 2 concepts when appropriate.

To study cases involving diagnosis, system-focused RCA approaches require several modifications (Table 1). In cases involving diagnosis, the investigation should begin immediately after the incident, the clinicians involved should be members of the RCA team, and the review must include consideration of how the clinical reasoning process went astray (or succeeded), in addition to using a human-factors perspective to consider the system-related contextual factors that might have played a role in the incident.

Why Examine Diagnosis-Related Cases?

Misdiagnosis (defined basically as wrong, missed or delayed diagnosis) derails medical care from the outset. The train is on the wrong track. The patient can suffer harm from the wrong treatment and from the delay or failure to get the right treatment.

When RCAs were first applied to healthcare, circa 2000, the issue of diagnostic error flew under the patient safety radar. The former Institute of Medicine (IOM) in its landmark 1999 reports on To Err is Human and the Quality Chasm series barely mentioned diagnostic error as a safety concern.

In 2015, the IOM (renamed as NASEM, the National Academies of Sciences, Engineering, and Medicine) published a new report identifying diagnostic error as an especially common problem associated with outsized patient harm. In 2019, ECRI designated diagnostic error as the #1 patient safety concern in healthcare, reflecting hundreds of published studies on diagnostic error and evidence from professional liability claims data. This body of research demonstrated that <u>diagnostic error is the most common, the most costly and the most catastrophic </u>of all medical errors (9)

> *"Understanding human decision-making is at the core of an RCA. Deficiencies in human decision-making are the trigger to most any resulting undesirable outcome. Understanding human reasoning and rationale is at the core of what true RCA is all about. Stopping short of that understanding will most certainly compromise the integrity of the analysis."*—
>
> **Bob Latino. The Top Frustrations of RCA Facilitators & How It Prevents Them from Being Effective (10)**

A second development since RCAs were initially applied to healthcare has been the emergence of the Patient Safety 2 concept, learning from what goes right in healthcare, rather than focusing only on what goes wrong. Safety 2 is particularly applicable to improving diagnosis given that most of the time, approximately 90% of the time, the diagnosis is right.

Table 1. Comparing System-Focused RCA to Systems PLUS Diagnosis-Focused RCA

	System-focused RCA	Systems PLUS Diagnosis-Focused RCA
Safety issue in the cases examined	The focus is squarely on system issues. The safety event is generally NOT diagnosis-related. Cases involving individual performance, including clinician judgment, are sent for peer review.	Systems-related PLUS diagnosis-related cases. Applies to many or most cases previously sent for peer review. Focus is on both systems-related and cognitive factors, and the human factors issues that tie them together
Where was the incident?	Typically inpatient care	Inpatient and ambulatory care PLUS cases involving care transitions.
RCA team members	Core members: Patient safety staff, clinician experts. Seldom included: involved clinicians and affected patients\family members.	Same core members PLUS the involved clinicians and staff with expertise in clinical reasoning and cognition PLUS patients\family members, if appropriate.
Steps of the RCA	Gather all the facts. Where did things go wrong? Why? How can this kind of problem be prevented going forward? Share lessons learned.	Same as system approach but start immediately PLUS include analysis and interventions focused on cognitive and contextual factors related to diagnosis.
Recommended actions	Focus on finding strong interventions. Avoid emphasis on education, training, reinforcing policy, and other weak actions.	Strong interventions PLUS education, as it may be more effective as an intervention in diagnosis- than in the system-focused RCA.

The learning objectives for this Handbook are:

- Users will be able to explain the importance and justify the addition of diagnosis-related cases to their institution's RCA process.
- Users will be able to triage cases appropriately to RCA vs peer review
- Users will be able to adapt the systems-focused RCA framework to include case-finding and analysis of diagnosis-related cases, incorporating a Safety 2 approach.
- Users will be able to craft credible interventions to improve diagnostic safety issues as well as systems-related safety issues.

Strengths and Weaknesses of Root Cause Analysis

The RCA approach and its regulatory underpinnings have successfully enabled frank discussions of patient safety events across the nation and internationally.(11) The Joint Commission reviews roughly 900 RCAs every year.(12) Although it is impossible to judge the aggregate impact of these analyses on health care safety, there is evidence of positive impact in many areas.(13-18)

There has also been criticism of the RCA approach, pointing out its weaknesses and limitations: (17-20)

- RCAs are resource- and staff-intensive and too infrequently lead to improvements. Institutional support for the RCA process is vital. RCA teams are well advised to avoid making an exhaustive list of root causes and recommendations. Focus on one or two areas where the root causes are relatively clear and propose practical interventions with the most potential for impact.
- RCAs are subject to hindsight bias. The retrospective nature of the RCA brings a built-in hindsight bias which can lead to oversimplified explanations of problems. Being able to make the correct diagnosis may seem obvious in retrospect, but this belies the complexity and uncertainty that existed at the time. RCA teams should try to imagine they were in the shoes of the clinicians evaluating the patient.
- RCAs are not reproducible. Teams should be advised there is no one right way to conduct an RCA: just use an organized, accepted approach that covers the bases. Another RCA team might fairly arrive at a different understanding of the case and different interventions.
- RCA's don't always improve practice effectively, especially if the proposed interventions are 'weak'. Education, reminders and reinforcement of policies are said to be weak interventions. For example, a sign advising caregivers to wash their hands would be considered weak, while installing handwashing stations outside each patient room would be considered stronger. A "hard stop" or "forcing function" intervention would be stronger still. Adding consideration of human factors to systems-focused RCAs can increase the strength of interventions. A recent study found evidence that considering human-factor elements increased the relevancy of analyses, the number of 'strong' interventions suggested, and overall staff satisfaction with the process and its results. (21) Education as an intervention may have more impact in cases involving diagnostic error, as many or most clinicians are not familiar with the cognitive aspects of diagnostic error, or how to address these.

Alternatives to RCA

Besides using root cause analysis, there are many other approaches and analytical tools available from high reliability organizations for improving organizational safety.(22) Several of these are formal, rigorous methods including the London Protocol used in the United Kingdom to investigate safety events,(23) the functional analysis method (24) and the Systems Theoretic Accident Model and Process (STAMP).(25)

There are also approaches to learning from safety incidents that promise to be faster and simpler than classical RCA:

- The SWARM. Li J, et al. conducted 170 SWARMs in a pediatric ICU at the University of Kentucky. (26) A SWARM is a novel, unit-focused approach where participants directly involved in a safety event are convened immediately afterward to review the facts with a focus on identifying causes. (26, 27).

- Hagley et al. reviewed seven different tools for analyzing safety events that are less burdensome than traditional RCAs,(17) including Learning from Defects,(28) and the 'Concise' tools from the NHS incident analysis system.(29)

- Donnelly et al. developed a streamlined approach that cuts the average time to complete an RCA from 118 days to 26 days.(30).

- Sanya Mathura described the EasyRCA method as intuitive to use with little team training required.(31).

- Dadlez et al. used mini-RCAs to study diagnosis-related errors of problem prone areas (e.g., actionable lab results that were missed).(32).

- The 'learning teams' method, was found to be simpler than formal RCA investigations, more reproducible, and able to generate twice as many system-focused recommendations.(33)

A recent trend is to aggregate the data from collections of RCAs investigating an overarching issue, such as diagnostic errors related to access, or in specific clinical areas, such as the Emergency Department.(32, 34, 35) These aggregated analyses provide interesting insights into the factors most commonly found in specific case types.

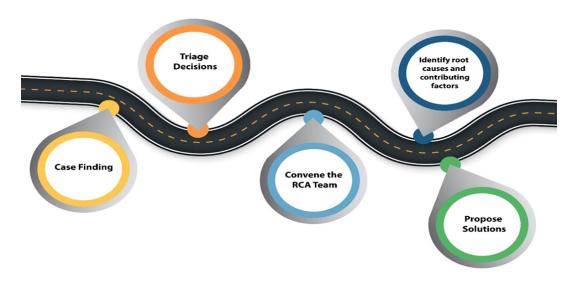# RECOMMENDED PRACTICES IN RCAs OF CASES INVOLVING DIAGNOSIS

Figure 1. Steps of an RCA for Cases Involving Diagnosis

The RCA Process: STARTING OUT

As in system-focused RCAs, an immediate response is needed after an adverse diagnosis-related safety event to ensure the clinical situation has been stabilized, the patient and family have been informed, hospital leadership is aware, and any artifacts relevant to the event are preserved. The subsequent steps of the RCA process are diagrammed in **Figure 1**.

The usual advice when conducting an RCA is to begin a detailed review *as soon as possible*, usually within 72 hours. In cases involving diagnostic errors, the review should begin even sooner, *immediately if possible,* in order to capture the context in which the events unfolded. Delays make it increasingly difficult for the involved staff, patients, and family members to remember the situation that existed at the time of the event, and these details are critical. Were the clinicians distracted? Were they tired or ill? How many other patients were they caring for that day? How many other admissions were waiting? Were there delays speaking with family members or consultants? What conversations took place that weren't captured in the medical record?

Expect to find both systems-related and cognitive factors at work in cases involving diagnosis.(36) In a series of 100 diagnostic error cases in internal medicine practice, 74% involved cognitive issues and half involved both cognitive and system factors.(37) Similarly, cognitive issues were also identified in 92% of 209 cases in the ED.[81] and in all but one of another 21 ED cases.[119] Understanding the cognitive perspective is, therefore, critical to unraveling most cases of diagnostic error, and although seldom considered, it is just as critical in understanding virtually all adverse events.

The RCA Process: CASE FINDING

Passive case finding (the case finds you) Individual cases of possible diagnostic error will arrive through malpractice claims, patient or family complaints, autopsy results, and incident reports filed by the clinical staff. These are the traditional pathways through which cases requiring an RCA come to attention.

Every physician is aware of diagnostic error cases, both their own and cases involving other clinicians, yet they rarely report them. In a national survey of health care organizations, 86% said that physicians "rarely or never" report safety breakdowns through incident reporting.(38) Fear of being investigated, fired or sued are the concerns clinicians most commonly cited as reasons for their non-participation, along with the embarrassment associated with committing an error.(39) A sample form for reporting diagnostic error cases is included in Appendix A.

The yield of diagnosis-related problems in passively-collected patient complaints has been similarly disappointing. One study found that only 2% of unsolicited patient complaints reflected *missed opportunities* in the diagnostic process,(40) and another found only 6-7% of patient-reported errors in ambulatory care were related to diagnosis.(41) Providing online portals for patients to report safety concerns has not improved reporting: A locally-developed online portal was designed to capture direct safety reports from hospitalized patients, but participation was minimal (0.6 submissions per 1000 patient-days).(42) At the national level, the Agency for Healthcare Research and Quality (AHRQ) developed and trialed a national safety-reporting hotline over 9 months but only received 37 reports.(43) As of 2024, the hotline had not yet been activated for use.

Active case finding (you find the cases)   Purposefully seeking out cases of diagnostic error is likely to be a much more productive approach compared to passive reporting pathways. Instances of diagnostic error can be found by asking patients and clinicians, by using standardized patients, and by searching the electronic medical record:

    <u>Active Case-Finding: Ask Patients</u>   Patients are clearly able to recognize safety breakdowns in their own care,(44-48) in both inpatient (49-51) and outpatient settings.(52) Bell et al. describe patients as uniquely positioned to observe firsthand breakdowns that may not even be apparent to other members of the health care team.(41)

Direct follow-up with patients after an acute-care visit is likely to be a valuable way to catch diagnostic errors and simultaneously build patient trust. (53) For example, patient follow-up calls may identify a worsening of symptoms, inadequate response to treatment, or adverse side effects from the treatment. Follow-up calls also provide an opportunity to review any late-breaking lab tests and incorporate them in diagnostic considerations.

Patients comprise the gold standard for judging whether communication about the diagnosis was appropriate, accurate, and timely. Gleason et al. piloted a follow-up survey tool (Leveraging Patient's Experience to Improve Diagnosis, the 'LEAPED' approach) with 53 patients recently seen in the ED.(54) Roughly one quarter reported not receiving a clear explanation for their health problem, with many not knowing the next steps to take. Going forward, ambulatory practices may contact patients after a visit to complete AHRQ's SOPS® (Surveys on Patient Safety Culture™). The recently-revised SOPS includes direct questions about diagnostic quality and has been trialed in over 100 practices to date. (55)

Active Case-Finding; Ask Physicians   Several strategies have proven to increase physician reporting. One approach is to incorporate reporting into physicians' daily workflow, making it easier to report errors, and advocacy by a physician champion.(56)

A pioneering program at Maine Medical Center established a simple way for physicians to text possible cases of diagnostic error to a hospitalist colleague. Over a 6 month period, 36 validated cases of diagnostic error were identified through this process, none of which had been identified via the existing incident-reporting pathways.(57) Similarly, a voluntary reporting system developed in the ED and championed by several of the ED physicians, was trialed and over a 5 year period received 509 reports, of which 209 concerned diagnostic errors.(58).

Voice messaging via telephone has been used to improve physician reporting, (59) and text messaging has also been productive. An adverse event reporting mobile 'app' for clinicians increased physician reporting 37-fold, and the fraction of adverse events reported by physicians of the total event reports increased 120-fold.(60). App-based reporting of diagnostic errors is actively used at Baystate Medical Center (Doug Salvador MD, personal communication, October, 2022).

Finally, another innovation that has boosted physician reporting is to reframe errors as diagnostic learning opportunities.(59). This approach fits perfectly in the learning health systems framework (61) as part of the goal to achieve diagnostic excellence.(62)

> *"Physician engagement improves when reportable events are clearly defined and the process of reporting is simple, nonpunitive, systems oriented, and confidential."*—
>
> **Marshall et al. Increased physician reporting of diagnostic learning opportunities (56)**

Active Case-Finding: Use standardized patients   An innovative and especially informative approach to evaluate the quality of diagnosis is to send standardized patients ('secret shoppers') into actual practice settings. Weiner and Schwartz pioneered this approach and found that directly observing care offered unique insights into the 'real world' diagnostic process. In their original study, secret shoppers visited 111 practices with one of four common

medical complaints; the diagnostic process was deficient in over 25% of these patients.(63) This approach is ideal for studying contextual factors that influence diagnosis and for evaluating the discordance between what is recorded in the medical record compared to what actually transpired in the care visit.(64) Using unannounced standardized patients to directly observe the care provided represents the gold standard for evaluating the quality and safety of diagnosis.(65)

Active Case-Finding: Mine the Electronic Data with Trigger Tools   Although one in ten diagnoses is likely to be wrong, it is difficult to detect these errors from chart reviews because only a fraction of those (roughly 1% of the 10%) will be associated with harm and, even in those cases, the error or its connection to harm may not be obvious. Efforts to improve the yield of chart reviews to detect harm have traditionally used occurrence screens. Reviewing the charts of all patients who died, for example, is an occurrence screen used to catch preventable medical errors.

A newer approach is to leverage the extensive data now available through electronic medical records (EMR) and use trigger tools (e-triggers) to select patients at risk and then explore their medical record to look for errors and harm. First pioneered by Classen and colleagues to monitor and improve medication safety,(66) e-trigger use has expanded in many directions, such as to monitor abnormal test results pending at discharge,(67) and to survey various aspects of inpatient care (68) and of safety breakdowns, more generally.(69, 70)

> *"Conventional approaches to identifying and quantifying harm such as individual chart audits, incident reports, or voluntary administrative reporting have often been less successful in improving the detection of adverse events. As a result, a new method of measuring harm—the trigger tool—has been developed. It is easily customized and can be readily taught, enabling consistent and accurate measurement of harm."* –
>
> **Resar et al: *Methodology and rationale for the measurement of harm with trigger tools.* (69)**

Appendix B includes a comprehensive list of diagnosis-related trigger algorithms. These programs offer the potential to detect harm events in near-real time in a cohort of cases, although to find the cases involving error or harm requires each medical record to be reviewed individually.(71)

Note that the Global Trigger Tool, the most widely-used instrument to screen charts for safety concerns, unfortunately does not generally detect diagnostic errors. (72, 73).

e-Trigger Tools have been developed specifically to improve diagnostic safety. (74). For example, Hautz and colleagues found that one in nine hospital patients had a different discharge

diagnosis compared to admission, and this patient cohort had longer hospital stays and higher mortality. (75)

An elegant and extensive set of e-triggers developed by the Kaiser Permanente Southern California Health System, now called the SureNet system, has many triggers specific to diagnosis. One set, for example, ensures that patients with elevated serum creatinine values are evaluated by Nephrology so as to detect renal insufficiency at the earliest opportunity. (76) Another e-trigger monitors for effective follow-up of colon cancer screening.(77). The SureNet approach is likely the most advanced system today, using 54 separate tracking programs to monitor healthcare quality and safety in real time.(78) The follow-up interventions attached to these trigger tools can be considered examples of "hard stop" or "strong" interventions with measurable results.

A further refinement of the e-trigger concept is 'SPADE', which identifies patients with specific symptoms paired to specific diseases.(79) In this approach, symptoms relevant to a particular diagnosis are specified and SPADE scans EMR records to identify symptoms and findings that might have been able to predict a serious event such as a stroke (the 'look back' approach). SPADE can also start with non-specific symptoms such as dizziness, and see what fraction ended up having a stroke (the 'look forward' approach).(79)

The RCA Process: DECIDING IS THIS A DIAGNOSTIC ERROR?

Some diagnostic errors are easy to recognize. These are cases where the correct diagnosis became clear at some point, and looking back there is agreement that the correct diagnosis was missed or could have been made much earlier.

In other cases, it is more difficult to say that a diagnostic error occurred. For instance, there are very few clear guidelines about the timeliness of diagnosis. How long SHOULD it take to diagnose a particular infection, cancer, or cardiovascular condition? In many cases, the initial presentation is non-specific, and the condition and diagnostic process evolves over time.

Table 2. Four Definitions of Diagnostic Error

DATE	2005	2009	2014	2015
AUTHOR	Mark Graber (36)	Gordon Schiff (80)	Hardeep Singh (81)	NASEM (82)
DEFINITION	Diagnostic error is unintentionally **delayed, wrong, or missed** as judged from the eventual appreciation of more definitive information.	Diagnostic error is any error of omission or commission **in the course of the diagnostic process.**	Diagnostic error reflects **a 'missed opportunity,' to have made the correct diagnosis** based on retrospective review.	The failure to establish an accurate and timely explanation of the patient's health problem or **(the failure to) communicate that explanation to the patient.**

There are now four definitions of diagnostic error in active use (**Table 2**). The Graber definition is foundational but can only be used in retrospect; the Schiff definition focuses on identifying the steps in the diagnostic process where errors occurred; Singh defines diagnostic error as a missed opportunity to have made the correct diagnosis, a definition that is now widely used in prospective research studies, because it focuses on the diagnostic process, where the ultimate diagnosis is not yet known. The IOM/NASEM definition focuses specifically on timeliness and accuracy, and adds the all-important patient viewpoint because the diagnostic process is not complete until it has been successfully communicated to the patient.

A useful tool in determining whether a case reflects a diagnostic error, and determining where in the diagnostic process the error occurred, is the Revised Safer Diagnosis Checklist developed by Hardeep Singh and colleagues(**Table 3**).(83) The first 12 prompts ask the reviewer to consider each stage of the diagnostic process. The higher the score, the more likely there was a missed opportunity at that particular stage. The final prompt asks the reviewer to consider the case as a whole, and consider whether or not there was a missed opportunity. Cases with an aggregate score of 5 or more on Question 13 generally suggest that there was a missed opportunity.

Table 3. The Revised Safer Dx Checklist

Rate the following items for the episode of care under review:
1—2—3—4—5—6—7

1 = Strongly Disagree   7 = Strongly Agree

Item	Score
1. The documented history was suggestive of an alternate diagnosis, which was not considered in the diagnostic process.	
2. The documented physical exam* was suggestive of an alternate diagnosis, which was not considered in the diagnostic process.	
3. Data gathering through history, physical exam, and review of prior documentation (including prior laboratory, radiology, pathology or other results) was incomplete, given the patient's medical history and clinical presentation.	
4. Alarm symptoms or "red flags" (i.e., features in the clinical presentation that are considered to predict serious disease) were not acted upon.	
5. The diagnostic process was affected by incomplete or incorrect clinical information given to the care team by the patient or their primary caregiver.	
6. The clinical information (i.e., history, physical exam, or diagnostic data) should have prompted additional diagnostic evaluation through tests or consults.	
7. The diagnostic reasoning was not appropriate, given the patient's medical history and clinical presentation.	
8. Diagnostic data (laboratory, radiology, pathology, or other results) available or documented were misinterpreted in relation to the subsequent final diagnosis.	
9. There was missed follow-up of available or documented diagnostic data (laboratory, radiology, pathology, or other results) in relation to the subsequent final diagnosis.	
10. The differential diagnosis was not documented OR the documented differential diagnosis did not include the subsequent final diagnosis.	
11. The final diagnosis was not an evolution of the care team's initial presumed diagnosis (or working diagnosis).	
12. The clinical presentation at the initial or subsequent presentation was mostly typical of the final diagnosis.	
13. In conclusion, based on all the above questions, the episode of care under review has a missed opportunity to make a correct and timely diagnosis.	

* Physical exam includes vital signs.

Additional information - please check "Yes" if applicable:

1. Care episode involves a management error.   ☐ Yes
2. Care escalation (e.g., hospitalization at subsequent visit) was related to worsening of an original correctly diagnosed condition that the patient initially presented with (rather than from something being missed initially).   ☐ Yes
3. Patient initially refused admission or additional evaluation.   ☐ Yes

Brief description of missed diagnostic opportunity or management error and any relevant thoughts and observations that helped with your decision (for or against).

The RCA Process: CASE TRIAGE: PEER REVIEW OR RCA?

In patient safety reviews, causal factor analyses tend to solely focus on system factors and avoidance of human error. However, a transparent, balanced analysis that addresses both system factors and individual accountability is fundamental for diagnostic safety events due to the contribution of individual cognitive factors. Use of a standardized approach such as the United Kingdom's National Patient Safety Agency (NPSA) Incident Decision Tree, based on Reason's "Culpability Tree" or Marx's "Just Culture" model, can help organizations determine which incidents can be routed to safety analysis and which will require peer review/disciplinary action.(84)

The NPSA Incident Decision Tree guides users through a series of questions about an individual's motives, behaviors, and actions to determine their level of accountability. The questions are grouped into four tests:

1. Deliberate harm – Were the actions intended?
2. Incapacity – Does there appear to be evidence of ill health or substance abuse?
3. Foresight – Did the individual depart from agreed protocols or safe procedures?
4. Substitution – Would another individual coming from the same professional group, possessing comparable qualifications and experience, behave in the same way in similar circumstances?

Depending on the answers to these questions, actions can range from coaching to discipline, including referral to law enforcement. With all determinations, systems factors and improvements are also considered.

Marx's "Just Culture" model has conceptual similarities and combines corrective actions. The model can be summarized most simply as follows (84) (84)

- Console human error
- Coach at-risk behavior
- Punish reckless behavior

Triage decisions should be based on evaluating the individual decisions made in the case and the actions taken, not on the outcome of the particular case.

In the absence of incapacity, deliberate harm, or a pattern of reckless behavior, cases of diagnostic error should be prioritized for RCA not for peer review. In organizations committed to establishing a culture of safety and learning, it is likely that many or most cases formerly sent for peer review can be more productively managed through RCA.

No matter which approach is adopted, it must be transparent, communicated, and shared within the organization to ensure all individuals know what to expect. Defining the process for triaging and designating the people who will be making these determinations is a prerequisite for an effective comprehensive analysis.

The RCA Process: CONVENING THE RCA TEAM

The team responsible for conducting the RCA must have sufficient knowledge and experience to understand what happened in a given case and propose relevant solutions. Consistent with system-related RCA practices, the team should comprise roughly 4-6 core members and invite *ad hoc* staff members or consultants as needed to understand key issues. A physician who understands the diagnostic process and is knowledgeable about the role of cognition in clinical reasoning should be part of the team. A nurse familiar with the care setting should also be a member of the team. A medical librarian should be included in cases involving knowledge-related issues.(85)

> *"If the team is provided a sufficiently diverse set of backgrounds, viewpoints, skills, and interests, then hidden assumptions are exposed; a broader repertoire of options, tactics, and tools is made available; tacit knowledge is made more explicit; and more interpretations and preferences are expressed."-*
>
> **Bob Wears and Ben-Tzion Karsh. Thick versus Thin: Description vs Classification in Learning from Case Reviews (86)**

The involved clinicians: In contrast to system-focused RCA, the clinical staff who were involved in the incident should routinely be included as members of the RCA review team. These individuals have first-hand knowledge of what happened and are most invested in ensuring a comprehensive and detailed safety review that reaches appropriate conclusions and proposes actions to reduce risk.

Physicians may be reluctant to discuss their role in diagnostic error cases and will need reassurance that these discussions are concerned with learning and practice improvement, not with criticizing and assigning blame. A guide for involving physicians and nurses in RCAs is included as Appendix D.

> *"All those involved in the process that led to the incident should participate in the RCA. Employees closest to the work understand vital information regarding workarounds and unsafe conditions and can pay special attention to deviations from standard workflow. In our experience, they are highly invested in understanding what happened after their involvement in an adverse event, and subsequently are highly motivated to design and implement quality improvement (QI) initiatives."*
>
> **Yael Heher. 2017. A Brief Guide to Root Cause Analysis (87)**

Patients and families: In system-focused RCAs, the patients or families who have been harmed by the safety breakdown may be interviewed but they are generally excluded from the RCA team. In diagnosis-related cases, involving patients or families in some fashion is a must. The patient or family can provide critical details on exactly what happened and what was said,

providing key contextual information that is typically missing from electronic medical record notes.(88, 89) Also, there is substantial value in restoring a relationship of trust, as the patient and family see that the organization is doing its best to understand what happened and how care can be improved going forward. Interviews with families after safety-related deaths have found that many want to participate in safety reviews and believe that their perspective is highly relevant to the analysis.(90, 91) A guide for involving patient/family members in the RCA process is available as Appendix E.

At a minimum, the patient or family should be interviewed. In some cases, depending on the patient or family and their interest, it may also be appropriate to include them on the RCA team. Including patients or families poses challenges, (92) and in some states in the US, legal issues may preclude their involvement. The foremost challenge is handling the emotions and expectations that inevitably arise when the injured parties first meet with representatives of the organization. If the patient or family is willing to participate in the RCA, they will benefit from an orientation to the RCA process and what their role in this will involve.

> "…assume that patients and families will be partners in investigation and where possible engage them fully from the beginning…"
>
> **Vincent et al. 2017. Safety analysis over time: Seven major changes to adverse event investigations. (88)**

In addition, they will require a briefing on the normal processes of care in the organization, and how specific conditions or diseases are managed. There may also be patients or families that do not wish to participate, or whose presence would be unmanageably disruptive to the safety review. Each patient or family will have different perspectives, needs, and values and whether and how to include them will have to be individualized in each case.

An alternative to their direct participation is to have a patient advocate sit in for (or with) the patient or family during the RCA meetings. Experienced advocates will be familiar with medical language, standard medical care processes, and safety analyses, and can report back to (or explain things to) the patient or family as needed. Someone from the organization's patient-family advisory council (PFAC) may be available to serve in this role or to help identify a suitable advocate.

Finally, it is very appropriate to check back with the patient or family as the analysis and action plans unfold – do they believe that the proposed interventions will solve the problem?

The RCA Process: IDENTIFY ROOT CAUSES AND CONTRIBUTING FACTORS

The steps for conducting an RCA of a diagnosis-related safety event are essentially the same as those in a system-focused RCA, although the particular details of some steps will differ.

The initial interviews and fact-finding

One key difference is the timing of the initial safety event review: The review should begin immediately to better capture the cognitive and human factors elements that might have contributed to the case. The involved staff and the patient and family should be interviewed as soon as possible because accurate recall of what happened and what else was happening at the time will fade within days.

A neutral party, ideally a peer, or someone with experience in these situations and knowledgeable about cognitive error, should conduct the interviews in a private setting, free from interruptions. The interviews should start with open-ended questions with little interruption, and the interviewees should be encouraged to freely associate about the event and try to recall their thoughts and feelings. Structured questions may be helpful, and questions should also probe the context of care.(93) The ASHRM Root Cause Analysis Playbook contains a detailed introduction to RCA interviews, (5) and a starter set of questions are listed in the box below.

> **Sample Interview Questions for the Involved Staff, Patient, and Family**
>
> - How were you involved in this case? What was your role?
>
> - What happened? (With as much detail as possible)
>
> - How did the case unfold? What do you recall about the sequence of events?
>
> - What else was happening? What was it like at the time? Who else was involved?
>
> - Were the patient's medical records available for review? Were they complete?
>
> - Was communication between the patient and the staff clear and effective?
>
> - What facts were available? What things were not known at the time?
>
> - Was there anything about the patient or the situation that was unusual or that evoked any particular emotions or feelings?
>
> - What were you thinking? What were you feeling?
>
> - What were you first considering? Why? Did anything else come to mind?
>
> - Did the diagnosis seem obvious? How certain were you about your impressions?

Using formal cognitive interviewing techniques (Appendix F) with the involved clinicians will help them recall more facts and insights about the case, and more details about specific issues. Organizations with sufficient resources should invest in training their safety staff in cognitive interviewing.

Where did things go wrong in the diagnostic process?

A good starting point for extracting lessons from diagnosis-related safety events is considering which steps of the diagnostic process worked well and which did not.(**Figure 2**).
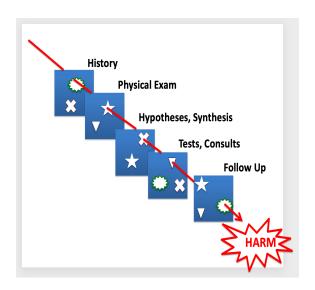
FIGURE 2. Steps of the diagnostic process

The best resource for this task is the 'DEER' taxonomy from Schiff and colleagues' Diagnostic Error and Evaluation and Research project (**Table 4**).(80) The DEER Taxonomy lists the steps in the diagnostic process including where and what the breakdowns may be, e.g., Access to Care, Patient presentation, History and Physical, imaging studies and lab tests ordered, Assessment, Referrals/Consultations and Follow-Up. Isolating where in the diagnostic process problems developed will be valuable to the safety review, allowing the RCA team to compare the actual event to best practices in that particular area, or involve subspecialists for their input and opinions. The RCA team or safety staff may be aware of other cases that involved breakdowns in a given step of the diagnostic process. Aggregating data from multiple RCAs can help identify specific issues that are ripe for performance improvement initiatives.

Table 4. The 'DEER' taxonomy (80)

Where in the Diagnostic Process	What Went Wrong
1. Access/Presentation	a. Failure/delay in presentation
	b. Failure/denied care access
2. History	a. Failure/delay in eliciting critical piece of history data
	b. Inaccurate/misinterpreted/overlooked critical piece of history data
	c. Failure in weighing critical piece of history data
	d. Failure/delay to follow-up critical piece of history data
3. Physical Exam	a. Failure/delay in eliciting critical physical exam finding
	b. Inaccurate/misinterpreted/overlooked critical physical exam finding
	c. Failure in weighing critical physical exam finding
	d. Failure/delay to follow-up critical physical exam finding
4. Tests (Lab/Radiology)	*Ordering (traditionally called "pre-analytic phase")*
	a. Failure/delay in ordering needed test(s)
	b. Failure/delay in performing ordered test(s)
	c. Error in test sequencing
	d. Ordering of wrong test(s)
	e. Tests ordered wrong way
	Performance (traditionally called "analytic phase")
	f. Sample mix-up/mislabeled (e.g., wrong patient/test)
	g. Specimen delivery problem
	h. Technical errors/poor processing of specimen/test
	i. Erroneous lab/radiology reading of test
	j. Failed/delayed reporting of result to clinician
	Clinician Processing (traditionally called "post-analytic phase")
	k. Failed/delayed follow-up of (abnormal) test result
	l. Error in clinician interpretation of test
5. Assessment	*Hypothesis Generation*
	a. Failure/delay in considering the diagnosis
	Suboptimal Weighing/Prioritizing
	b. Too little consideration/weight given to the diagnosis
	c. Too much weight on competing/coexisting diagnosis
	Recognizing Urgency/Complications
	d. Failure/delay to recognize/weigh urgency
	e. Failure/delay to recognize/weigh complications of a diagnosis
6. Referral/Consultation	a. Failure/delay in ordering referral/consult
	b. Failure/delay in obtaining/scheduling ordered referral
	c. Error/suboptimal quality in diagnostic consultation performance
	d. Failed/delayed communication/follow-up of consultation
7. Follow-up	a. Failure/delay in timely follow-up/rechecking of patient
	b. Failure to refer patient to close/safe setting/monitoring
	c. Failure/delay in needed monitoring or lab (BP, INR, repeat CXR)
	d. Failure/delay in communicating findings among healthcare providers

Identifying root causes: The Fishbone Diagram

Once the RCA team has an initial understanding of what happened, they need to consider what factors contributed to the event. There are many different approaches that can be used to identify causal and contributing factors,(94-97) and a collection of different taxonomies is presented in Appendix C. Teams can use whatever approach they are most familiar with or that seems most appropriate for the case.

As a general starting point, we recommend using a framework that recognizes both the *micro* and *macro* aspects of diagnosis. Micro issues relate to the clinician's reasoning process, the cognitive issues which play a role in most cases of diagnostic error. Macro issues relate to how the context of care and particulars about the patient and the case influence the clinician's diagnosis. Each of the 4 domains in **Figure 3** should be reviewed in every case.

Figure 3. Four Domains Relevant to Diagnosis

We recommend the use of Fishbone (Ishikawa) diagrams to map out the various contributions to cases of diagnostic error (or success). These diagrams provide a pragmatic way to visualize at a glance the 4 domains relevant to understanding what happened in a given case.(98) A generic version is illustrated in **Figure 4**, and the key domains can and should be modified depending on the details of the case. Examples of fishbone diagrams for various case types are presented in Appendix J.
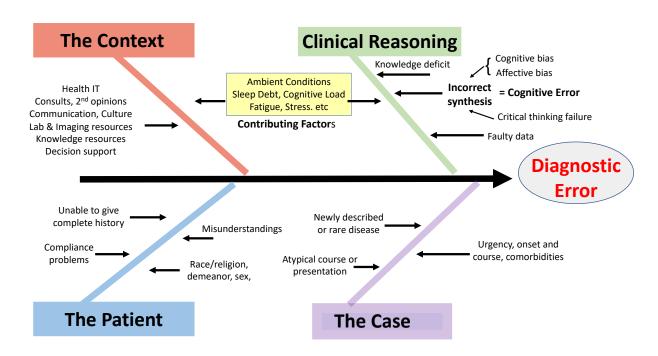
Figure 4. A Generic Fishbone Diagram for Considering Root Causes of Diagnostic Error

The Case. Every case is unique. The particulars of how the patient's condition presents and evolves, how they describe it, and when they seek care can all determine whether the diagnosis will be easy and correct, or problematic. The exact same disease can present in uncommon ways in different patients. Appreciating the urgency of making a diagnosis is a critical factor in some cases, such as stroke, aortic dissection, and sepsis where delays can be disastrous. Cases that present in the classic, textbook manner will usually be recognized and diagnosed quickly and accurately. Conversely, cases that present in atypical fashion, and unusual or rare conditions will be problematic and identifying them correctly is often delayed.

The Patient. Characteristics of the patient or the family can play a role in contributing to diagnostic error. Some of these reflect patient characteristics that evoke affective bias, where the clinician is put off by the patient's age, sex, personality, or ethnic background, or perhaps by a coexisting mental health condition or a rude comment. Patients who are angry, drunk, or confrontational often evoke reactions and emotions on the part of the clinician that detract from clear clinical reasoning.

A common concern in cases of diagnostic error is whether the patient clearly communicated their symptoms. Communication failures can be encountered with infants, patients who don't speak English, and patients who are intoxicated, intubated, or unconscious, among others. Communication problems can even occur in awake and alert patients if they misunderstand a question, or do not accurately explain their symptoms or course of illness. Patients missing scheduled appointments or tests can sometimes be a factor contributing to delayed diagnoses.

The Context of Care. The context of care includes a very wide set of factors that can support or sometimes degrade diagnosis. System-related issues are identified in most cases of diagnostic error.(36, 99) Safety officers typically have extensive experience exploring system-related aspects of safety events, and these same dimensions apply to diagnostic errors. An overview of system factors relevant to diagnosis is illustrated in **Figure 5**.(94)
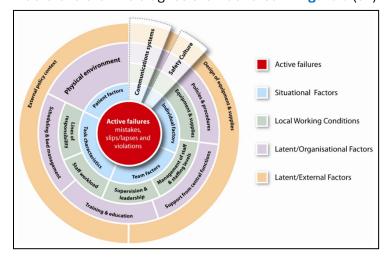
FIGURE 5. General Framework for Considering Root Causes of Safety Events

A detailed approach to considering contextual factors is presented in **Appendix 1F** and includes these critical elements:

- Access to care; Communication; Care coordination
- Access to expertise and second opinions
- Access to appropriate imaging and tests
- Health informatics systems and resources
- Culture, especially teamwork; Human factors & contextual issues
- Diagnostic setting and circumstances

It will also be worthwhile to consider contributing human factors, sometimes referred to as 'error promoting conditions' that may have derailed the diagnostic process. Fatigue, stress, illness, production pressure, cognitive overload, burnout, and a host of other human factor

considerations are often identified as contributing factors in cases of diagnostic error. Identifying the role these factors may have played, and understanding how they arose may be the most important findings in a given case and may provide key insights to optimize the diagnostic setting and circumstances in the future.

Clinical Reasoning. Clinical reasoning is the clinician's ability to synthesize all the available information of the case to arrive at the most likely diagnostic possibilities, based on his\her knowledge and experience. Faulty clinical reasoning is a factor in most cases of diagnostic error. This domain involves an exploration of the cognitive aspects of diagnosis, the part of the RCA process that differs most from reviews of system-related cases. The key elements of the clinical reasoning process are illustrated in **Figure 6**.
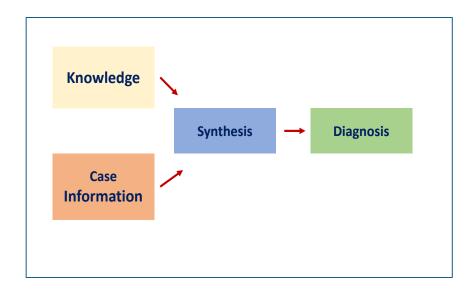
Figure 6. The Elements of Clinical Reasoning

Knowledge: The ability to make a timely, accurate diagnosis depends on the ability to recognize or identify the condition based on knowledge acquired during training or experience. There are over 10,000 known conditions, but medical training, and most textbooks, typically cover only those that are common, typically <1000 conditions. Although every clinician has probably seen the most common conditions, not every clinician will have learned about or seen unusual presentations of these conditions, or the many rare diseases that inevitably present at some point in time. Only 3% of faulty diagnoses in one study were due to faulty knowledge.(36)

Case information: Diagnosis requires obtaining a complete and detailed medical history, conducting an appropriate physical examination, understanding the diagnostic test results, and
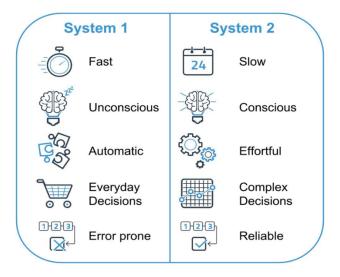
reviewing available consult reports. In that same study, 14% of diagnostic errors involved situations where key data was either not available, not sought, or available but misinterpreted.(36). Cases with handoffs predispose to problems in this domain because information is often lost or distorted passing from one person or care site to the next.

Synthesis: Synthesis represents the cognitive tasks involved in considering the diagnostic possibilities. Errors in this step may reflect either breakdowns in critical thinking (System 2) or in the subconscious, intuitive aspects of diagnosis (System 1).(93, 100, 101) Faulty syntheses is by far the leading cause of diagnostic error, encountered in 83% of cases.(102)

System 1 and System 2: Fast and Slow Thinking. The dual processing paradigm, thinking fast vs thinking slow,(103) is the best framework for understanding the nature of diagnosis and the cognitive aspects of diagnostic error (104) **(Figure 7)**. In this framework, diagnosis starts with whether the clinician recognizes (Yes/No) a symptom or sign or a collection of findings.

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Figure 7. Features of System I vs System 2 Cognition

Reproduced with permission from Vanderbyl (105).
Modified with permission from a figure by Philip Jordanov, figure by Neurofied (https://neurofied.com

- System 1, the intuitive system: If the symptoms and findings are recognized, as they most often are, the diagnosis emerges within milliseconds using a subconscious automatic process often referred to as System 1. This is an intuitive process that is often successful in reaching the correct answer but can go astray due to cognitive bias, leading to diagnostic error.

- System 2, the rational system: If the findings are not recognized, the clinician needs to stop and think. This is System 2, the purposeful, deliberate, and hopefully rational process of reviewing what is known and consciously considering what the answer might be. System 2 is much slower than System 1. System 2 is considered a more reliable approach to finding the correct answer, but it is also occasionally wrong. In practice, diagnosis typically involves some mix of the intuitive and rational systems.

The dual process paradigm describes not only diagnosis but how we process most information in our daily lives, where most things and situations are recognized and we know automatically how to respond or what to do. However, sometimes we encounter a novelty that requires conscious thought. Think about how you learned to ride a bike or play a musical instrument – these were stressful and difficult tasks early on, but with time became effortless and automatic. Similarly, first year students process most clinical problems using System 2, and as they acquire knowledge and familiarity, they gradually transition to the intuition and reflexivity of System 1 to handle things.

Many breakdowns in clinical reasoning reflect inappropriate shortcuts or assumptions, and many involve the subconscious tendencies we all have that detract from optimal cognition. The cognitive biases encountered in diagnosis and diagnostic error are the same ones found in everyday life and are simply part of our human nature. Over 175 biases are catalogued in Wikipedia, and fall into four main groups (106). See Appendix H for a table describing these biases and how they relate to medical diagnosis and decision-making. What are the drivers for taking these shortcuts?

- **There is too much information to process, so we filter it through our various biases.**
- **When there's not enough meaning, we fill in the gaps**. We generalize when we should not, and we fill in the gaps in our understanding with assumptions.
- **We can't remember everything**. We recall the gist of things more than the specifics. What we store in memory is influenced by how things are experienced, and not all of our memories are accurate.
- **We generalize and we stereotype**, and all of this is subconscious.
- **We need to act fast.** Life is short and we need to make decisions quickly and see the next patient waiting. This bias surfaces as the commonly-encountered phenomenon of premature closure in diagnosis, where clinicians settle on the first thing that makes sense, in lieu of constructing a differential diagnosis. In one study of diagnostic errors, there was no differential diagnosis documented in 80% of the medical records.(107) Our minds favor simple, straightforward explanations over more complex ones that we don't fully understand or don't want (or can't) take the time to explore. We jump to conclusions and are overconfident that these decisions are correct. Overconfidence is regularly encountered in diagnostic error cases. (108)

Common cognitive biases   As an introduction to cognitive bias, here are four that are commonly encountered (**Figure 8**):

Premature closure. Also known as 'search satisficing.' This bias is our human tendency to be too quickly satisfied with the first diagnosis that comes to mind that explains most of the key findings in the case. Most everyone with a dog is familiar with this tendency – we just fall in love with the first puppy/dog and don't go searching other litters or shelters. Herbert Simon received the Nobel prize for describing this concept in the field of economics. He called it 'satisficing'.(109) In diagnosis, satisficing is the opposite of optimizing, constructing a differential diagnosis of the likely possibilities.

Context errors. If you see a patient with a chief complaint of vomiting, you automatically start thinking of gastrointestinal (GI) causes. The diagnosis may well be a GI problem, but if you focus strictly on the GI context, you may not consider other 'don't miss' causes, like poisoning, sepsis, or intracranial hypertension, among others. If you are looking in the wrong context, you will never make the correct diagnosis.
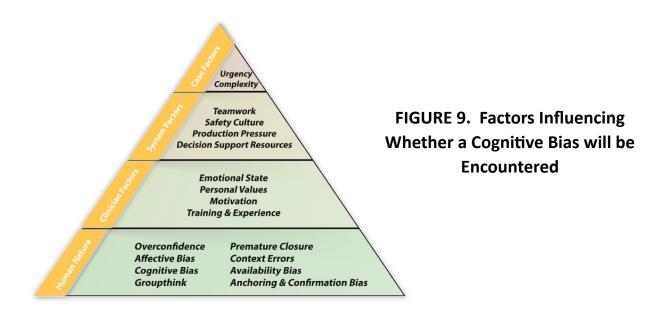
Figure 8. Common Cognitive Biases Encountered in Cases of Diagnostic Error

Anchoring. This is our tendency to be satisfied with a new or pre-established diagnosis without rethinking the case. In support of our initial belief, we tend to favor evidence consistent with it and discount evidence against it.

Affective bias. This reflects our subconscious tendency to favor certain people and disfavor others, whether because of their age, sex, socio-economic status, ethnicity, appearance, or behavior. Their medical conditions may be yet another factor that influences cognition. For example, there is good evidence that patients with mental health disorders are treated differently in diagnostic settings. The alcoholic patient returning to the ED for the fourth time this month is likely to negatively impact diagnosis-related cognition, while the clinical department head who is rushed to the ED with chest pain will get extra consideration and the red carpet treatment.(110, 111)

Although there is great variability in whether or if cognitive bias will influence the accuracy of a given diagnosis, there is some consistency in the various stages of the diagnostic process when bias occurs. The anchoring bias, for example, would occur in the early stages if the patient has already been given a diagnosis or one has been suggested. 'Group think' would be more distal, after various clinicians have weighed in.

Will cognitive bias derail diagnosis? The situation, patient, clinician, and particulars of the case are all relevant factors in determining whether or not cognitive bias will be a factor in a given case.(112) In RCAs of diagnostic error, it may be important to review each of these dimensions.(**Figure 9,** modified with permission)

FIGURE 9. Factors Influencing Whether a Cognitive Bias will be Encountered

The individual variability in clinical decision making, and the likelihood of being influenced by bias are important variables.(113) Each clinician has had different exposures and experiences during their education and training, and as a result, diagnosis in practice is idiosyncratic. Two clinicians presented with the identical patient story and set of medical facts may come up with very different impressions of what the diagnosis might be.

Gender differences provide an interesting example of this variability.(113) Female physicians, for example, tend to be more effective in encouraging patient engagement and questioning than male physicians, and are more likely to explore psychosocial issues. They are less comfortable with uncertainty, order more tests and consults and are more compliant with clinical guidelines. They also exhibit less implicit racial bias than their male counterparts. Similarly, diagnostic success will vary among clinicians because of the individual variability in age, religion, training experience, and their innate patience, rationality, and ability to employ critical thinking.

> "A significant body of evidence has now made it clear that cognitive biases manifest themselves automatically and unconsciously over a wide range of human decision making. Besides their psychology and sociology origins, they are now acknowledged in business, marketing, the judicial system and many other domains. Events on the world stage are influenced by them. It is important for everyone to recognise just how pervasive biases are and the need to mitigate them."—
>
> **Pat Croskerry: Our better angels and black boxes.(114)**

The RCA Process: CRAFTING INTERVENTIONS FROM YOUR RCA

Given that any type of diagnostic error is likely to recur, and perhaps repeatedly in both the same organization and more broadly, the goal of each RCA is to consider interventions that will minimize this possibility. The RCA review is incomplete if it does not include at least one high-priority recommendation.

> *"…(An RCA investigation is) meaningless to patients if it did not lead to action and change……A properly crafted process or outcome measure should be specific, quantifiable, and provide a timeline on when it is going to be assessed."*
>
> **Charles et al. How to perform a root cause analysis for workup and future prevention of medical errors: a review. (115)**

Specific errors point to specific solutions, but the most important interventions for improving diagnosis will center around leadership and culture. If leadership strongly endorses the goal of achieving diagnostic excellence, if champions for diagnostic safety are visible amongst their colleagues, if teamwork is the norm, and if errors and solutions are openly discussed, the prognosis for improving diagnostic outcomes is bright. Until these foundational elements are established, they should be included as recommendations in every RCA.

System-related factors are identified in most cases of diagnostic error. However, because organizations have extensive experience reviewing the problems and interventions in this domain, we will not consider them in detail except to point out the important progress made in 'catching' diagnosis-related safety breakdowns before they lead to patient harm. The Kaiser-Permanente - Southern California health care organization has pioneered the use of 'safety net' systems in the United States to catch potential delays in diagnosis that could lead to harm. Examples include electronic monitoring to ensure that patients with a positive test for fecal occult blood receive endoscopic evaluation, and patients with escalating PSA values are evaluated in Urology. The safety net concept is well established in the United Kingdom as a primary care intervention and is effective in reducing delays in cancer diagnosis.

Another area of active research concerns interventions to tackle lapses in follow-up care. These represent 'low-hanging fruit' in efforts to improve the reliability of diagnosis, including failures to follow-up on incidental findings, abnormal screening tests, alertable test results, tests pending at discharge, and patients with concerning but non-specific symptoms.

Cognitive errors. Addressing cognitive errors is likely to be a new challenge for healthcare organizations. "Hardwired" solutions, such as forcing functions, top the list of possible interventions whereas education and training are always at the bottom and labeled the weakest choice.(116-118)

It is worthwhile noting that these 'strength' hierarchies are passed down as wisdom from the sages more than evidence-based conclusions. Education and training interventions may actually have greater impact on cognitive reasoning skills and may be perfectly reasonable solutions in certain cases for the following reasons:
- There is no course on diagnosis in medical education today. Doctors and the many other clinicians involved in the diagnostic process have never received formal training on clinical reasoning or on critical thinking in general. Most have only passing familiarity with decision support resources.
- Clinicians are not generally aware of the many ways that human factor elements can impact diagnosis, for better or for worse.

- Clinicians generally have never learned about heuristics and biases, and that human decision-making is beset by universal subconscious tendencies that can detract from best judgment. Inappropriately, many or most view themselves as unbiased and immune from affective influence.
- Finally, clinicians tend to think of themselves as excellent decision-makers. Overconfidence is the rule, and though the concept of calibration may be appreciated at a subconscious level, it is not something clinicians think about as a critical determinant of their skill in diagnosis.

All of these issues may potentially be addressed productively through education. Simulation training is more likely to engender retained knowledge and skills than book learning, and many of the interventions proposed to address cognitive issues are ripe for simulation-based training. Several authorities make the point that education that is content and even case-specific is likely to be a more effective intervention than general education on clinical reasoning and bias. Examples of focused education include practice on differentiating diseases with similar presentations, and practice expanding a differential diagnosis list.

For cases where clinical reasoning is a key issue, Croskerry divides cognitive interventions into those focusing specifically on steps the individual clinician can take to avoid error, and those that use system-based approaches. **Table 5** presents these options for improving diagnosis. The relative impact of these suggestions has not yet been evaluated.

TABLE 5. Interventions to Improve Diagnosis

Focused on the Clinician	
Reflection	Stop and think. Use deliberate reflection and critical thinking
Get help	Get second opinion and consults
Checklists & cognitive aids	Use checklists of common conditions; use decision support resources
Education	On recognizing cognitive bias; consistent feedback

Focused on the System	
Hardwiring; Forcing functions	Automatic reviews of patients without a clear diagnosis Decision support - active
Improve teamwork	Diagnosis by groups; More consults and expert involvement
Simplifying a process	AI summaries of patient's history; AI identification of key problems
Work conditions	More time for diagnosis; Reduce interuptions and distractions
Culture change	Culture of safety; open discussions of errors; RCA's of diagnostic error
Leadership involvement	Leadership designates diagnostic error is a priority; Colleagues are champions of diagnostic excellence

Interventions focused on the individual. These are the 'cognitive pills for cognitive ills' that primarily involve metacognitive skills, meaning, being able to consider the actions and decisions one is making and reflect on whether these can be improved. "Stop and Think" captures the essence of these interventions. If clinicians could routinely adopt this approach, it would provide them the opportunity to employ effective forcing functions that would improve diagnostic decision-making.(119, 120) Asking, "what else could this be?"; and "what emotions could be affecting my judgment in this case?" are worthwhile questions to ask in every case involving diagnosis.

After metacognition, the most consistent advice to address cognitive error is to promote awareness of the cognitive and affective biases leading to diagnostic error. Many cognitive biases are hardwired, and cannot be unlearned.(103) Others, including many of social biases, are acquired.(121)   In either case, biases can be mitigated by learning about them. This provides the possibility to _recognize_ bias in one's own thinking, or in the diagnostic decisions made by others, and this, in turn, provides the opportunity to reconsider decisions before there is harm.(122, 123) Clinicians involved in diagnosis should know about the dual-processing framework and how biases can detract from optimal decision-making.

In cases where affective bias played a role, implicit bias training may be helpful for clinician education,(124) along with organizational efforts to promote equity in access to care and services.(110)

There is early evidence that cognitive interventions may be effective in addressing diagnostic error,(125-127) but organizations should keep abreast of new research likely to emerge in this area in the future. It seems likely that interventions that are more specific and case-focused may have more impact over those that are more general, like "Stop and Think".

Interventions focused on the system. Diagnosis is especially dependent on the context of care. When developing interventions to address diagnostic error, interventions should target these contextual connections. Diagnostic decision-making is inherently error-prone, and interventions that either help the clinician make these decisions, or involve others in this process, will likely be beneficial. Below are several recommendations:

Improve teamwork. This was the top recommendation in the National Academy of Medicine report on _Improving Diagnosis in Health Care_.(82) If group-think problems can be avoided, team members can provide fresh perspectives on a case and help catch cognitive errors. Involving the patient, family, and nurse colleagues are positive steps that can improve diagnosis organization-wide.

Get second opinions and consults. There is strong evidence that second opinions improve diagnosis in pathology and radiology. Second opinions result in important changes in a diagnosis for between 2% to 5% of cases.(128-130) It is highly likely that even greater benefit will be seen in frontline diagnostic settings. A study of second opinions in the ED found that

consulting a colleague about active cases reduced diagnostic errors by one-third.(131) Group-based (collective) diagnosis is an emerging area with substantial potential to reduce the likelihood of error.(132, 133) Crowd-based decisions may much more accurate than the 'stop and think' approach of reconsidering a case on your own. Improving access to expert consultants is another avenue likely to improve diagnosis.

Provide decision support. Checklists, mnemonics, and various other decision aides are available to help with diagnosis but are underutilized.(134) These can be helpful tools for metacognition by helping the clinician think of conditions and organ systems they had not considered. More sophisticated, web-based tools to aid in differential diagnosis have been available for some time, and have demonstrated value.(135) It is possible that emerging AI-based systems will be even better, and integrations in which suggestions are 'pushed' to clinicians instead of them having to search for potential choices will be especially helpful.

Make it easier: Reduce any error-promoting factors; improve access to knowledge sources. Many clinicians believe they would do a better job with diagnosis if they just had adequate time to think. Production pressures and distractions should be minimized. Offload time-consuming tasks that detract clinicians from patient care (eg negotiating with insurance companies on the patient's behalf, many prescription renewals).

Provide feedback (136) to improve calibration. The best diagnosticians are those with profound expertise and experience in a given area, and those with modest expertise who are well calibrated, meaning they have a good sense of what they know, what they don't know, and when they need to slow down and seek help. Providing feedback to clinicians is an effective way to improve calibration, and organizations should consider ways for clinicians to learn whether their initial diagnostic impressions are correct or incorrect.(137, 138)

CONCLUSIONS AND EARLY EVIDENCE

Root cause analysis has become the most accepted approach to address adverse safety events in health care organizations today. With suitable adaptations to consider human factors and the cognitive issues surrounding clinical reasoning, RCAs can also be used productively to review cases of diagnostic error:

- Trowbridge et al. pioneered the use of RCAs for cases of diagnostic error, using fishbone diagrams to help identify contributing factors.(98)

- Gurley et al. used a formal RCA to understand the system-related and cognitive issues involved in a case of epidural abscess that was missed in the ED.(139)

- Dadlez et al. used mini-RCAs to study three problems in the diagnostic process: missed actions on abnormal lab tests, missed hypertension, and missed adolescent depression.

They conducted 184 mini-RCAs on cases from 28 different practices and identified several common breakdown points, and appropriate generalizable interventions.(32)

- Su et al. reviewed 61 cases from EDs using a fishbone diagram to consider root causes, 89% of which included cognitive issues.(140)

- In studies from The Netherlands, Hooftman et al aggregated over 100 RCA's of cases involving diagnosis across hospitals;(96) and Baartmans et al considered 23 cases arising in emergency departments;(97) and Zwaan et al explored diagnostic reasoning in 247 patients with dyspnea.(93)

- Giardina et al. reviewed 111 RCAs of cases encountered in Veterans Affair's settings related to team-based diagnosis-related decision-making.(141) Similarly, Zenati et al. conducted an RCA to consider team-related cognitive issues involved in a near-miss medication error,(142) illustrating that including cognitive analyses in RCA investigations can be effectively applied to other patient safety events outside of diagnosis.

Over the past 20 years, there has been substantial progress in understanding diagnostic error. We now appreciate the size of the problem – diagnostic errors are common in every setting and may cause substantial harm. We have also learned a great deal about where and why these errors occur, including an expanding understanding of how cognition plays a critical role in both diagnostic success and diagnostic error. A host of interventions have been proposed to address the various factors that contribute to harm from these errors. The time has come to begin seriously studying which of these interventions work and which ones offer the most benefit. Root cause analysis provides a critically important tool for health care organizations to identify and learn from their own cases, which hopefully will provide the motivation, advice, and tools necessary to begin addressing the problem.

Post Script on Safety-II

The ultimate goal of RCAs is to improve the safety and quality of health care using the lessons extracted from adverse safety events that demonstrate inherent flaws in the process of care. An alternative and complementary approach is to apply the Safety 2 perspective, which is to extract lessons from what went right in a given case or across cases dealing with similar problems (**Figure 10).** There are many key advantages of using the System 2 approach:

- There are many more cases to learn from. Diagnosis succeeds far more often than it fails.

- Safety 2 discussions are easier than discussions that focus on error. Clinicians are more likely to report cases and participate in Safety 2 analyses and discussions.

- Safety 2 analyses are more suitable for prospective analyses, avoiding the problems of hindsight bias. Aggregating cases offers the potential to identify practice variation.

- Safety 2 analyses can reveal novel approaches to problem-solving. Individual clinicians or small practice groups may have created unique solutions to problems that might not have been discovered otherwise.

- Safety 2 discussions can reveal the elements of resilience that so often are critical in surmounting the inherent barriers in health care delivery.

- Safety 2 work enhances the culture of safety, and the willingness of clinicians to work on safety concerns

Safety leaders have advocated for using Safety 2 reviews to complement traditional RCAs that use the Safety 1 retrospective approach. We encourage organizations to also consider combining both approaches to study a particular problem. In a case of missed diagnosis, for example, pair the Safety 1 RCA analysis with the Safety 2 review of a case where the diagnosis was established quickly and accurately. What particular contextual factors might explain the different outcomes?

Figure 10. New Views of Safety

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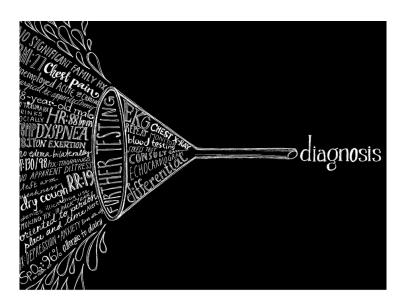
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Sujai Manohar. The Diagnosis Funnel; with permission

APPENDIX

ROOT CAUSE ANALYSIS OF CASES INVOLVING DIAGNOSIS

Mark L Graber, MD FACP & Gerry Castro, PhD, MPH

May, 2024

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A. Diagnosis Error Case Reporting Form

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  - Delays in conducting RCA's

Appendix A: A Form for Reporting Cases of Diagnostic Error

This form provides a systematic way for clinicians and staff to collect, review and present a case of diagnostic error. The form can be used as a standalone document or fields can be integrated into an electronic reporting system. It also can be adapted for collecting and categorizing cases into a data set for surveillance or research.

1. Diagnosis Initial diagnosis: Enter the patient's initial or interim diagnosis (leave blank if no diagnosis was made)

Final/correct diagnosis: Enter the patient's final/correct diagnosis

2. Summary Provide a brief description of the diagnostic safety event, what happened and why. Follow your organization's standards for protecting patient information and confidentiality.

   a) How did the patient initially present?   What were symptoms, how did they evolve, where and how did patient present for medical evaluation
   b) What was the initial diagnostic assessment?
   c) How did the symptoms/disease/assessment evolve?
   d) What went wrong?
      • Misdiagnoses, delays, cognitive errors, or other missed opportunities for an accurate and timely diagnosis
   e) How was correct diagnosis established? What factors led to recognition of the correct diagnosis?
   f) Were there diagnostic testing Issues? Including any failures to order, false positives/negatives, misinterpretation, follow-up failures
   g) Patient outcomes Describe patient outcomes (including patient harms, if any) related to the event

3. Contributing Factors/Issues/Pitfalls.   If you or your organization has identified factors that may have contributed to causing this diagnostic error or delay, please list or describe them here.

4. Corrective Suggestions, Measures, Lessons If you or your organization has taken any action and/or you have ideas or suggestions to prevent the same or similar diagnostic errors in future, please list/describe.

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Appendix B – Trigger Tools Used to Identify Cases Involving Diagnosis

Area	Trigger Tool Reference	Metrics
Cancer		
	Murphy, D.R., et al. (2014). "Electronic health record-based triggers to detect potential delays in cancer diagnosis"[1]	Overview of using e-triggers to efficiently identify diagnostic errors and 'missed opportunities' in cancer diagnosis
	Murphy, D.R., et al. (2015). "Electronic trigger-based intervention to reduce delays in diagnostic evaluation for cancer: A cluster randomized controlled trial"[2]	Triggers were effective in reducing time-to-diagnosis for prostate and colorectal cancer
	Murphy, D.R., et al. (2016). "Computerized Triggers of Big Data to Detect Delays in Follow-up of Chest Imaging Results"[3]	Used e-triggers to identify delayed evaluation of abnormal chest X-rays in a VA patient database
	Murphy, D.R., et al. (2018). "Development and Validation of Trigger Algorithms to Identify Delays in Diagnostic Evaluation of Gastroenterological Cancer"[4]	Developed and used triggers to detect delays in the diagnosis of colorectal and hepatocellular cancer
Emergency Medicine		
	Rising, K. L., et al. (2014). "Patient returns to the emergency department: the time-to-return curve."[5]	ED re-visits in the same state within 30 days
	Hudspeth, J., et al. (2015). "Use of an Expedited Review Tool to Screen for Prior Diagnostic Error in Emergency Department Patients."[6]	Earlier visit to an ambulatory care clinic within 14 days of an ED visit
	Medford-Davis, L., et al. (2016). "Diagnostic errors related to acute abdominal pain in the emergency department."[7]	Two cohorts: Adults with 1) abdominal pain as the presenting symptom and discharged home; or 2) return visit to the ED with abdominal pain and admission
	Howard, I., et al. (2018). "Application of the emergency medical services trigger tool to measure adverse events in prehospital emergency care: a time series analysis"[8]	Adapted the IHI Trigger Tool to identify adverse events in pre-hospital emergency services
	Griffey, R.T., (2020). "The Emergency Department Trigger Tool: A Novel Approach to Screening for Quality and Safety Events"[9]	Explored yield of 97 different triggers relating to care in the ED, settling on 30 that yielded 1 or more adverse events
	Griffey, R.T., (2023). "Near-Miss Events Detected Using the Emergency Department Trigger Tool"[10]	Further application of their ED-specific trigger tools to look at diagnostic delays and near misses
Home Health Care		
	Schildemeijer, K.G.I.S., et al.(2018). "Adverse events in patients in home healthcare: a retrospective record review using trigger tool methodology"[11]	Manually screened the records of home health care patients in Sweden for 38 triggers
Inpatient Care		
	Shenvi, E. C. and R. El-Kareh (2015). "Clinical criteria to screen for inpatient diagnostic errors: a scoping review."[12]	Review of 30 articles on inpatient-related triggers; Best triggers were death, ICU transfer, cardiac arrest and prolonged stay
	Bhise, V., et al. (2018). "An electronic trigger based on care escalation to identify preventable adverse events in hospitalised patients."[13]	Rapid response team call or transfer to the ICU within 15 days of admission
Pediatrics		
	Unbeck, M., et al. (2014). "Validation of triggers and development of a pediatric trigger tool to identify adverse events."[14]	88 triggers relevant to pediatric inpatient care were developed and tested

	Stockwell, D. C., et al. (2016). "Development of an Electronic Pediatric All-Cause Harm Measurement Tool Using a Modified Delphi Method."[15]	An expert panel recommended 51 triggers relevant to pediatric inpatient care
	Landrigan, C. P., (2016). "Performance of the Global Assessment of Pediatric Patient Safety (GAPPS) Tool"[16]	Further refinement of their pediatric inpatient triggers; final set of 30 all had yields over 10% for adverse events
	Davalos, M. C., et al. (2017). "Finding Diagnostic Errors in Children Admitted to the PICU."[17]	Unexpected transfers, patients autopsied, and patients seen as outpatients within 2 weeks of admission were screened. The SaferDx tool was used to determine presence of diagnostic errors
	Howard, I., et al. (2018) "Application of the emergency medical services trigger tool to measure adverse events in prehospital emergency care: a time series analysis"	Used patient parameter triggers (fever, hypoxemia, others) to screen for adverse events in pre-hospital care
	Lam, D., et al.(2021). "Use of e-triggers to identify diagnostic errors in the paediatric ED"[18]	Used e-triggers to identify diagnostic errors in the paediatric ED, and compared yield to other approaches of harm detection
	Mahajan, P., et al. (2021) "Electronic Triggers to Study Diagnostic Errors In Pediatric Emergency Departments"[19]	Compared 3 triggers to screen for adverse events in children seen in the ED. Return visits to the ED and transfers to higher levels of care had the best yields.
	Reinhart, R.M., (2023). "A Customized Triggers Program: A Children's Hospital's Experience in Improving Trigger Usability"	Developed a unique, customizable pediatric triggers program to provide near real-time reports on inpatient safety breakdowns with an improved yield of adverse events
Primary Care		
	Singh, H., et al. (2012). "Electronic health record-based surveillance of diagnostic errors in primary care."[20]	Primary care visit followed by an unplanned admission or 1 or more unscheduled visits, within the next 2 weeks
	Al-Mutairi, A., et al. (2016). "Accuracy of the Safer Dx Instrument to Identify Diagnostic Errors in Primary Care."[21]	Unexpected admissions and return visits after a PC visit. Used the SaferDx tool to determine presence of diagnostic errors
	McNab, D., (2016). "The Primary Care Trigger Tool: Practical Guidance"[22]	Use of general primary care triggers to screen for adverse events in Scotland
SPADE methods to study single conditions		
	Sharp, A.L., et al.(2020). "Missed acute myocardial infarction in the emergency department- standardizing measurement of misdiagnosis-related harms using the SPADE method" [23]	Used SPADE methodology to look for diagnostic errors in patients discharged from the ED after symptoms of chest pain, finding 1.3% incidence of missed MI; forward-looking study found 0.2% error likelihood
	Horberg, M.A., et al.(2021). "Rate of sepsis hospitalizations after misdiagnosis in adult emergency department patients: a look-forward analysis with administrative claims data using Symptom-Disease Pair Analysis of Diagnostic Error (SPADE) methodology in an integrated health system"[24]	Used SPADE methodology to screen 4549 ED discharges for missed sepsis; found 26 sepsis admissions over the next 30 days.
	Vaghani, V., (2021). "Validation of an electronic trigger to measure missed diagnosis of stroke in emergency departments"[25]	Screened 7,752,326 admissions for possible stroke using a symptom-based trigger. Of 398 screen-positive patients, 124 had missed opportunities for diagnosis in the Emergency Department

Example	Red flag (inclusion) criteria	Clinical exclusion criteria	Data requirements
Tests pending at discharge from hospital or emergency department (ED)[35, 36] Test results that return after a patient is discharged from the hospital or ED are a high risk for delays in follow up. This is especially true for tests with long turn-around times, such as send-out labs.			
Missed diagnosis of urinary tract infection at discharge	Abnormal urine culture (ie, >100,000 colony forming units and growth of ≤2 organisms) that result after date/time of hospital discharge	**Clinical Exclusion** ▪ Deceased at discharge or code status was comfort measures only at the time of discharge **Appropriate Follow-up** ▪ Antibiotic prescribed at time of discharge to which organism found to be susceptible	▪ Coded urine culture reports (ie, results and antibiotic sensitivities) ▪ Standard medication coding system used for antibiotic sensitivities and medications
Abnormal test results lacking timely evaluation[37, 38] Triggers can identify instances when certain high-risk test results have not received expected follow-up in the outpatient setting (such as after an office visit or diagnostic procedures). Many of these test results remain "unacknowledged" in providers' EHR inboxes for extended periods of time, which is another way to identify them.			
Missed abnormal findings that warrant colorectal cancer evaluation	Positive fecal immunohistochemical test (FIT)	**Clinical Exclusion** ▪ Terminal illness; prior colectomy or known colorectal cancer **Appropriate Follow-up** ▪ GI visit or colonoscopy within 60 days	▪ Access to patient demographics ▪ Coded diagnosis/problem list data (ICD-10) ▪ Coded lab results (FIT & FOBT) ▪ Access to schedule of visits ▪ Coded procedures (CPT)
Unanticipated escalations of care[39, 40] Unexpected escalations in care may indicate the presence of a diagnosis that was missed early on, leading to unexpected worsening in patient's conditions.			
Missed appendicitis with bowel perforation	Child transferred to ICU unexpectedly from acute care floor after a rapid response and required vasoactive medications and/or endotracheal intubation due to decompensation within 24 hours	▪ Expected transfer to surgical ICU after an elective surgery	▪ Access to data on medication use ▪ Access to data on intubation ▪ Access to admission/discharge/transfer (ADT) data ▪ Access to RRT call/response data
Missed diagnosis of deep venous thrombosis and subsequent pulmonary embolus	Patient age < 65 when admitted to an adult inpatient service, and Charlson Comorbidity Index < 2 with transfer to ICU after activation of Rapid Response Team	▪ Transfers for post-procedure care ▪ >2 prior hospitalizations in the past year ▪ Transfer to hospice or palliative care in 6 months prior to hospitalization	▪ Access to admission/discharge/transfer (ADT) data ▪ Ability to calculate Charlson Comorbidity index ▪ Access to RRT call/response data
Unexpected hospitalization after an ED or primary care visit[41,42] An unscheduled return visit may signal a possible deviation from expected care. Previous studies have linked return visits to ED, particularly those resulting in hospital admission, to diagnostic error.			
Missed diagnosis of new-onset stroke	Unexpected hospitalization with new stroke within 10 days of being seen in primary care or ED	▪ Patients with known stroke and no new stroke diagnoses between admission and discharge	▪ Access to admission/discharge/transfer (ADT) data
Incomplete referrals[43, 44] When referrals for certain conditions are not followed upon on a timely basis, delays in diagnosis can occur in the outpatient setting.			
Delay in lung cancer diagnosis due to delayed referral	Referral to pulmonary clinic for evaluation of abnormal chest imaging not completed	▪ Referral scheduled within 30 days	▪ Access to referral-related ICD-10 or CPT structured codes ▪ Access to referral data

ICD-10 = International Classification of Disease version 10; CPT = Current Procedural Terminology; RRT = Rapid Response Team; FOBT = Fecal Occult Blood Test

EHR-based triggers for record review[26]

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Appendix C: Frameworks and Classification Systems for Analyzing Cases Involving Diagnosis

Developing an understanding of patient safety events requires the team to consider of a wide range of system-related and cognitive factors. Many different approaches have been described and used for this purpose, and there is no clear evidence that any one approach is superior to any other.

The approach we recommend for analyzing cases of diagnostic error or success is presented in Section 2E of "How to Do It". This approach incorporates a socio-technical perspective of patient safety, and combines elements from the cognitive classification system used by Graber *et al*[1] and the contributory-factors from Croskerry and Campbell.[2]

In this Appendix we present some of the other commonly-used alternative for users who might prefer something different. This list is by no means exclusive.

Comprehensive models   Page C-2
- Charles Vincent approach, and James Reason's "Model of Unsafe Acts"
- TRIPOD framework of Hudson et al (and TRIPOD – Delta)
- The Eindhoven classification framework
- The SEIPS framework by Pascale Carayon et al
- The socio-technical model of Singh and Sittig
- The DEER classification of Gordy Schiff
- A comprehensive framework by Rebecca Lawton et al

Simpler models   Page C-13
- The Revised SaferDx classification by Hardeep Singh, Dean Sittig, Andrea Bradford et al
- The SHEL model of Gerard Molloy and Ciaran O'Boyle
- The classification table of Nina Dadlez et al

Models for considering cognitive elements   Page C-16
- Pat Croskerry's 60 factors relating to cognitive performance
- Dimara classification of cognitive biases
- Cognitive bias codex

AHRQ format for error reporting   Page C-19
- The AHRQ Common Formats for Error Reporting – Diagnostic Errors

Comprehensive Models

Charles Vincent and James Reason   Efforts to analyze adverse events in healthcare were pioneered by Charles Vincent and colleagues,[3, 4] who combined a human factors approach with James Reason's framework of human error.[5] Vincent's framework (Figure 1) envisioned error arising from combinations of active failures on the part of the individual (errors, or unintended actions, and violations) and latent, contributory factors in the environment and organization. Most modern analyses of diagnostic error use some variant of this approach.
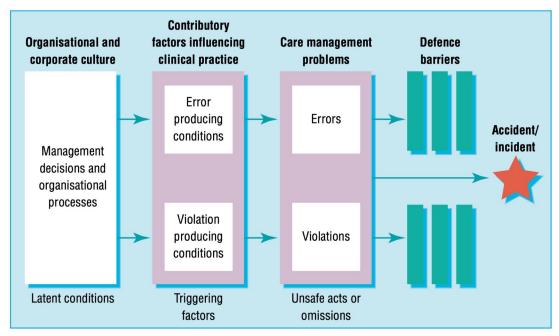
Figure 1. Vincent's organizational model of error in healthcare[4]

The active errors in Vincent's framework incorporated Reason's classification of human error, depending on whether actions were intentional (representing rule violations and mistakes) or unintentional (representing slips and lapses).(Figure 2) Baartmans et al recently used Reason's approach to analyze diagnostic errors encountered in the Emergency Department.[6]

Figure 2. James Reason's framework of human error ('active' errors)[3]
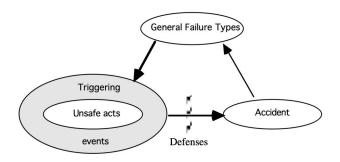
Applying Reason's framework is not intuitive, as it is challenging to differentiate slips from lapses and violations from mistakes. Baartmans et al provided this guidance on using Reason's approach:

"Intended actions can be subdivided into mistakes and violations. A mistake occurs if a plan is performed as intended, but the plan was not adequate to reach the outcome that was intended (rule-based mistakes: e.g., misapplication of good rule, application of bad rule, and knowledge-based mistakes). A violation in this context does not imply malicious intentions but is an action that is not in line with the protocols, guidelines, or rules (e.g., routine violations, exceptional violations, efficiency-thoroughness trade-off). An example of a violation is a trade-off between doing your job fast (using erroneous shortcuts) and doing it thoroughly, also known as "efficiency-thoroughness trade-offs."

Unintended actions can be subdivided into lapses and slips, which are related to errors in execution. Slips occur when the correct action is executed poorly (attentional failures: e.g., intrusion, omission, reversal, misordering, mistiming). Lapses occur when the execution involves a failure in memory (e.g., omitting planned items, place-losing, forgetting intentions)."

"It is important to emphasize that this model classifies acts, not the outcomes of acts. The SAE-related outcomes are generally unintended, but the actions causing these outcomes can still be intended. For example, when a nurse decides to not adhere to an infection prevention protocol because compliance takes too much time and the work pressure is high, then, the action of not disinfecting hands is intended, while the outcome (e.g., infecting a fragile patient) is unintended."

The Tripod model was developed to improve safety in petroleum transportation industry, and has also been used in health care.[7, 8] This framework assumes that accidents represent unsafe acts by human actors interacting with triggering events, and failure of existing defenses to prevent harm. The general failure types were identified from field studies. Using the Tripod model pro-actively to assess risk is known as the Tripod-Delta approach.

- *Hardware* (HW)
- *Maintenance Management* (MM)
- *Error Enforcing Conditions* (EC)
- *Incompatible Goals* (IG)
- *Communication* (CO)
- *Defenses* (DF)

- *Design* (DE)
- *Procedures* (PR)
- *Housekeeping* (HK)
- *Organization* (OR)
- *Training* (TR)

The Eindhoven Classification System is another widely-used general classification framework that distinguishes human failure from system-related issues, and subdivides the latter into organizational and technical issues. A final 'all other' category catches everything else.[9] The approach has been used to classify factors underlying diagnostic errors in Dutch hospitals.[10]
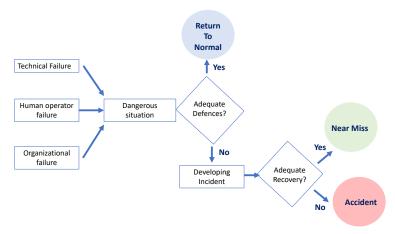
Figure 3. The Eindhoven framework of organizational accidents [4,5]

Code	Subclass	Definition
Human failure (H)		
Hex	External	Human failures originating beyond the control and responsibility of the investigating organisation.
HKK	Knowledge-based behaviour	The inability of an individual to apply his/her existing knowledge to a novel situation.
HRQ	Qualifications	An incorrect fit between an individual's training or education and a particular task.
HRC	Coordination	A lack of task coordination within a healthcare team in an organisation.
HRV	Verification	The correct and complete assessment of a situation including related conditions of the patient and materials to be used before starting the intervention.
HRI	Intervention	Failures that result from faulty task planning and execution.
HRM	Monitoring	Monitoring a process or patient status.
HSS	Slips	Failure in performance of highly developed skills.
HST	Tripping	Failures in whole body movements. These errors are often referred to as 'slipping, tripping, or falling'.
Organisational failure (O)		
Oex	External	Failures at an organisational level beyond the control and responsibility of the investigating organisation.
OK	Transfer of knowledge	Failures resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff.
OP	Protocols	Failures relating to the quality and availability of the protocols within the department (too complicated, inaccurate, unrealistic, absent or poorly presented).
OM	Management priorities	Internal management decisions in which safety is relegated to an inferior position when faced with conflicting demands or objectives. This is a conflict between production needs and safety.
OC	Culture	Failures resulting from a collective approach and its attendant modes of behaviour to risks in the investigating organisation.
Technical failure (T)		
Tex	External	Technical failures beyond the control and responsibility of the investigating organisation.
TD	Design	Failures due to poor design of equipment, software, labels or forms.
TC	Construction	Correct design, which was not constructed properly or was set up incorrectly.
TM	Materials	Material defects.
Other		
PRF	Patient-related factor	Failures related to patient characteristics or conditions, which are beyond the control of staff and influence treatment.
X	Other	Failures that cannot be classified in any other category.

Table 1. Factors contributing to error in the Eindhoven model [5]

SEIPS   Originally described in 2006 by Pascale Carayon and colleagues, the SEIPS model is an evolution of the Vincent and Eindhoven frameworks that describes how people interact in a healthcare environment, and these processes produce health outcomes. [11] This 'socio-technical' framework has proven to be exceptionally useful in understanding how safety evolves (or is degraded) in healthcare delivery.
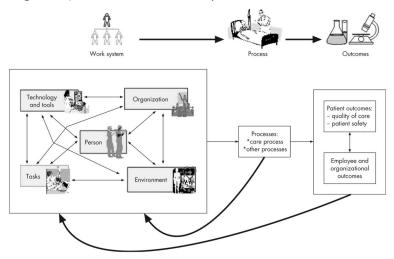
Figure 4. SEIPS 3.0 framework of healthcare delivery [6]

The most recent iteration of this approach, SEIPS 3.0, focuses on understanding the patient's journey in healthcare, and incorporates the important concept of organizational learning that should occur to improve safety going forward.[12]
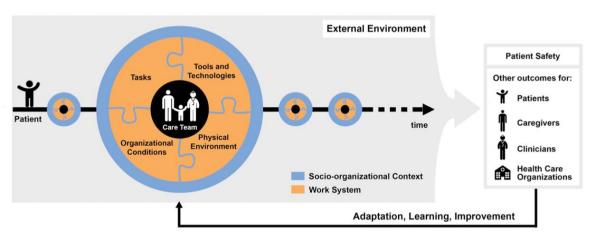
Figure 5.   SEIPS 3.0 framework, incorporating learning and a patient-centered perspective

In one further evolution, termed SEIPS 101, a simplified version of the SEIPS approach may be especially useful in RCA's of patient safety investigations.[13]
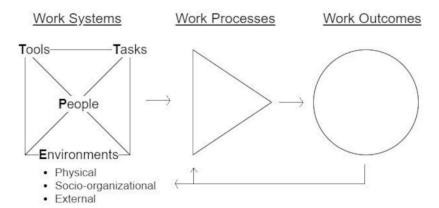
Figure 6. The SEIPS 101 conceptualization of healthcare delivery and its outcomes

"*it is a simplified, practically minded sketch of the most essential SEIPS components". "The SEIPS 101 model retains the three major SEIPS components, represented by unique shapes in the figure: work systems (square); work processes (triangle) and work outcomes (circle). Work systems are comprised of interacting structural elements that together produce performance. Every work system minimally has the components people, environments, tools and tasks, whose first letters spell 'PETT'. The environments, fully described in other SEIPS models, are physical, socio-organisational and external. The physical environment refers to physical layout, location and factors such as lighting, noise and temperature. The socio-organisational environment describes the attributes of an organisational unit (eg, a hospital, department, clinic, home or programme) such as structure, procedures, roles and responsibilities, relationships and organisational culture. The external environment is that which affects the unit of interest from outside, for example, the regulatory, legal, economic, political, cultural or societal contexts.*

Work processes are how the work is done and how it flows. Work processes are physical, cognitive, social-behavioural or a combination. 4 They can be performed by healthcare professionals, patients and families or collaboratively between professionals and nonprofessionals. Work outcomes result from work systems and work processes. These are desirable or undesirable, distal or proximal. They affect professionals, patients/families or the organisation. Arrows between systems, processes and outcomes represent causal feedback loops."[8]

The SEIPS 101 publication also includes several useful tools in conducting RCA's:

1. **PETT scan** - is a checklist and documentation tool to ensure one considers the full breadth of the work system, namely its people, environments, tools and tasks.
2. **People map** - represents the various people involved in a work system and how they relate or interact in practice
3. **Tasks and tools matrices** - describe the work system's tasks, tools and task-tool interactions
4. **Outcomes matrix** identifies and organises the various outcomes of interest, whether they represent project goals, measures to be collected or evaluation criteria
5. **Journey map** - is a tool to explain one or more work processes while simultaneously depicting other relevant factors or conditions over time
6. **Interactions diagram** - depicts how work system factors interact
7. **Systems story** – Recreates the safety incident as a story. Stories are compelling and easy to understand, remember, reshare and repurpose, yet convey much information and complexity.

	Admission	Pre-rounds	Before round	During round	After round
Who	• Patient & family • Attending physician, senior resident, intern, nurse, unit clerk	• Patient & family • Senior resident, intern, medical student, nurse, unit clerk	• Senior resident, intern, medical student	• Patient & family • Attending physician, senior resident, intern, medical student, nurse, pharmacist, case manager, social worker	• Attending physician, senior resident, intern, medical student, nurse, pharmacist, case manager, social worker
Tasks of family	• Exchange information • Build relationships • Make decisions	• Exchange information • Build relationships • Make decisions		• Exchange information • Build relationships • Make decisions	
Tasks of healthcare team	• Explain family-centered round process to family	• Gather labs and tests • Consult nurses, pharmacist or others • Check consult notes • Plan discharge • See patient & family • Make a plan	• Update EHR • Discuss the plan • Prepare for the presentation for round	• Present overnight events, tests, labs, ... • Discuss assessment and plan • Conduct physical exam • Enter orders into EHR • Conduct teaching	• Discuss issues not addressed during round • Teaching • Update EHR • Follow-up with patient & family
Physical environment	• Before the patient arrives on the nursing or medical unit (e.g. ED)	• Hallway • Patient room	• Resident workroom	• Hallway • Patient room	• Hallway • Patient room • Resident workroom

Figure 7. Example of a 'journey map', from SEIPS 101 [8]

Hardeep Singh, Dean Sittig and collaborators have described a related 'socio-technical' framework for understanding healthcare delivery, encompassing 8 dimensions (Figures 8 and 9).[14]
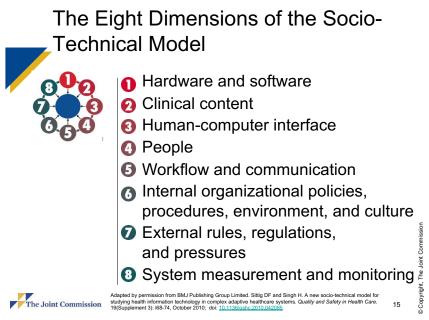
Figure 8. The 8 dimensions of the socio-technical model of Singh and Sittig [9]
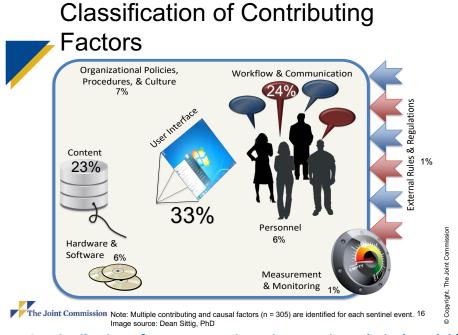
Figure 9. Distribution of error categories using a socio-technical model [9]

DEER model: Gordy Schiff and colleagues published one of the first classification systems for studying diagnostic error, identifying where in the diagnostic process breakdowns were evident.[15] More recently, this scheme has been updated to include reasons why errors might have occurred (Table 2), along with a table of additional factors to consider (Table 3). [16]

Where in diagnostic process			What went wrong
1. Access/Presentation		A	Failure/delay in presentation
		B	Failure/denied care access
2. History		A	Failure/delay in eliciting critical piece of history data
		B	Inaccurate/misinterpretation
		C	Failure in weighing
		D	Failure/delay to follow-up
3. Physical Exam		A	Failure/delay in eliciting critical physical exam finding
		B	Inaccurate/misinterpreted
		C	Failure in weighing
		D	Failure/delay to follow-up
4. Tests (Lab/Radiology)			*Ordering*
		A	Failure/delay in ordering needed test(s)
		B	Failure/delay in performing ordered test(s)
		C	Error in test sequencing
		D	Ordering of wrong test(s)
		E	Test ordered wrong way
			Performance
		F	Sample mixup/mislabeled (eg, wrong patient/test)
		G	Technical errors/poor processing of specimen/test
		H	Erroneous lab/radiology reading of test
		I	Failed/delayed reporting of result to clinician
			Clinician Processing
		J	Failed/delayed follow-up of (abnormal) test result
		K	Error in clinician interpretation of test
5. Assessment			*Hypothesis Generation*
		A	Failure/delay in considering the diagnosis
			Suboptimal Weighing/Prioritization
		B	Too little consideration/weight given to the diagnosis
		C	Too much weight on competing/coexisting diagnosis
			Recognizing Urgency/Complications
		D	Failure/delay to recognize/weigh urgency
		E	Failure/delay to recognize/weigh complication(s)
6. Referral/Consultation		A	Failure/delay in ordering referral
		B	Failure/delay obtaining/scheduling ordered referral
		C	Error in diagnostic consultation performance
		D	Failure/delayed communication/follow-up of consultation
7. Follow-up		A	Failure to refer patient to close/safe setting/monitoring
		B	Failure/delay in timely follow-up/rechecking of patient

Rebecca Lawton and colleagues conducted an exhaustive review of classification systems used for studies of errors in health care.[17] A total of 95 publications were identified as of 2010, and a total of 1676 contributing factors were reported. The authors distilled this list into 20 distinct categories (Table 2) and produced a comprehensive model for considering failures in healthcare delivery (Figure 10).

Factor	Definition
Active failures	Any failure in performance or behaviour (eg, error, mistake, violation) of the person at the 'sharp-end' (the health professional)
Communication systems	Effectiveness of the processes and systems in place for the exchange and sharing of information between staff, patients, groups, departments and services. This includes both written (eg, documentation) and verbal (eg, handover) communication systems
Equipment and supplies	Availability and functioning of equipment and supplies
External policy context	Nationally driven policies / directives that impact on the level and quality of resources available to hospitals
Design of equipment and supplies	The design of equipment and supplies to overcome physical and performance limitations
Individual factors	Characteristics of the person delivering care that may contribute in some way to active failures. Examples of such factors include inexperience, stress, personality, attitudes.
Lines of responsibility	Existence of clear lines of responsibility clarifying accountability of staff members and delineating the job role
Management of staff and staffing levels	The appropriate management and allocation of staff to ensure adequate skill mix and staffing levels for the volume of work
Patient factors	Those features of the patient that make caring for them more difficult and therefore more prone to error. These might include abnormal physiology, language difficulties, personality characteristics (eg, aggressive attitude).
Physical environment	Features of the physical environment that help or hinder safe practice. This refers to the layout of the unit, the fixtures and fittings and the level of noise, lighting, temperature etc.
Policy and procedures	The existence of formal and written guidance for the appropriate conduct of work tasks and processes. This can also include situations where procedures are available but contradictory, incomprehensible or of otherwise poor quality
Safety culture	Organisational values, beliefs, and practices surrounding the management of safety and learning from error
Scheduling and bed management	Adequate scheduling to manage patient throughput minimising delays and excessive workload
Staff workload	Level of activity and pressures on time during a shift
Supervision and leadership	The availability and quality of direct and local supervision and leadership
Support from central functions	Availability and adequacy of central services in support the functioning of wards/ units. This might include support from Information Technology and Human Resources, portering services, estates or clinically related services such as radiology, phlebotomy, pharmacy.
Task characteristics	Factors related to specific patient related tasks which may make individuals vulnerable to error
Team factors	Any factor related to the working of different professionals within a group which they may be able to change to improve patient safety
Training and education	Access to correct, timely and appropriate training both specific (eg, Task related) and general (eg, Organisation related)

Table 2. 20 dimensions to consider in patient safety investigations [10]

Figure 10. Lawton et al's comprehensive model of factors determining patient safety [10]

SaferDx Checklist

Hardeep Singh and colleagues have developed the "SaferDx Checklist" to help identify cases involving diagnostic error.[18] The 'MeasureDx' handbook published by Andrea Bradford and colleagues and published by AHRQ includes a tool derived from this work for categorizing factors potentially contributing to cases of diagnostic error.(Table 3) [12]. It is organized to follow the diagnostic process, like the DEER approach above.

Dimensions (select all that apply)	
1) Patient Related	☐ Delay in seeking care ☐ Lack of adherence to appointments ☐ Other, please specify:
2) Patient-Provider Encounter	☐ Problems with history ☐ Problems with physical exam ☐ Problems ordering diagnostic tests for further work up ☐ Failure to review previous documentation ☐ Problems with data integration and interpretation ☐ Other, please specify:
3) Diagnostic Tests	☐ Ordered test not performed at all ☐ Ordered tests not performed correctly ☐ Performed tests not interpreted correctly ☐ Misidentification ☐ Other, please specify:
4) Follow-Up & Tracking	☐ Problems with timely follow-up of abnormal diagnostic test results ☐ Problems with scheduling of appropriate and/or timely follow-up visits ☐ Problems with diagnostic specialties returning test results to clinicians ☐ Problems with clinicians reviewing test results ☐ Problems with clinicians documenting action or response to test results ☐ Problems with notifying patients of test results ☐ Problems with monitoring patients through follow-up ☐ Other, please specify:
5) Referrals	☐ Problem initiating referral ☐ Lack of appropriate actions on requested consultation ☐ Communication breakdown from consultant to referring provider ☐ Other, please specify:

Reprinted with permission from Singh H, Khanna A, Spitzmueller C, Meyer AND. Recommendations for using the Revised Safer Dx Instrument to help measure and improve diagnostic safety. Diagnosis 2019;6(4):315-23. https://doi.org/10.1515/dx-2019-0012. Accessed April 6, 2022.

Table 3. Factors potentially contributing to diagnostic error. Appendix E in "MeasureDx"[19]

Challenging disease presentation
- Atypical presentation
- Non-specific symptoms and signs
- Unfamiliar/outside specialty
- Findings masking/mimicking another diagnosis
- Red herring misleading findings
- Rapidly progressive course
- Slowly evolving blunting onset perception
- Deceptively benign course

Patient factors
- Language/communication barriers
- Signal:noise -- patients with multiple other symptoms or diagnoses
- Failure to share data (to be forthcoming with symptoms or their severity)
- Failure to follow-up

Testing challenges
- Test not available due geography, access, cost
- Logistical issues in scheduling, performing
- False positive/negative test limitations
- Performance/interpretation failures
- Equivocal results/interpretation
- Test follow-up issues (e.g., tracking pending results)
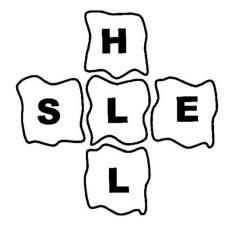
Stressors
- Time constraints for clinicians and patients
- Discontinuities of care
- Fragmentation of care
- Memory reliance/challenges

Broader challenges
- Recognition of acuity/severity
- Diagnosis of complications
- Recognition of failure to respond to therapy
- Diagnosis of underlying etiologic cause
- Recognizing misdiagnosis occurrence

The SHEL model

Described by Gerard Molloy and Ciaran O'Boyle, the 'SHEL' model presents a simple and easy-to-recall approach to considering the various elements and human factors relevant to patient safety analyses.[20]

Figure 11.   The SHEL model [13]

S = Software   The policies and procedures in use, the computer software and programs available, including decision support tools. The EMR and its functionality

H = Hardware   The physical tools available, the access to care

E = Environment   The context of care, the resources available, the safety culture

L = Liveware   The patient, the staff, and the clinicians involved in healthcare delivery, including their thoughts, decisions, and actions

Nina Dadlez et al used a simplified approach to classify the factors contributing to diagnostic error in a series of mini-RCA's.[21]

Patient Factors	Clinician/Admin Factors	Systems Factors
Sex \ Age	Type of provider	Patient volume that day
Insurance status	Provider training	Nurse\clerical staffing that day
Reason for visit	Provider fatigue/impairment	Time of day of visit
Language barriers	Personal stressors of providers	Clinic mileu
Acute illness	Provider disagreements	Written\Verbal communication
Agitation of patient/family	Provider knowledge	Computer hardware\software
Social issues	Provider beliefs	Non-computer equipment
Other factors	Other factors	Other factors

Table 4. A scheme to categorize factors contributing to cases of diagnostic error [14]

Pat Croskerry has pioneered the consideration of cognitive factors involved in and relevant to clinical diagnosis. He describes some 60 discrete elements that can be distinguished, falling into 6 general 'clusters', illustrated in Figures 12 and 13. His recommended approach to conducting RCA's of diagnostic error is shown in Figure 13. Cases involving breakdowns in clinical reasoning require a 'cogntiive root cause analysis' (CRCA) and consideration of the 60 elements.

Croskerry describes 3 main sources of rationality failure that contribute to diagnostic error: (personal communication)
1. cognitive miserliness (tendencies to treat information superficially or with insufficient effort),
2. mindware gaps (missing bits of critical information, failures in probability reasoning etc), and
3. mindware contamination – logical failures in reasoning, cognitive biases, eccentric reasoning
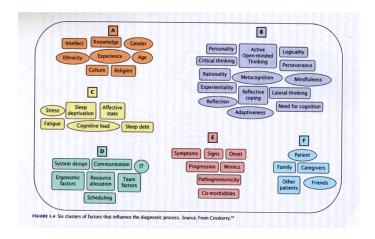
Figure 12. 60 factors relevant to decision making in diagnosis.
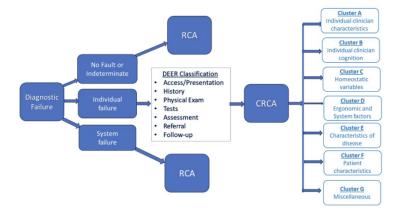
Figure 13.   An approach to conducting root cause analyses of diagnostic error cases

Cognitive bias Codex   The psychologists who study cognition have described close to 200 cognitive and affective (involving the emotions) biases. Many of these are encountered in cases of diagnostic error. Two general frameworks for considering cognitive bias have been published. The Cognitive Bias Codex by Buster Benson and John Manoogian divides the biases into 4 main categories:[22]

<div align="center">

Too much information

Not enough meaning

The need to act fast

What should we remember?

</div>
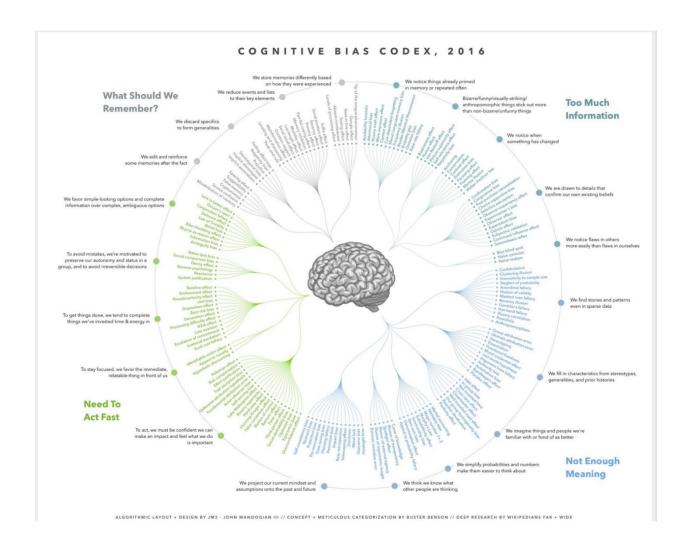
Figure 14. The Cognitve Bias Codex.   John Manoogian III and Buster Benson.   Wikepedia

Evanthia Dimara et al have presented a review of various ways to categorize cognitive biases, and devised their own approach, compiling 154 different biases in information processing and categorized them into 7 clusters (Figure).[23]
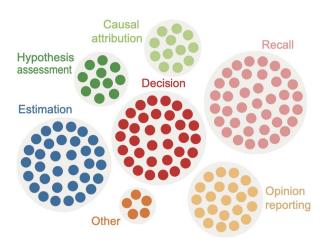
Figure 15. 154 biases relevant to information processing [17]

AHRQ Classification for Error Reporting   The Agency for Healthcare Research and Quality (AHRQ) has developed a comprehensive system for capturing factors relevant to cases involving diagnosis.[24] Their "Common Formats for Event Reporting – Diagnostic Safety" approach includes several sections:

Where in the diagnostic process did the event happen?
- History
- Vital Signs
- Physical Exam
- Lab Tests\Pathology
- Imaging
- Other Clinical Tests
- Consultation\Referrals
- Follow-Up\Tracking

What issues were involved?
- Communication
- Access to Care
- Patient Factors
- Clinician Factors
- Performing Clinician/Personnel Factors
- Work Environment/Equipment
- Work processes/Workflow
- Health Information Technology
- Other

> **Access to Care Factors**
> - Patient \ family circumstances
> - Health coverage issue
> - Making appointments
> - Communication assistance
> - Problem with patient contact
> - Organization's health information technology
> - Other

Organizational Factors
- Communication
- Safety Climate, Culture
- Resources, Support for diagnostic improvement
- Workload, Staffing
- Consideration of intensity of patient needs
- Consideration of clinician qualifications, proficiency
- Supervision, Support
- Policies, Procedures, Protocols
- Handovers, Handoffs, Care Transitions
- Crisis situations

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Appendix D: Participating in Root Cause Analysis - A Guide for Physicians and Nurses

When a patient experiences harm related to a diagnostic error, it is very appropriate to consider how this happened as the first step in trying to improve the process of care going forward. Most organizations use the process of root cause analysis to conduct these investigations. If you were involved in the care of the patient, the RCA team will ask you to participate.

It is perfectly normal to feel uncomfortable discussing cases involving your own patients. Most physicians involved in adverse safety events experience significant distress. This is compounded in cases of diagnostic error, because these cases may involve questions of competency or some act of omission that in retrospect is embarrassing.

Hopefully you work in an organization with a culture that values openness and learning, and provides psychological safety for error discussions. Being able to have honest conversations about errors can only happen in these environments. The value of learning and having the opportunity to make healthcare safer going forward will hopefully outweigh everyone's normal reluctance to review one's own decisions and actions. RCA investigations aren't about assigning blame or evaluating competency; the goal is simply to understand what happened and why those decisions and actions made sense at the time. In other words, it isn't about you, is about how the diagnostic process works in your practice or organization.

Keep these things in mind:

- Every clinician is fallible. One in every ten diagnoses, on average, is wrong.

- There are literally hundreds of factors that detract from perfection in diagnosis, involving particulars of the case, of the patient, of the context in which the case was managed, and in the clinical decision-making involved. Most of the factors that lead to errors in clinical judgment are 'human nature' – shortcomings that affect everyone. Every clinician is susceptible to error, and error-promoting conditions in the context of care are often identified.

- There will be other clinicians on the RCA team who've been through these investigations many times before, and will be able to guide and support your participation. These are your colleagues, and they are interested in improving safety, not in criticizing.

- Patients and families who've been harmed from medical error are less likely to file a malpractice claim when the organization openly admits responsibility and conducts a comprehensive root cause investigation.

Reviewing cases involving diagnosis often involve understanding the clinical reasoning process. Breakdowns in clinical reasoning involve one or more of these 3 components:

Clinical knowledge – This is a problem in just a few cases, and it worthwhile pointing out that there are over 10,000 diseases and no one can know them all. Physician and nurse education and training is idiosyncratic, and everyone's experience will be different.

Finding and using data - Sometimes a key fact is missed in taking the patient's history, a physical finding isn't identified, or a laboratory test result is overlooked or misinterpreted. There are often circumstantial factors that play a role in these situations: pressure of time, distractions, cumbersome EMR's, etc.

Synthesis - The goal of clinical reasoning is to use your medical knowledge, given the facts in the case, to determine possible diagnoses to consider. There are a host of factors that can contribute to problems synthesizing everything appropriately, and many of these involve the concept of cognitive 'bias'. Physicians and nurses should understand that this term is not pejorative, and it doesn't imply anything about your character, your values, or your beliefs. It is a term borrowed from the field of psychology and it refers in a general sense to the tendencies that affect all humans making judgments and decisions, in every setting.

Most of these cognitive 'biases' are subconscious, and are hard-wired – they can't be un-learned. They are important to understand, however, because they can be recognized, and this opens the door to improving diagnosis going forward. It is much easier, for example, to recognize cognitive 'bias' in someone else's thinking than in your own. Common situations include 'search satisficing', where the physician seems to readily accept the first diagnosis that comes to mind, instead of making a differential diagnosis. Context errors are another common 'bias': The physician might think a patient who is vomiting has a GI condition, when in fact it represents poisoning, or sepsis.

There are many interventions that could be helpful in mitigating these problems, including reflection, the use of decision-support, and getting input from a colleague or a consultant.

The bottom line is that studying cases involving diagnosis are critical to improving the quality and safety of healthcare in your practice or organization. RCA's will be of little value without the direct involvement of physicians and any other clinicians involved in the patient's care. Physicians and nurses bring a unique appreciation for the complexity of diagnosis in general, and if you were involved in the case, your unique perspective on the particulars relevant to the diagnostic process for this particular patient.

Successful RCA's lead to interventions that ultimately improve patient safety and the quality of care, and you will have contributed to this outcome.

Appendix E: Participating in a Root Cause Analysis
– A Guide for Patients

Introduction and background   You or a family member has just experienced a breakdown in the quality of healthcare. Hopefully, this was a close call, and despite the breakdown no one was harmed. However, you or your family member may have suffered far worse with either minor or major harm, or death. These events are traumatic in the extreme, and it is perfectly normal for patients and families in these situations to experience a wide range of emotions, including surprise, shock, grief, and anger.

If the clinic or hospital has not contacted you first about a possible safety breakdown, you can and should file a patient safety complaint.   Every healthcare organization has a pathway for patients and families to file these reports. You can always contact the organizations 'risk manager' or patient safety director as a first step, or the clinic manager.

You will also wonder why this happened. Hospitals and healthcare organizations dedicate themselves to providing safe, effective, and efficient care. When breakdowns lead to harm, they are obliged to review what happened, what went wrong, and how events such as this one can best be prevented in the future. They have several options for conducting a safety review of the incident. The most formal approach to conducting a safety review is called a 'root cause analysis' (RCA). This is a comprehensive review process to obtain an in-depth understanding of the various factors that might have contributed, and to then recommend interventions to prevent the same kind of error from happening again.

This guide was developed to help you understand the RCA process, and help you decide if and how you wish to be involved. In Part 1 of this document we review some of the basics about these safety investigations. Part 2 present more detailed information if you want to learn more, and a glossary of terms.

You have three options for interacting with the safety review team:

- **Be interviewed**   You may be asked to share your story, and many patients feel better having the chance to tell their side of things. The team will want to learn your perspective on what exactly happened, what was the sequence of events, and what was said or not said. You may have relevant background information that is relevant to the event, but that isn't available from reviewing the medical records.

- **Be involved**   Besides providing this information through an interview, you may be asked to participate as a member of the RCA team. As part of the review team, you will be involved in how the review is conducted and what it concludes and recommends. This may be difficult emotionally and it will be time-consuming, but it will give you the

assurance that the safety review is complete, and that the conclusions and recommendations are satisfactory from your perspective.

- **Be involved through a patient advocate**   You may elect to have a patient advisor participate on the RCA team on your behalf, if one is available. This could be an official patient advocate from the hospital or health system, but there are no formal requirements for someone to act as an advocate; it could be a family member or close friend, someone who is comfortable with medical conversations and is familiar with your care experience. The advocate will represent your interests, and keep you informed of how the review is proceeding.

At the completion of the review process, the RCA team creates a summary of what was learned and makes recommendations to the leadership of the organization to improve safety going forward. You should receive a copy of these reports, and you may request to speak with someone from the safety department if you have questions or concerns.

What you need to know to participate: The most important things you need to know are the facts relevant to the patient: What were their first symptoms? How did their illness progress?   When and where did the patient seek healthcare, and what happened? What events led up to the eventual safety breakdown? You are the expert about these facts, and these facts are critically important to understanding what happened. Your direct knowledge of these facts makes you uniquely qualified to contribute in the safety review.

Suggestions

- You may want to connect with the Patient and Family Advisory Council (PFAC), if the organization has one. If not, connect with local or national patient-based safety organizations, or talk to other patients and families who have been involved in safety breakdowns themselves.   Being able to get support and information from someone who's been through this before is invaluable.

- Ask questions, and when team members use medical lingo or acronyms, ask them to explain what they mean. Please know that your perspective is invaluable and you are not only welcome, but encouraged to be fully engaged in the proceedings.

- Going through the details of the safety event may be upsetting or retraumatizing; please know that becoming emotional is understandable, and the RCA team can suggest resources to help with managing feelings that may emerge.

- While the discussions may be difficult, the culture and setting for the RCA process is one of collaboration; all team members are expected to treat each other with respect, even

if they disagree. If you do not feel you are being respected or treated appropriately, please let your RCA team liaison know.

- The organization will follow up with the RCA team members to inform them about the progress of the recommendations and results of any implementation; if you have not heard from anyone, you may want to follow-up

- Because the RCA process is collaborative, and must result in approaches that the organization can reasonably take on, please do not be disappointed if the final recommendations are slightly different than what you had in mind. Your input is critical and undoubtedly will make the process better.

If you want to learn more   If you would like to participate as a member of the RCA team, you may feel more comfortable doing so if you become familiar with some of the language and concepts that are likely to come up during the process. We have included additional information on patient safety, the diagnostic process, and safety investigations in the attached Addendum.

Summary and conclusions   Participating in a root cause analysis may be stressful and even re-traumatizing, but the process is essential to improving patient safety. The final conclusions and recommendations will be better thanks to your participation. The voice of the patient and family is critical to fully understand the safety breakdown, and to ensure that the final recommendations are appropriate, and will have impact to improve care going forward.

Addendum – for patients contributing to an RCA

The Root Cause Analysis (RCA) process   The Joint Commission (the non-profit organization that accredits most US hospitals) requires healthcare organizations to conduct a safety investigation when an unexpected serious safety breakdown leads to substantial harm or death. The Joint Commission designates these as 'sentinel events'. The investigation must be completed within 45 days, and The Joint Commission reviews each report to ensure that the investigation was thorough and that the proposed interventions to prevent a repeat of the event are feasible and appropriate.

Most healthcare organizations use the RCA approach to conduct these investigations. Comprehensive guidelines for conducting an RCA investigation have been published by several leading patient safety organizations, including The Joint Commission, ASHRM (the Association of Healthcare Risk Management), and the Institute for Healthcare Improvement. The IHI guide, called RCA ^{2} ("RCA two") is used by many organizations and is available on the internet here: (https://www.ihi.org/resources/tools/rca2-improving-root-cause-analyses-and-actions-prevent-harm). However, there are many variations in how organizations conduct an RCA, and there are also other ways to investigate safety breakdowns that use other processes entirely. You should ask your liaison to the RCA team which process they intend to use.

The investigations usually follow some of the same general steps:

1. The members of the hospital team who are focused on safety conduct an initial study of the safety breakdown.
2. If a more formal process like an RCA is going to take place, the organizational leadership must first approve it.
3. After approval, the members of the RCA team are identified and given instructions. The team will include staff from the safety office, and may include clinicians and patients or families involved in the safety event.
4. The RCA team conducts its own review of what happened.
5. The team tries to identify the root causes of the safety event, and will then propose interventions designed to address the problems identified.
6. The organizational leadership reviews the team's report and recommendations, and then is responsible for implementing the most important recommendations. Even large healthcare organizations have finite resources and staff, and it is unusual for all of the RCA team's recommendations to be implemented.

RCA teams are encouraged to propose 'strong' interventions, ie those that are most likely to ensure that the correct steps are taken. Strong interventions include things like forcing functions (things can only be done 1 way), simplifying complex processes, and standardizing how things are done. Weak interventions include options like double-checking, warning signs,

reminders, training and education. Intermediate measures are interventions that increase staffing, adding checklists, or reducing distractions.

The healthcare delivery process. Participating effectively on an RCA team requires having some sense of knowing 'how things are done' in the healthcare organization. RCA teams will either include staff familiar with day-to-day operations, or will interview staff who have specialized knowledge. Many procedures are standardized by policy, while others may be just 'the routine we always use'. Although healthcare delivery is more or less uniform from one institution to another, there are always many particulars that may be unique to a given organization, or a certain department, or to specific clinicians and staff. A large part of RCA investigations involves looking at the delivery steps in detail to see if they are error-prone, or could be improved to prevent error.

Current understandings of patient safety. The model for organizational safety evolved from aviation, starting first with safety work at NASA, and then a great deal of work in commercial aviation. The safety record of aviation is remarkable, given that half of the first airmail pilots died in airplane crashes. Decades of work on the part of manufacturers, air traffic controllers, the Aviation Safety Board, and safety experts have resulted in an enviable safety record: There have been no deaths on a commercial airline flight in the US for the past 13 years. Safety in aviation is truly 'Job #1'.

Healthcare is much more complex than aviation. Although every Boeing 737 is essentially the same, every patient is different, every clinician has had different educational and training experiences, and the way healthcare is organized and delivered varies from one organization to the next. A patient's healthcare journeys may play out over time, in different settings, and may involve seeing many different clinicians. Each of these transitions is an opportunity for information to get lost or misinterpreted. There is complexity and variability at every step.
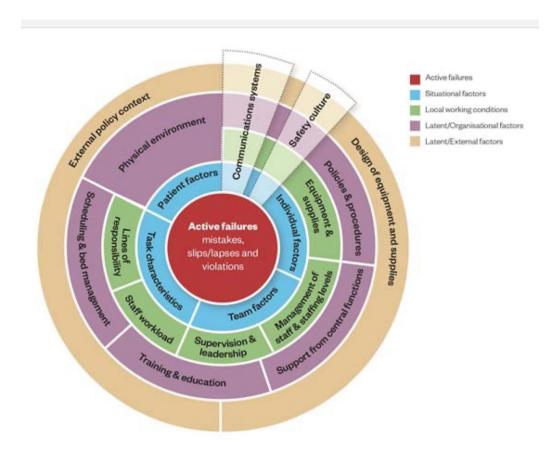
Most healthcare organizations are committed to delivering safe health care, and they devote considerable resources towards this end. Safety is important, but not a top priority. Safety in health care received little attention until the publication in 1999 of "To Err is Human" by the Institute of Medicine. At the national level, the Agency for Healthcare Research and Quality and the Centers for Disease Control are the lead groups working to improve patient safety and important contributions have also come from the National Patient Safety Foundation, the Institute for Safe Medication Practices, The Joint Commission, the National Quality Forum, and other groups. Many accident-prone areas have been identified and addressed. Examples include protocols to prevent infections acquired in the hospital, and to prevent harm from medication errors, falls, and wrong-site surgery.

Current thoughts on patient safety use a framework that envisions health care as a complicated process taking place in a certain 'socio-technical' setting. Ultimately, health care is delivered by the staff, and the quality of this care will depend on many individual factors, like competency,

experience, dedication, being careful and mindful, etc. The success or failure of individual action, however, is influenced by many different factors particular to the setting, in particular the culture of safety, and communication effectiveness. This constant interplay between the individual clinician and the system and the context of their work environment are at the heart of every safety investigation.

A culture of safety helps ensure that everything possible is being done to provide care in a safe manner, errors are openly discussed, and the focus is on learning and improvement. The opposite of a culture of safety is a culture of blame, where accidents and breakdowns are viewed as primarily a problem caused by an individual. This creates a toxic environment where secrets are hidden, and staff cover up problems, concerns, and mistakes. Focusing on the system, and how to optimize it is a core concept of modern safety thought.

Detailed guides are available to help consider all of the different elements at play. One approach to ensure that all of the dimensions are considered is illustrated in Figure 3, but many healthcare organizations prefer their own, or some other approach to ensure that the investigation is broad and inclusive. Breakdowns in communication and care coordination are the most commonly-cited factors.

Factors that influence the safety of healthcare.   From Lawton et al. Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review. BMJ Qual Saf 2012;21:369e380.

Cases involving diagnosis

To help preserve a culture of safety, most RCA's focus solely on the system-related aspects of care to identify breakdowns and consider ways to improve. They may identify 'human error' as a contributing factor, but they don't delve any deeper into these issues. In cases of diagnostic error, however, considering the human element is unavoidable. The key aspect of diagnosis is the clinical reasoning process, and to understand how this goes awry requires an understanding of the cognitive elements involved.

A primer on diagnosis and diagnostic error

Diagnosis is a process – it starts out with the patient seeking health care. The clinician obtains the patient's history, and conducts a physical examination based on the main things the patient is concerned about—sometimes called the "chief complaints". The diagnosis may be obvious at that point. If not, the clinician may order lab tests or imaging tests (such as an x-ray), or request advice from a subspecialist. Or it may be appropriate to wait and watch, to see if the symptoms resolve or how things progress. Behind all of this, is what's called the "clinical reasoning process", where the clinician tries to make sense out of the findings, given their medical knowledge and their ability to synthesize all of the available information.

Diagnosis always takes place in a particular setting—such as in an emergency room or in a primary care physician's office, and this location and the circumstances around it are critically important to the diagnostic process. For example, where the diagnosis is taking place can determine how much time the clinician has to see that patient, how easy or hard it is to get another clinician to weigh in on the case or to order diagnostic tests, and what kinds of resources are available to help with diagnosis, such as decision-support tools that help narrow down the number of possible options.

Research studies have concluded that roughly 1 in 10 diagnoses made in what are called "front-line healthcare settings" (primary care, internal medicine, pediatric, geriatrics, emergency medicine) is wrong. Fortunately, very few of these result in harm; the patient gets better in spite of not having the right diagnosis, the correct diagnosis is eventually made, or the treatment that was given worked, even though the diagnosis was incorrect. Unfortunately, depending on the disease and the circumstances, many patients with diagnostic errors will be harmed if the correct diagnosis is delayed or wrong, or if no diagnosis is ever made.

Most diagnostic errors involve breakdowns in the clinical reasoning process, problems involving the 'system', or the context (location and circumstances) in which care is delivered. On average, there are 4-6 relevant factors at play in cases of diagnostic error. It is unusual for there to be only one factor or reason for a diagnostic error.

Even well-trained, highly competent, and well-intended clinicians can make mistakes or be involved in diagnostic errors. The opportunities for error are numerous and often there are not enough safeguards in place to catch the ones that do occur. An important aspect of the RCA process is that even though it seeks to find out how errors happened, and why, the goal is not to blame those involved, but to learn from the event and work to ensure it does not happen again. This approach promotes a culture of safety.

Over the past decade, we have learned a great deal about diagnostic errors in terms of how likely they are and why they happen. There are also a wide range of interventions proposed to address breakdowns in the diagnostic process, but research regarding which ones work, or work the best, is just getting started. Some of the options that focus on the individual clinician are presented in Table 1.

Table 1. Interventions to improve the reliability of the clinical reasoning process

Get second opinions from colleagues and consults from sub-specialists

Use decision support tools to help consider all of the diagnostic possibilities

Learn about cognitive error & bias; Learn about critical thinking

Be reflective. Stop and Think. Make a differential diagnosis. Ask: "What else could this be?"

Get better feedback on your own diagnostic performance

Be more conscientious about following up with patients and their test results

Promote teamwork:

- Empower nurses & patients to be engaged.
- Meet regularly with Radiologists and Laboratorians

Appendix F: Cognitive Interviewing

Cognitive interviewing refers to an approach that helps a subject recall the details of an event they witnessed, or that involved them directly. The approach was developed by cognitive psychologists specializing in the study of memory, and has been used and validated in a very wide range of investigations, including crimes, intelligence and military operations, accident investigations, and now in trying to reconstruct safety events in health care.[1-3] Pat Croskerry describes cognitive interviewing as the most effective way to develop a deep understanding of cases involving diagnostic error by getting a sense of what the clinician was thinking and feeling at the time. Croskerry describes this as a 'cognitive autopsy'. [4, 5]

Recalling the many details surrounding a safety incident may be difficult, especially if the patient was harmed. A basic premise of cognitive interviewing is that much of what people recall about an incident is a reconstruction of what actually happened, not an accurate reproduction. To circumvent this problem, cognitive interviewing encourages the subject to re-live the event, hopefully accessing their primary memory and not their reconstructed versions. The approach has the best chances of success if used immediately after the event; the ability to recollect details fades very quickly as time goes by.

The interviewer should first have an initial understanding of the incident in question, and may want to consult with a subject matter expert before interviewing the subject to know what questions to ask. The interview should take place in a quiet space, and should be conducted by a neutral party trained and experienced in using the cognitive interviewing approach. A note-taker should be present, and should be introduced, but then remain silent.

> "Across over 100 laboratory and field experiments and using a variety of test conditions and subjects, the CI has typically elicited considerably more information, and at a comparable or higher level of accuracy, than conventional information-gathering interview protocols."
> Molinaro et al. Train-the-trainer: Methodology to learn the cognitive interview.[6]

These are the sequential steps in the cognitive interviewing process:

Introduction: The interviewer should introduce herself and the note-taker, and state that the goal is to have a complete picture of what happened, from the perspective of the subject.

Establish rapport   The first goal is to put the clinician at ease and establish trust. Use his or her name, show interest in them, thank them for taking the time for the interview. Smile, use 'open' body language. Emphasize that the whole purpose is not to blame anyone, but rather to improve the safety of care going forward, and to do that you need their help.

The next goal is to 'activate' the clinician. You want them to tell you everything they can recall. "I wasn't there; you were. Don't wait for me to ask questions. Tell us _everything_ you recall, every detail; don't leave anything out. It doesn't matter if its out of order - we'll sort it all out later."

The most successful approach is to ask them to just close their eyes and walk you through their day or their shift, starting before event and ending after it. You want the subject to go back in time and re-create the context. "How did your day (or shift, etc) start out? What were the first things you recall? What else was going on? Who else was involved? What were you thinking? What were you feeling?"

Once the subject starts talking, DON'T INTERRUPT !!

Focused probing   After the clinician has completed their recall, you should a general sense of what the subject knows, and you can then circle back with focused probing. Divide up their story into time chunks or scenes, and walk through the event again. Avoid skipping around in time. "Tell me more about 'x'? Can you describe 'y' in more detail? What was your impression of …? What did you think when you saw …? What did you think was happening when…? What were you thinking\feeling right then?"

In the case of diagnostic errors, it may be helpful to have them walk through the sequential steps of the diagnostic process: "What did you learn from the history? Tell me how the patient looked? What things did you include in the physical exam? What was your impression – did the patient appear sick? In distress? If they didn't impress you as being sick, what was it about their appearance that was reassuring? What happened then….?"

Depending on the type of case, having a sense of the factors that most commonly contribute to error may be helpful in constructing probes and prompts. Just as an example, if the case involved the delayed diagnosis of cancer, review the common root causes for this in advance, (See Appendix ZZZ) and have them available during the interview.

Use 'special opportunities' to enhance recall: After the clinician has finished telling their story, you can attempt to probe further. Try these different approaches:
- Change their perspective: Ask them to tell you the story again, but focusing on a different person
- Ask them to diagram the scene, or the sequence of events
- Ask them to walk you through the event _backwards,_ starting at the end

The review phase
Summarize what you heard and let the subject have the chance to recall or clarify details, Use teach-back. "I'm going to tell you what I think I've heard; Let me know what I've missed or got wrong". Invite the subject to share anything ELSE they remember later that they may not have mentioned. Try to leave a positive impression – they them how helpful their story is and

that you appreciate them taking the time to be with you. If the subject was emotionally traumatized by the event, try to offer emotional support and convey your sympathy.

Based on materials presented by Al Duke MBA BSN RN CPPA, and Jon Stewart, JD, MSc, MS, RN. Beta Healthcare

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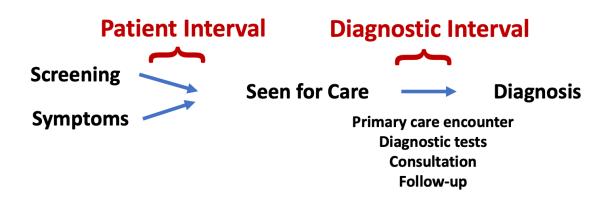
Appendix G: Factors to consider in root cause analysis

Delayed diagnosis   One approach to considering the factors that contribute to delayed diagnosis uses a framework that envisions a pathway to diagnosis that includes a patient interval and a diagnostic interval. (Figure below). The diagnostic interval includes many steps, starting with screening or detection of symptoms, encounters in primary and specialty care, diagnostic tests, and appropriate follow-up. Commonly-encountered factors within each of these intervals are listed below, using delayed diagnosis of cancer as the example.
[1-13]

The Cancer Diagnosis Pathway

Patient Interval   **Diagnostic Interval**

Screening
Symptoms   **Seen for Care**   **Diagnosis**

Primary care encounter
Diagnostic tests
Consultation
Follow-up

The patient interval

Screening
- Delayed screening or no screening: Patient reluctance; logistical issues; financial issues;
- False negative screening tests; results lost or not communicated;
- Positive results not followed-up

Symptoms
- Vague, non-specific symptoms, chronic symptoms
- Reluctance to seek care; delays moving from contemplation to action
- Health literacy; family and social support; psychological state
- Difficulty engaging in care: financial; limited access; time off from work; other logistical issues
- Seeking care from non-medical advisors: Family, religious advisors, friends, internet, holistic practitioners
- Equity issues: Distrust; financial issues; logistical issues; health literacy issues; language barriers

The diagnostic interval

Primary care encounter
- Delays getting an appointment
- Disease presentation: Non-specific or masked symptoms; atypical symptoms; rare cancer type
- Provider issues: Burnout; distractions;
- Patient issues: Chronic conditions; too many problems; not a good historian
- System issues: Not enough time for new patients; clumsy EMR;
- Cognitive error

Consultation
- Not available; not affordable; not convenient; not timely
- Reports delayed or not communicated
- Confusion over who is responsible for follow-up; adequacy of communication with primary care provider and the patient
- Cognitive error

Diagnostic testing
- Not available; not affordable; not sensitive or accurate or complete
- Results delayed or not communicated

Follow-up and care coordination
- Patient issues: Adherence to follow-up; Insurance coverage issues; Problems arranging coverage for work, home duties
- Provider issues: Failure to follow-up on tests, consults, non-specific symptoms
- System issues: Losing patient to follow up; staffing shortages; disjointed care across departments or healthcare organizations

Case-related factors
- Atypical presentations
- Non-specific symptoms and signs
- Unfamiliar/outside specialty
- Symptoms masked by another condition
- Red herrings and misleading findings
- Rapidly progressive course
- Slowly evolving course or deceptively benign course
- Delays in seeking care
- Inadequate follow-up

Patient Factors
- Age, sex, race, ethnicity, religion, political beliefs
- Language & communication barriers
- Issues related to personality, demeanor, courtesy, agitation, cooperation
- Disturbing and distracting issues: Suicide patients, prisoners and criminals, abortion complications, patients with mental health conditions
- Signal-to-noise issues (patients with multiple other symptoms or diagnoses)
- Failure to share data (patients who aren't forthcoming with their symptoms or their severity)
- Failure to follow-up with visits, consults, testing, trial of treatment
- Failure to keep prior doctor's notes and test results

Diagnostic testing
Pre-analytical
- Clinicians not familiar with appropriate diagnostic tests (or sequences) to order
- Pre-analytical issues (contamination, storage, etc)
- Test or test result not available due to cost, access, geography, etc
- Logistical problems scheduling or performing
Analytical
- False positive/negative test limitations; missed findings; wrong findings
- Test not available, not done, mislabeled
- Inherent delays; send-out tests; other delays (equipment down, reagents on order, …)
Post-analytical
- Result interpretation issues; equivocal results; normal result but trend not appreciated

- Breakdowns in test result communication or follow-up
- Problem not knowing the next test to order

Consult issues
- Subspeciality consult not available, or low quality
- Delays obtaining consult appointments
- Timely communication of results
- Anchoring effects (consultant accepted the referring diagnosis)
- Context errors (disease was in a different sub-specialty)
- Ambiguity over who will follow-up or manage the patient

Physician\Clinical Factors
- Knowledge and experience
- Specialty area
- Beliefs, values, understandings that affect diagnosis
- Fatigue, stress, sleep deprivation, burnout, frustration, etc – see contributing factors
- Inadequate\inaccurate history, physical exam, data interpretation
- Synthesis errors:
  o Cognitive and affective bias
  o Critical thinking error
- Case management issues: failures to communicate, follow-up
- Documentation issues: inaccurate, incomplete, delayed
- Poor calibration
- Provider disagreement

Contributing Factors; Error-producing conditions [14]
- Fatigue
- Sleep deprivation
- High-stress situation
- Corridor consultation (Curbside consult)
- Transition of care and fragmented\discontinuous care
- Production pressure and time constraints
- SATO (Speed vs Accuracy Trade Off) - Speed-Accuracy trade-off
- RACQITO (Resource availability – continuous quality improvement trade-off)

- Cognitive overload
- Rapid task switching
- Poor feedback
- Time delay error
- Various system-related and contextual factors

System and Contextual factors

- Workload\time pressure
- Distractions
- Culture; teamwork; trust
- Communication and coordination issues
- Communicating test results, consults
- Adequacy of follow-up after positive screening test, new incidental finding, consult requests, patients with non-specific symptoms
- Continuity issues; handoff, transitions, disjointed care;
- Care at multiple sites or outside system
- Availability of support staff: office staff; nursing\pharmacy\nutrition\social work staff
- Availability and quality of resources for diagnosis: labs, imaging, consults
- Health IT resources: EMR, telehealth, patient portal
- Availability of patient records
- Familiarity with setting\resources
- Hardware\software issues
- Supervision of trainees
- External interference (insurance, medical records unavailable, etc)
- Clustering; normalization of deviance (pattern of the same error type recurring)
- Inadequate or unclear policies and procedures
- Decision support issues

"No Fault" Factors

- Atypical or masked presentation
- Atypical course
- Rare or unknown disease
- Patient uncooperative, deceptive

Health IT Factors – Classification of Magrabi et al[15]

Information input problems
Machine data capture device down or unavailable
Human data entry and record manipulation
- Wrong input
- Wrong data
- Failure to update data
- Fail to communicate\carry out task

Machine information transfer problem
Network down or too slow
Software interface issues

Information output problems
Output device down or unavailable
Record unavailable
Output\display error

Data retrieval error
- Wrong record retrieved
- Missing data (did not look at complete record)
- Human did not look
- Not alerted

General technical
Computer system down or slow
Software not available
Access problem (unable to log in)
Software issue
- Software functionality
- Software\system configuration
- Software interface with devices
- Network configuration
Data loss

Human contributing factors
Staffing/training
Cognitive load
- Interruption
- Multitasking
Fail to carry out duty

Fail to log off

Health IT Factors – Joint Commission classification [2]

Top 10:[16]
1. Communication among team members
2. Data entry or selection (entry or selection of wrong patient, providers, drug, dose,…)
3. Clinical content – unexpected software design issue
4. Sub-optimal support of teamwork (situational awareness)
5. Decision support – missing recommendations or safeguards
6. Information hard to find
7. Information display or interpretation issue (font size, color, location of information on the screen, etc)
8. Mismatch between user mental models\expectations and health IT
9. Human computer interface – unexpected software design issues
10. Hardware location (awkward placement for use, etc)

Hardware and software computing infrastructure
Incompatibility between devices
Equipment/device maintenance
Hardware failure or problem
Network failure or problem
Security, virus, or malware issues
Unexpected software design issue
Interactions with other care systems
Inadequate secured data
Software not available
Data retrieval error

Human-computer interface contributing factors
Ergonomic
- Data entry or selection (e.g., entry or selection of wrong patient, wrong provider, wrong drug, wrong dose)
- Information hard to find
- Difficult data entry
- Information display or interpretation (e.g., font size, color of font, location of information in display screen)
- Unexpected software design issue (i.e., event in which the safety issue is caused by an unforeseen or unexpected aspect of the software design) related to the human-computer interface
- Hardware location (e.g., awkward placement for use)
- Alert fatigue/alarm fatigue

- Inadequate feedback to the user
- Data retrieval error—(human) missing data (i.e., did not look at complete record)
- Excessive demands on human memory

Equipment/device function
- Image orientation incorrect or distorted
- Image measurement/corruption
- Incorrect test results

People
Human factors
- Stress
- Inattention
- Health issues
- Cognitive load; Interruptions; multitasking
- Failure to carry out duty; failure to log off

Data retrieval error – did not look
Staff qualifications: competence, training
Mismatch between user mental model and health IT expectations

Workflow and communication contributing factors
- Communication—Among team members; supervisor to staff; staff to patient
- Suboptimal support of teamwork (situation awareness)
- Mismatch between user mental models/expectations and health IT
- Communication—Staff to patient or family

Clinical content contributing factors
Unexpected software design issue (i.e., event in which the safety issue is caused by an unforeseen or unexpected aspect of the software design) related to clinical content

IT contributed to entry of data in the wrong patient's record
Patient information routed to the wrong recipient
Faulty reference information
Unpredictable elements of record available only on paper\scanned
    documents
Inaccurate natural language processing
Incorrect or inappropriate alert

Decision support—Missing recommendation or safeguard
- Excessive recommendations
- Faulty or missing recommendations

- Inadequate clinical content
- Inappropriate level of automation

Equipment\device function
- Lost or delayed data; data accuracy; data legibility
- System returns or stores data that do not match patient
- Incorrect software programming calculation
- Incorrect or inappropriate alert

Internal organizational policies, procedures, and culture

Environment
- Culture of safety
- Management
- Physical surroundings

Supervision/support: Clinical supervision; Managerial supervision

Policies and procedures: Presence; clarity

Local implementation
- Faulty local configuration or programming
- Inadequate local testing
- Inadequate software change control
- Inadequate control of user access
- Suboptimal interface management
- Organizational policy contributed to entry of data in wrong patient record

External rules, regulations, pressures

Vendor factors
- Faulty vendor configuration recommendations
- Unusable software implementation tools
- Nonconfigurable software
- Inadequate vendor testing or change control
- Inadequate control of user access
- Faulty software design or specification

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Appendix H: 50 Cognitive and Affective Biases

Pat Croskerry MD, PhD; Dalhousie University, May 2013

See detailed descriptions and examples of these and others here: Achieving Quality in Clinical Decision Making: Cognitive Strategies and Detection of Bias. Pat Croskerry. Acad Emerg Med, 2002. 9(11):1184-1204

***Aggregate* bias**: when physicians believe that aggregated data, such as those used to develop clinical practice guidelines, do not apply to individual patients (especially their own), they are invoking the *aggregate fallacy*. The belief that their patients are atypical or somehow exceptional, may lead to errors of commission e.g. ordering x-rays or other tests when guidelines indicate none are required.

Ambiguity effect: ambiguity is associated with uncertainty. The ambiguity effect is due to decision makers avoiding options when the probability is unknown. In considering options on a differential diagnosis**,** for example, this would be illustrated by a tendency to select options for which the probability of a particular outcome is known, over an option for which the probability is unknown. The probability may be unknown because of lack of knowledge, or because the means to obtain the probability (a specific test, or imaging) is unavailable.

Anchoring: the tendency to perceptually lock on to salient features in the patient's initial presentation too early in the diagnostic process, and failing to adjust this initial impression in the light of later information. This bias may be severely compounded by the *confirmation* bias.

***Ascertainment* bias**: occurs when a physician's thinking is shaped by prior expectation; *stereotyping* and *gender* bias are both good examples.

Attentional bias: the tendency to believe there is a relationship between two variables when instances are found of both being present. More attention is paid to this condition than when either variable is absent from the other**.**

Availability: the disposition to judge things as being more likely, or frequently occurring, if they readily come to mind. Thus, recent experience with a disease may inflate the likelihood of its being diagnosed. Conversely, if a disease has not been seen for a long time (is less available) it may be under-diagnosed. The ***availability cascade*** occurs when a collective belief becomes more plausible through increased repetition e.g. 'I've heard this from several sources so it must be true'.

Bandwagon effect: is the tendency for people to believe and do certain things because many others are doing so. Groupthink is an example and may have a disastrous impact on team decision making and patient care.

Base-rate neglect: the tendency to ignore the true prevalence of a disease, either inflating or reducing its base-rate, and distorting Bayesian reasoning. However, in some cases clinicians may (consciously or otherwise) deliberately inflate the likelihood of disease, such as in the strategy of 'rule out worst case scenario' to avoid missing a rare but significant diagnosis.

Belief bias: the tendency to accept or reject data depending on one's personal belief system, especially when the focus is on the conclusion and not the premises or data. Those trained in logic and argumentation appear less vulnerable to the bias.

Blind spot bias: the general belief people have that they are less susceptible to bias than others, due mostly to the faith they place in their own introspections. This bias appears to be universal across all cultures.

***Commission* bias**: results from the obligation towards beneficence, in that harm to the patient can only be prevented by active intervention. It is the tendency towards action rather than inaction. It is more likely in over-confident physicians. Commission bias is less common than omission bias.

***Confirmation* bias**: is the tendency to look for confirming evidence to support a diagnosis rather than look for disconfirming evidence to refute it, despite the latter often being more persuasive and definitive.

Congruence bias is similar to confirmation bias but refers more to an over-reliance on direct testing of a given hypothesis, and a neglect of indirect testing. Again it reflects an inability to consider alternative hypotheses.

***Contrast effect*:** occurs when the value of information is enhanced or diminished through juxtaposition to other information of greater or lesser value. Thus, if an emergency physician was involved in a multiple trauma case and subsequently saw a patient with an isolated extremity injury, there might be a tendency to diminish the significance of the latter.

Diagnosis Momentum: once diagnostic labels are attached to patients they tend to become stickier and stickier. Through intermediaries, (patients, paramedics, nurses, physicians) what might have started as a possibility gathers increasing momentum until it becomes definite and all other possibilities are excluded.

Ego bias: in medicine, is systematically overestimating the prognosis of one's own patients compared with that of a population of similar patients. More senior physicians tend to be less optimistic and more reliable about patient's prognosis, possibly reflecting ***reverse ego bias.***

Expectation bias: occurs when researchers tend to believe, certify and publish data that are in accord with their own expectations for the outcome of an experiment, or downgrade or minimize data that appear to be in conflict with those expectations. See also ***experimenter bias*** and ***myside bias.*** It can lead to researchers unconsciously manipulating their data to obtain an expected result.

Feedback sanction: is a form of *ignorance trap* and *time-delay trap* bias. Making a diagnostic error may carry no immediate consequences as considerable time may elapse before the error is discovered, if ever, or poor system feedback processes prevent important information on decisions getting back to the decision maker. The particular bias that failed the patient persists because of these temporal and systemic sanctions.

Framing effect: how diagnosticians see things may be strongly influenced by the way in which the problem is framed e.g. physicians' perceptions of risk to the patient may be strongly influenced by whether the outcome is expressed in terms of the possibility that the patient may die or that they might live. In terms of diagnosis, physicians should be aware of how patients, nurses and other physicians frame potential outcomes and contingencies of the clinical problem to them.

Fundamental attribution error: the tendency to be judgmental and blame patients for their illnesses (dispositional causes) rather than examine the circumstances (situational factors) that might have been responsible. In particular, psychiatric patients, minorities and other marginalized groups tend to suffer from this bias. Cultural differences exist in terms of the respective weights attributed to dispositional and situational causes.

Gambler's Fallacy: attributed to gamblers, the fallacy is the belief that if a coin is tossed 10 times and is heads each time, the 11th toss has a greater chance of being tails (even though a fair coin has no memory). An example would be a physician who sees a series of patients with chest pain in clinic or the emergency department, diagnoses all with an acute coronary syndrome, and assumes the sequence will not continue. Thus, the pre-test probability that a patient will have a particular diagnosis might be influenced by preceding, but independent events.

Gender bias: the tendency to believe that gender is a determining factor in the probability of diagnosis of a particular disease when no such pathophysiological basis exists. Generally, it results in an over-diagnosis of the favored gender and an under-diagnosis of the neglected gender.

Hawthorne effect: the tendency for people to perform or behave differently (usually making themselves look better than they really are) when they know they are being observed.

Hindsight **bias**: knowing the outcome may profoundly influence perception of past events, and prevent a realistic appraisal of what actually occurred. In the context of diagnostic error, it may compromise learning through either an underestimation (illusion of failure) or overestimation (illusion of control) of the decision maker's abilities.

Illusory correlation: the tendency to believe that a causal relationship exists between an action and an effect, often because they are simply juxtaposed in time. It is also the basis of stereotyping, assuming that certain groups of people and particular traits go together.

Information bias: the tendency to believe that the more evidence one can accumulate to support a decision the better. It is important to anticipate the value of information and whether it will be useful or not in making the decision, rather than collect information because we can, or for its own sake, or out of curiosity.

Multiple alternatives **bias**: a multiplicity of options on a differential diagnosis may lead to significant conflict and uncertainty. The process may be simplified by reverting to a smaller subset with which the physician is familiar, but may result in inadequate consideration of other possibilities. One such strategy is the three diagnosis differential: 'it is probably A, but it might be B, or I don't know (C)'. While this approach has some heuristic value, if the disease falls in the C category and is not pursued adequately, it will minimize the chances that some serious diagnoses can be made.

Mere exposure effect: the development of a preference for something simply because you are familiar with it. Also known as the *familiarity principle*, it can have widespread effects in medicine e.g. merely seeing a pharmaceutical product or being told about it may increase the likelihood of choosing it over other products.

Need for closure: is the bias towards drawing a conclusion or making a verdict about something when it is still not definite. It often occurs in the context of making a diagnosis where the clinician may feel obliged to make a specific diagnosis under conditions of time or social pressure, or to escape feelings of doubt or uncertainty. It might be preferable to say instead that the patient's complaint is 'not yet diagnosed' (NYD).

Omission bias: is the tendency towards inaction and rooted in the principle of non-maleficence. In hindsight, events that have occurred through the natural progression of a disease are more acceptable than those that may be attributed directly to the action of the physician. The bias may be sustained by the reinforcement often associated with not doing anything, but may prove disastrous. Omission biases typically outnumber commission biases.

Order effects: information transfer is a U-function: a tendency to remember the beginning part (primacy effect) or the end (recency effect) are referred to as serial position effects. Primacy effect may be augmented by anchoring. In transitions of care, where information transferred from patients, nurses, or other physicians is being evaluated, care should be taken to give due consideration to all information, regardless of the order in which it was presented.

Outcome bias: the tendency to opt for diagnostic decisions that will lead to good outcomes, rather than those associated with bad outcomes, thereby avoiding chagrin associated with the latter. It is a form of *value* bias in that physicians may express a stronger likelihood in their decision making for what they hope will happen rather than what they really believe might happen. This may result in serious diagnoses being minimized.

Overconfidence bias: there is a universal tendency to believe we know more than we do. Overconfidence reflects a tendency to act on incomplete information, intuitions or hunches. Too much faith is placed in opinion instead of carefully gathered evidence.

Playing the odds: also known as *frequency gambling*, is the tendency in equivocal or ambiguous presentations to opt for a benign diagnosis on the basis that it is significantly more likely than a serious one.

Posterior probability error: occurs when a physician's estimate for the likelihood of disease is unduly influenced by what has gone before for a particular patient. It is the opposite of the *Gambler's fallacy* in that the physician is gambling on the sequence continuing e.g. if a patient presents to the office five times with a headache and is correctly diagnosed as migraine on each visit, it is the tendency to diagnose migraine on the sixth visit.

Premature closure: is a powerful bias accounting for a high proportion of missed diagnoses. It is the tendency to apply premature closure to the decision making process, accepting a diagnosis before it has been fully verified. The consequences of the bias are reflected in the maxim 'when the diagnosis is made, the thinking stops'.

***Psych-out* error**: psychiatric patients appear to be particularly vulnerable to the biases described in this list, and to other errors in their management, some of which may exacerbate their condition. They appear especially vulnerable to *fundamental attribution error*. In particular, co-morbid medical conditions may be overlooked or minimized. A variant of psych-out error occurs when serious medical conditions (e.g. hypoxia, delirium, metabolic abnormalities, CNS infections, head injury) are mis-diagnosed as psychiatric conditions.

Reactance bias: the tendency towards doing something different from the rules, regulations or protocol because they are seen as threatening autonomy and constraining freedom of choice. This may also occur, for example, when a patient suggests a diagnosis based on what they found on Google to match their symptoms; the clinician's reaction might be due to a perception that they are being undermined or that their clinical acumen is being challenged.

Representativeness restraint: drives the diagnostician towards looking for prototypical manifestations of disease: 'if it looks like a duck, walks like a duck, quacks like a duck, then it is a duck'. Yet, restraining decision making along these pattern recognition lines leads to atypical variants being missed.

Search satisficing: reflects the universal tendency to call off a search once something is found. Co-morbidities, second foreign bodies, other fractures, and co-ingestants in poisoning may all be missed.

Self–serving bias: the tendency to claim more responsibility for successes than for failures. Clinicians may overestimate the number of times they have made a brilliant or insightful diagnosis and fail to remember their diagnostic failures.

Semmelweis reflex: the tendency to reject new evidence or new knowledge because it contradicts established norms, beliefs or paradigms. The bias takes its name from the reaction of the medical community against the findings of Dr. Ignaz Semmelweiss, the Hungarian physician who showed that hand-washing by physicians in an antiseptic solution before delivery reduced puerperal sepsis in the mother by 90%.

Sutton's slip: takes its name from the apocryphal story of the Brooklyn bank-robber Willie Sutton who, when asked by the Judge why he robbed banks, is alleged to have replied 'Because that's where the money is!' The diagnostic strategy of going for the obvious is referred to as *Sutton's Law.* The slip occurs when possibilities other than the obvious are not given sufficient consideration.

Sunk costs: the more clinicians invest in a particular diagnosis, the less likely they may be to release it and consider alternatives. This is an entrapment form of bias more associated with investment and financial considerations. However, for the diagnostician, the investment is time and mental energy, and for some ego may be a precious investment. *Confirmation bias* may be a manifestation of such an unwillingness to let go of a failing diagnosis.

Triage cueing: the triage process occurs throughout the health care system, from the self-triage of patients to the selection of specialist by the referring physician. In the emergency department, triage is a formal process that results in patients being sent in particular directions, which cue their subsequent management. Many biases are initiated at triage, leading to the maxim: 'geography is destiny'. Once a patient is referred to a specific discipline, the bias within that discipline to look at the patient only from their own perspective is referred to as ***déformation professionnelle.***

Unpacking principle: failure to elicit all relevant information (unpacking) in establishing a differential diagnosis may result in significant possibilities being missed. If patients are allowed to limit their history-giving, or physicians otherwise limit their history-taking, unspecified possibilities may be discounted.

Vertical line failure: routine, repetitive tasks often lead to *thinking in silos* – predictable, orthodox styles that emphasize economy, efficacy and utility. Though often rewarded, the approach carries the inherent penalty of inflexibility. In contrast, lateral thinking styles create opportunities for diagnosing the unexpected, rare or esoteric. An effective lateral thinking strategy is simply to pose the question: 'What else might this be?'

***Visceral* bias**: the influence of affective sources of error on decision-making has been widely underestimated. Visceral arousal leads to poor decisions. *Countertransference*, involving both negative and positive feelings towards patients, may result in diagnoses being missed.

Yin-yang out: when patients have been subjected to exhaustive and unavailing diagnostic investigations, they are said to have been worked up the Yin-Yang. The *yin-yang out* is the tendency to believe that nothing further can be done to throw light on the dark place where, and if, any definitive diagnosis resides for the patient i.e. the physician is let out of further diagnostic effort. This may prove ultimately to be true, but to adopt the strategy at the outset is fraught with a variety of errors.

Zebra retreat: occurs when a rare diagnosis (zebra) figures prominently on the differential diagnosis but the physician retreats from it for various reasons: perceived inertia in the system and barriers to obtaining special or costly tests, self-consciousness and underconfidence about entertaining a remote and unusual diagnosis, and gaining a reputation for being esoteric, the fear

of being seen as unrealistic and wasteful of resources, under or overestimating the base-rate for the diagnosis, the ED may be very busy and the anticipated time and effort to pursue the diagnosis might dilute the physician's conviction, team members may exert coercive pressure to avoid wasting the team's time, inconvenience of the time of day or weekend and difficulty getting access to specialists, unfamiliarity with the diagnosis might make the physician less likely to go down an unfamiliar road, fatigue or other distractions may tip the physician toward retreat. Any one or a combination of these reasons may result in a failure to pursue the initial hypothesis.

Appendix J - RCA Examples

RCA's involving the "Big 3" diagnostic error categories

RCA's involving the clinical laboratory:

Other RCA's

Delayed Diagnosis of Breast Cancer

A 60-year-old woman was seen for a routine visit by a physician assistant (PA) at a family medicine practice. A right breast mass was palpated and felt likely to be benign. However, the PA ordered a diagnostic mammogram and ultrasound examination. The radiologist reviewed the images, noting focal asymmetry in the right breast. The assessment was challenging due to dense breast tissue. Ultimately, the films were interpreted as "probably benign" findings (BI-RADS Category 3) and follow-up imaging at 6 months was recommended to ensure stability. The report noted that a biopsy should not be delayed if a "suspicious mass" is present on physical exam. Reassured by the report, the PA did not order a biopsy or refer the patient to a breast surgeon.

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The fishbone diagram below depicts in GREEN boxes the events/factors that contributed in a positive way towards diagnosis; the events and factors that interfered with the diagnosis are depicted in RED boxes.

The Context

- Timely appointments in primary care
- Specialty imaging available and performed
- Ambiguity re whether patient or surgeon was to arrange appointment
- Failure detecting delayed surgical consult

Clinician & Reasoning

- Adequate knowledge & experience managing breast mass?
- Failure interpreting radiology report (known mass would have changed actions taken)
- Breast mass palpated

The Patient

- Sought care

The Case

- Ambiguity inherent in BiRads 3 classifiations

Delayed diagnosis of breast cancer

REFERENCE

Case presented and discussed here:

Delayed Breast Cancer Diagnosis: A False Sense of Security. Saul N. Weingart, MD, MPP, PhD, Gordon D. Schiff MD, and Ted James, MD, FACS. PSNet, December 23, 2020.

https://psnet.ahrq.gov/web-mm/delayed-breast-cancer-diagnosis-false-sense-security
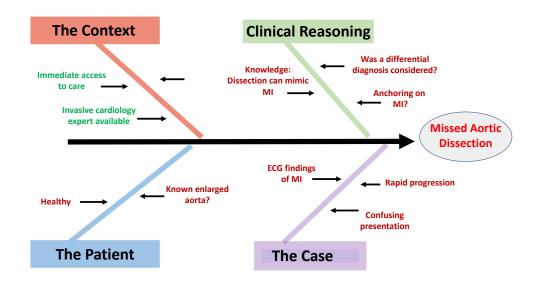
Missed diagnosis of aortic dissection: The case of John Ritter

John Ritter was an actor and comedian, famous for his role as Jack Tripper in the '3's Company' television show. He was in the Walt Disney Studios rehearsing for his role in '8 Simple Rules for Dating My Teenage Daughter' when he suddenly fell ill and began to experience problems with his heart. Sweating profusely, vomiting, and complaining of chest pain, he was taken across the street to Providence Saint Joseph Medical Center.

An emergency room doctor ordered tests, including a chest X-ray, and prescribed aspirin and anti-nausea medicine, records show. His ECG was suggestive of myocardial infarction. He was anticoagulated and taken for cardiac catheterization, but his condition worsened, a large aortic dissection was found, and he expired in the cath lab.

A body scan two years early may have shown an enlarged aorta, but the final report did not mention this. Patients with chest pain are about 100 times more likely to be suffering a heart attack than an aortic dissection. His aortic dissection involved the coronary artery, explaining the findings consistent with myocardial infarction.

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Similar case: Schleifer JW, Centor RM, Heudebert GR, Estrada CA, Morris JL. NSTEMI or not: A 59-year-old man with chest pain and troponin elevation. J Gen Intern Med. 2013;28(4):583–90.

Wrong diagnosis of Epilepsy;
Missed diagnosis of Long QT Syndrome – The Case of Jessica Barnett

We describe the case of Jessica Barnett, an adolescent girl whose repeated episodes of syncope and near-syncope were ascribed to a seizure or anxiety disorder. The correct diagnoses (congenital long QT syndrome; arrythmogenic right ventricular cardiomyopathy) were established by autopsy and genetic studies only after her death at age 17.

Jessica Barnett (**Figure 1**) was first evaluated at age 12 for episodes of syncope and near-syncope over the preceding three years. Many of the episodes were precipitated by a sudden, startling event. She reported that the episodes started with a dizzy feeling, often with blurring of vision or a buzzing in her ears, followed by loss of consciousness, typically lasting just a few minutes. She would awake with a sense of being shaky, short of breath, and groggy. During some of the episodes she was described by observers as having upward deviation of gaze, shaking of her arms and legs, and occasionally urinary incontinence. She was repeatedly evaluated at her local emergency department for many of these episodes with no clear diagnosis established.

FIGURE 1 - Jessica Barnett

Jessica was otherwise healthy and there was no family history of sudden death, cardiac conditions, seizures, or other health problems.

Her primary care physician referred her to a pediatric neurologist who documented a normal physical exam. A sleep-deprived EEG was ordered and was read as being normal, although

Jessica did not fall asleep during the examination. The neurologist's diagnostic impression was that the episodes were related to hyperventilation. The neurologist documented, "I also did a hyperventilation challenge (requesting that the patient take overly deep breaths at a rapid rate). She almost immediately broke into a fairly free-ranging hyperventilation pattern. Within seconds she complained of her vision being blurry with increasing ringing in her ears. … She said this was absolutely identical to the events that were described."

On a follow-up visit 9 months after her neurology evaluation, 12 year-old Jessica described having had several episodes, all occurring at night and awakening her from sleep, and not

precipitated by startling. This prompted the neurologist to revise his diagnostic impression: "I have a hard time reconciling the nocturnal events with hyperventilation. These may be nocturnal seizures". Treatment with clobazam was initiated for suspected seizures, and an MRI of the brain was normal.

At a follow-up visit 3 months later, additional episodes had occurred, and the clobazam dosage was increased. The family reported that an ECG done in the interval between visits had shown a possible prolonged QT interval, but a repeat ECG was within normal limits. Two months later, two near-syncope events had occurred during the daytime, one at a soccer practice and the other without any clear precipitant. The family again raised the possibility of long QT syndrome. Jessica and her family were exasperated: "No one knows what's the matter with me," she said at one point.

The pediatric neurologist requested a second opinion from a colleague: "I asked my colleague to briefly review the story with me, and I read the content of my first two major meetings with this family. At the end of that I asked what she thought the diagnosis was and she questioned my original thoughts about an underlying anxiety disorder. I then asked her what she thought about prolonged QT syndrome as the underlying condition for these events, and she emphatically felt that this could not be." The neurologist offered to arrange a cardiology consultation, but the family declined after the second neurologist's opinion. Repeating the sleep-deprived EEG was considered, along with possibly convening a larger group of neurology specialists to review the case.

At age 14, Jessica was seen by another pediatric neurologist for a formal second opinion. The syncopal and near-syncope events had persisted, some with clear precipitants and others without. MRI of the brain and EEG were normal. Several ECGs were performed, including one with a borderline QT interval. The hyperventilation trial was repeated and again reproduced her typical pre-syncope symptoms: "This is exactly how all her attacks began". Again, the diagnostic impression was syncope and presyncope secondary to hyperventilation. Clobazam was stopped, and Jessica was instructed to try controlling presumed hyperventilation attacks with breathing exercises. A cardiology consultation was also requested.

The pediatric cardiologist obtained a history of several additional attacks and documented: "most precipitated by fright and several while asleep. The noise awakens her and she feels her heart being squeezed and short of breath. The description of syncope following an episode of fright is certainly somewhat suspicious and as such we have chosen to investigate her further." An exercise stress test was reported as normal except for a brief period of bigeminy. Holter monitoring results were unavailable.

The cardiologist requested a second opinion from a colleague who specialized in congenital arrhythmia disorders. The response was: " ...I think that observation would suffice. Signal average ECG may be useful in some and in cases I [consider] an MRI. I have not placed [longer term recording] devices in this subgroup but if the family is worried, that might be warranted. I

do not think I would do biopsy or electro-physiologic studies, especially if the history is generally reassuring for reflex mediated syncope"

Jessica experienced her final episode at age 17, described as syncope followed by seizure-like activity, followed by cardiac arrest and unsuccessful resuscitation.
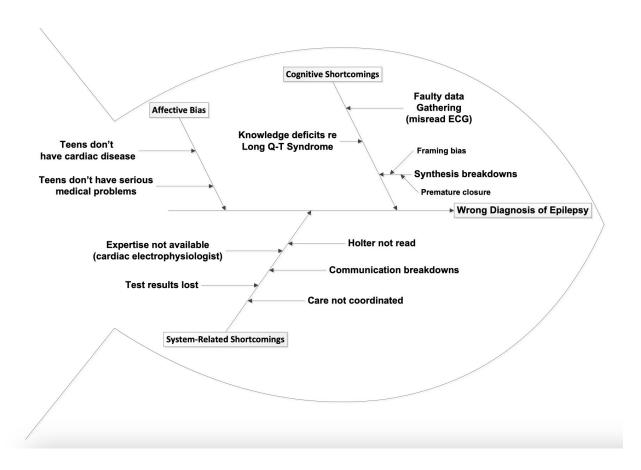
The Holter report, reviewed post-mortem was read as being normal. A second review, with knowledge of the fatal outcome, noted periods of QT-prolongation on the Holter monitor.

AUTOPSY FINDINGS:

The autopsy revealed a normal brain and a dilated right ventricle with fibrofatty replacement most prominent in the anterior free wall, with focal areas of transmural involvement. There was focal fibrosis of the left ventricle that was 'likely greater than expected for age'. Genetic testing revealed a mutation in KCNH2 associated with long QT syndrome. There were polymorphisms but no classical mutations in the gene associated with arrhythmogenic right ventricular cardiomyopathy. The impression from the autopsy was: "The most likely cause of death is Long QT Syndrome based on the cardiac arrest, the antecedent ECG findings, and the genotype results. The pathologic findings raise the possibility that the decedent may have also had ARVC (arrhythmogenic right ventricular cardiomyopathy)."

Of note, the same mutation was subsequently identified in Jessica's father, who had one isolated unexplained syncopal event in mid-life, and was treated with an implanted defibrillator as secondary prevention. Two brothers were tested with no identified mutations.

TESTS AND DATES	SUMMARY	REPORT
Electrocardiograms		
Dec 2002	Abnormal – QTc 510 msec	Normal sinus rhythm was T-wave flattening and notching in multiple leads
May 2004	Normal – QT 456 msec; QTc 436 msec	NSR with diffuse T-wave flattening and notching in lead II and V5. QTc appears to be 460 msec HR 55. QRS 76 msec
June 2004	Normal – QTc 420 msec	NSR with T wave flattening with subtle bifid appearance in lateral precordial leads.
Jan 2006	Normal – QT\QTc = 460\451 msec	NSR with t wave flattening/notching but the QTc interval appears to be approximately 440 msec HR 58 QRS 74 msec
MRI July 2004	Normal	Unenhanced study. No abnormalities detected
EEG July 2003	Normal	Sleep deprived but 'patient defeats the purpose with a cup of coffee'. Awake recording: fragments of occipital dominant activity at 9 Hz. Prominent mu, more so on the right than the left. Symmetrical background. Hyperventilation = no activation. Photic stimulation = some driving is present. No epileptic discharge.
Exercise ECG April 2006	Normal	Showing exercise-associated bigeminy. No strips available for review. No mention of abnl T waves or QT interval. "Nml QT response to exercise" Max HR 187; Max mets 16. No sx. Single ventricular couplet and bigeminy during stage 3-4 that resolved and did recur during recovery
Holter Monitor April 2006 (Not reviewed antemortem)	Abnormal	Predominantly NSR with rare PVCs and PACs. Two monomorphic ventricular couplets. 'On several occasions repolarization becomes abnormal with QT lengthening and T wave notching' 89 ventricular beats (<1%); 85 isolated, 2 couplets, 60 bigeminal, 0 runs
Genetic Testing (Postmortem)	Abnormal	Class 1 (disease associated) mutation in KCNH2 (Ala 565 Thr).

Cognitive Shortcomings

Faulty data
Gathering
(misread ECG)

Affective Bias

Knowledge deficits re
Long Q-T Syndrome

Teens don't
have cardiac disease

Framing bias

Synthesis breakdowns

Teens don't have serious
medical problems

Premature closure

Wrong Diagnosis of Epilepsy

Expertise not available
(cardiac electrophysiologist)

Holter not read

Communication breakdowns

Test results lost

Care not coordinated

System-Related Shortcomings

Missed diagnosis of cerebellar infarction

Note: This case was published from the "Case Records of the Massachusetts General Hospital" in the New England Journal of Medicine.(1) These case discussions present the facts of the case in a time-ordered fashion, with an expert diagnostician discussing the significance of the findings as they emerge, and his\her diagnostic reasoning at each stage.

Case: A 39-year-old Sri Lankan male physiotherapist presented to an emergency department in Toronto with a three-day history of headache, chills, diarrhea, nausea, vomiting, and neck stiffness. He reported having had vertigo, left-sided facial paresthesia, incoordination, and dysarthria, which had lasted for several minutes at the onset of his illness. These symptoms disappeared and were followed by the other symptoms noted above. His history was significant only for type 2 diabetes mellitus and chronic neck symptoms following a motor vehicle collision seven years earlier.

The patient reported that his symptoms had begun shortly after he had eaten a dorado fish that was freshly caught and imported from the Dominican Republic by his brother. He was worried about possible poisoning due to "red tide," a contamination of water by toxic algae. A physician was contacted in the Dominican Republic where the fish had been caught, who reported that the algae containing ciguatoxin were not in bloom.

On examination, the patient appeared acutely ill, with a dazed appearance, a heart rate of 96 beats per minute, a respiratory rate of 14 breaths per minute, a blood pressure of 124/80 mm Hg, and a temperature of 35.8°C. The neurologic examination was normal except that the patient was drowsy and had a sustained horizontal nystagmus on left- ward gaze. His neck was supple and was negative for Kernig's and Brudzinski's signs. The remain- der of the physical examination was normal. The results of initial laboratory tests were as follows: hemoglobin level, 15.2 g per deciliter; white-cell count, 13,100 per cubic millimeter (neutrophilia); platelet count, 267,000 per cubic millimeter; and normal levels of electrolytes, creatinine, glucose, and prothrombin and a normal partial-thrombolastin time.
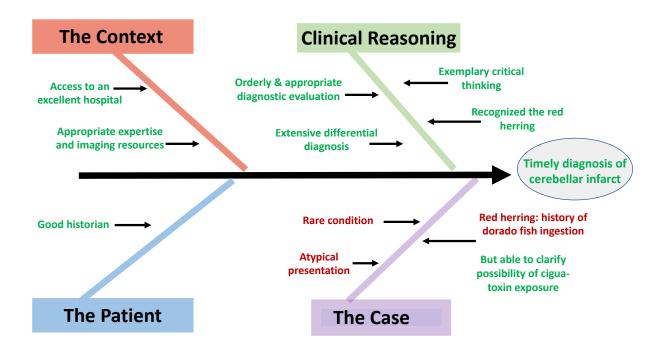
CT scanning of the head showed no evidence of a space-occupying lesion or an intracranial hemorrhage. And emergency room physician then performed a lumbar puncture, which was uncomplicated and successful. The CSF fluid showed 197 leukocytes per cubic millimeter and 7690 anthracites. In the fourth tube there were 237 leukocytes and 4700 erythrocytes. Stains were negative for bacteria and yeast.

Treatment was started with broad-spectrum antibiotics and acyclovir. When questions further, the patient reported that a chiropractor had manipulated his neck in an attempt to alleviate his chronic neck pain a few hours before presentation.

MRI of the brain showed an abnormality in the left cerebellar hemisphere. It was increased signal intensity, with enhancement in the territory of the left posterior inferior cerebellar artery, and irregularities of the left vertebral artery at C 1–2, establishing the diagnosis of cerebellar infarction from vertebral artery dissection.

The patient was anticoagulated and over the next days and weeks; his symptoms resolved, and he was discharged.

This case illustrates the timely diagnosis of a patient with complicated symptoms and findings. It can be used to illustrate how diagnosis works at its best, and the fishbone diagram below is used to portray this type of "Safety 2" analysis. Elements that positively influenced the diagnostic process are shown in **GREEN**, and elements are shown in **RED**.

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Delayed Diagnosis of Sepsis: The Rory Staunton Case

Rory Staunton was a 12-year-old boy with the dream to grow up to be a pilot -- he had fallen in love with the story of "Sully" and the miracle landing of the disabled jet on the Hudson River.

Rory was diving for a ball at recess one day. He got the ball but scraped his arm. Two nights later (**Wednesday**) he awoke with fever, chills, and vomiting.

Thursday AM: He felt worse. He was seen in the office of his pediatrician. T 102; HR 140; RR 36; BP 100/60. His skin was described as "mottled". The abdomen was benign. The assessment was: Gastroenteritis and he was referred to a local emergency department.
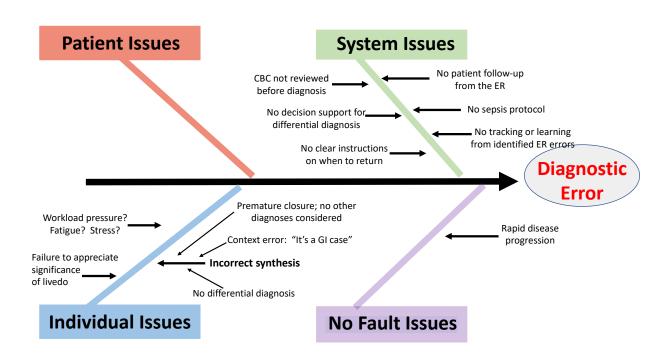
That afternoon in the ED: T 100; HR 143; RR 20; BP 94/46. The abdomen was again described as benign; There was no skin exam documented. The assessment was again "Gastroenteritis". He was given ondansetron, 1 liter of normal saline IV, and sent home. His lab tests returned after his discharge disclosing WBC 14.7 with 53% bands.

Friday   At home Friday he was worse. His skin was sensitive to touch, turning splotchy and blue with red spots. His parents called the pediatrician multiple time but didn't speak with him\her directly. A nurse advised acetaminophen.   His parents took him back to the ED later Friday night, where he was admitted to the ICU.

Saturday The diagnosis of **Streptococcal sepsis** was established and he was treated aggressively with fluids and appropriate antibiotics, but he died the next day.

Patient Issues

System Issues

CBC not reviewed
before diagnosis

No patient follow-up
from the ER

No decision support for
differential diagnosis

No sepsis protocol

No tracking or learning
from identified ER errors

No clear instructions
on when to return

Diagnostic Error

Workload pressure?
Fatigue? Stress?

Premature closure; no other
diagnoses considered

Context error: "It's a GI case"

Rapid disease
progression

Failure to appreciate
significance
of livedo

Incorrect synthesis

No differential diagnosis

Individual Issues

No Fault Issues

Case: Jim Dwyer. An infection, unnoticed, turns unstoppable. NY Times. July 12, 2012

Missed Diagnosis of Ebola Infection: The Case of Thomas Eric Duncan
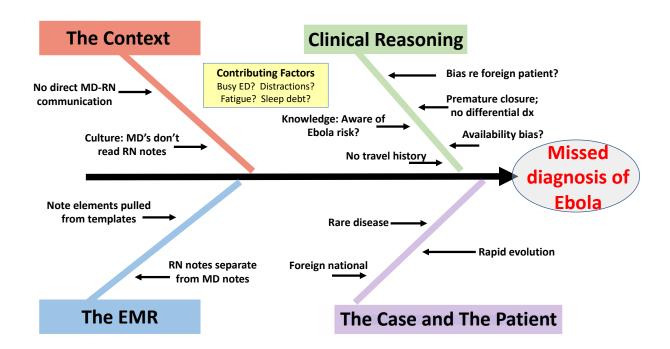
On September 15, 2014, the family of Marthalene Williams, who later died of Ebola, could not call an ambulance to transfer the pregnant Williams to a hospital. Duncan, their tenant, helped to transfer Williams by taxi to an Ebola treatment ward in Monrovia. Duncan rode in the taxi to the treatment ward with Williams, her father and her brother.[

On September 25th, Mr. Duncan presented with a temperature of 100.1F, dizziness, nausea, abdominal pain, a sharp headache, and decreased urination. 3.5 h into the patient's visit to the ED his temperature spiked to 103 degrees. The patient rated his "severe pain" at eight on a scale of 1 to 10. He related a history of travel from Liberia to the nurse, and this was recorded in her notes. The physician apparently did not obtain a travel history and did not speak with the nurse or read her notes. CT scans of the head and abdomen were 'negative'. The impressions at discharge 4 hours after admission included sinusitis and abdominal pain.

On September 28th, the patient's condition had deteriorated; he returned to the hospital, was admitted, and died days later with an autopsy-confirmed diagnosis of Ebola infection. Two nurses who cared for Mr Duncan subsequently developed Ebola infection, but recovered.

The patient was seen at the height of an Ebola epidemic in Western Africa, and the CDC had issued numerous alerts to health care providers nationwide to be alert to the possibility of infection in international travelers. He was the first known case of Ebola infection diagnosed in the United States.

Fishbone (Ishikawa) diagram: Missed diagnosis of Ebola

The Context
- No direct MD-RN communication →
- Culture: MD's don't read RN notes →

Contributing Factors
Busy ED? Distractions?
Fatigue? Sleep debt?

Clinical Reasoning
- Bias re foreign patient? ←
- Premature closure; no differential dx ←
- Availability bias? ←
- Knowledge: Aware of Ebola risk? →
- No travel history →

The EMR
- Note elements pulled from templates →
- RN notes separate from MD notes ←

The Case and The Patient
- Rare disease →
- Rapid evolution ←
- Foreign national →

Missed diagnosis of Ebola

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1.	Upadhyay D, Sittig D, Singh H. Ebola US Patient Zero: lessons on misdiagnosis and effective use of electronic health records. DIAGNOSIS. 2014;1(4):283-6.
2.	Wikipedia: Thomas Eric Duncan

Missed Diagnosis of EBV Infection: The Case of Julia Berg

Clinical Course

Julia was a 15 year old previously healthy girl who presented to urgent care with one week of fevers, fatigue, and a sore throat. She developed a prolonged nosebleed, which was unusual for her, prompting her parents to bring her in to the urgent care clinic. In the clinic, she was found to have leukocytosis (11.8 K/mm^3) with 76% lymphocytes and 9% monocytes as well as thrombocytopenia; a blood smear showed reactive lymphocytes. Urinalysis was notable for large leukocyte esterase, bilirubin and urobilinogen, 10-20 WBC/HPF, 5-10 RBC/HPF, 'many' bacteria with few squamous cells and no casts. The presumptive diagnosis was a urinary tract infection, and a culture subsequently grew > 100,000/ml pansensitive E Coli. She was started on oral cephalexin. Two days later, she was seen for followup in her pediatrician's office by one of her pediatrican's partners whom she had never seen before. She had fever to 102°F with chills, headache, abdominal cramps and another nosebleed, along with being "very tired" but denied dysuria. She had been encouraged to drink extra fluids but couldn't because of a sore throat. She also complained of sharp right upper quadrant abdominal and flank pain that was rated 7-9/10 in intensity, and worse on palpation during inspiration. There was also left upper quadrant abdominal pain and tenderness of lesser intensity.   A repeat CBC showed 79,000 platelets/mm^3, and 18,100 WBC/mm^3 with 79% lymphocytes. The impression at this followup visit was a possibly resistant bacterial urinary tract infection. She was given ceftriaxone 2 gm intramuscularly and started on oral ciprofloxacin.

She was seen again 2 days later (now 11 days after the onset of her illness) in her pediatrican's office. Her fevers had abated and her appetite had improved, but she continued to have right-sided flank pain with tenderness with palpation at the costovertebral angle. An urgent CT scan was ordered to exclude a perinephric abscess that showed no evidence of abscess or pyelonephritis but the right ureter appeared minimally dilated. The liver was normal in size and homogenous in appearance. The gallbladder appeared markedly abnormal with thickened walls and pericholecystic fluid. The spleen was 'upper limits of normal' in size. The radiologist's impression of the CT was recored as: "cholecystitis and diseases which can affect the gallbladder secondarily such as hepatitis." A repeat urine culture was sterile after 24 hours.

She was admitted electively to a tertiary children's hospital for suspected cholecystitis and evaluation for other possible diagnostic considerations, such as pancreatitis, choledocholithiasis, and nephrolithiasis.

On admission she was again febrile (38.8°C). Labs were notable for elevated bilirubin (7.2 mg/dL), predominantly conjugated (5.2 mg/dL) with elevated aminotransferases (See Table 1). Amylase and lipase were normal. Her CBC continued to reveal marked lymphocytosis, although this was not commented upon in the admission notes.

An abdominal ultrasound noted a positive sonographic Murphy's sign (increased RUQ pain with palpation), and marked thickening of the gallbladder wall. The common bile duct was normal in size. There was no suggestion of cholelithiasis or choledocholithiasis, "although the marked increase in echogenicity of the wall as well as the minimal intraluminal fluid makes it difficult to definitively exclude the presence of a small stone." The liver and intrahepatic biliary tree were otherwise normal. The impression was "consistent with cholecystitis". She was started on IV piperacillin/tazobactam and a surgical consultation obtained. The surgery team reviewed the CT and ultrasound findings and concluded that Julia had hyperbilirubinemia and fever, consistent with cholecystitis and possible biliary obstruction.

A pediatric gastroenterology consultation on the second hospital day noted the abnormal liver function tests (LFT's) and imaging studies, but again did not mention the hematologic abnormalities. Their impression was cholecystitis without ductal dilation, although the 'elevated direct bilirubin was concerning'. The consultant stated they "...would not search for alternative etiology for increased labs as they can be explained by cholecystitis". The plan was to repeat imaging if the bilirubin increased and consider an endoscropic retrograde cholangiopancreaticogram (ERCP). The surgical consultant concurred with the impressions of cholecystitis and possible cholangitis.

Over the next two days, she remined febrile to 38.9 °C and continued to have marked right upper quadrant tenderness to palpation, although her appetite and oral intake improved. Her aminotransferases and bilirubin were again noted to be elevated but her persistent lymphcytosis was not commented upon in the progress notes. Given her lack of definitive improvement, a HIDA scan was performed on the fifth hospital day that revealed: "Excellent hepatic extraction of isotope is seen. At no time is there visualization of the GB or activity in the intestinal tract".

The next day, pediatric and surgery continued to note the persistent elevations of LFT's without mentioning the CBC abnormalities. An ERCP was performed that revealed no stones and normal biliary flow. *The endoscopist made a prescient comment: "Have we found unifying diagnosis?"*

On the seventh hospital day, now over 2 weeks into Julia's illness, the surgical consultant documented a discussion including the surgeon and both GI consultants (the consultant and physician who performed the ERCP). The decision was made to proceed was a laparascopic cholecystectomy with a liver biopsy. A GI note notes the ERCP findings and persistently elevated bilirubin and LFT's. The pre-operative platelet count was 147K/mm^3.

Julia was taken to the operating room for a laparoscopic cholecystectomy and liver biopsy. Anesthetic agents and adjunctive medications included fentanyl, midazolam, rocuronium, lidocaine, propofol, and ondansetron.At the initiation of the surgical procedure, an nasogastric tube was passed with return of a small amount of blood. This cleared immediately, but 1 unit of fresh frozen plasma was ordered and transfused. The laparascopic procedure was uneventful

with minimal (10 cc) blood loss. The surgical field and biopsy site were noted to have achieved hemostasis before surgical closure. The surgeon's dictated postoperative note mentions gallstones demonstrated on one of the pre-operative imaging exams, in conflict with the imaging reports which specifically report the absence of visible stones.

Approximately 2 hours post-operatively Julia became hypotensive, hypoxic, unresponsive, and a "code blue" was called.   A blood gas revealed a pH of 7.14, with a pO2 of 90 mmHg and pCO2 of 58 mmHg. A repeat pH was < 6.8. A serum calcium was grossly elevated; serum potassium was >10 mEq/L. Hgb was 7.5 gm/dL (compared to 11.3 pre-op); on repeat, the Hgb was 5.8 gm/dL. She was given fresh frozen plasma, packed red blood cells, and crystalloids. Aggressive cardiac resuscitation did not achieve return of sponatenous circulation, and Julia was pronounced dead one hour later.

Autopsy Examination

Gross findings were notable for petechiae of the skin and palette, blood in the GI tract, and adrenal medullary hemorrhage, all thought to reflect disseminated intravascular coagulation (DIC). There was hepatosplenomegaly (liver weight 2100 gms) but there were no gallstones.

Microscopic examination of the liver revealed chronic-appearing hepatitis with peri-portal inflammation and bile stasis, with mild steatosis. The lobules showed prominent lymphocytosis, with mild canaliculuar cholestasis, mild to moderate miicrovasicular steatosis, and a slight pericentric accentuation of the inflammation with minimal hepatocellular necrosis. In special stains the lymphocytes were predominantly T cells (CD3 positive) with only scattered B Cells (CD20 positive). In situ hybridization for Epstein-Barr virus (EBV) showed a moderate number of positive cells.

Histologic sections of the GB showed a dense chronic inflammatory infiltrate within the subepithelial lamina propria, muscularis propria and in patches in the adventitia, similar to that seen in the liver."   Flourescent in situ hybridization (FISH) staining disclosed severe hepatitis and sinusoidal inflammation of the gall bladder. The infiltrate contained an equal number of Epstein Barr virus positive B and T cells. No clonal populations were detected by PCR
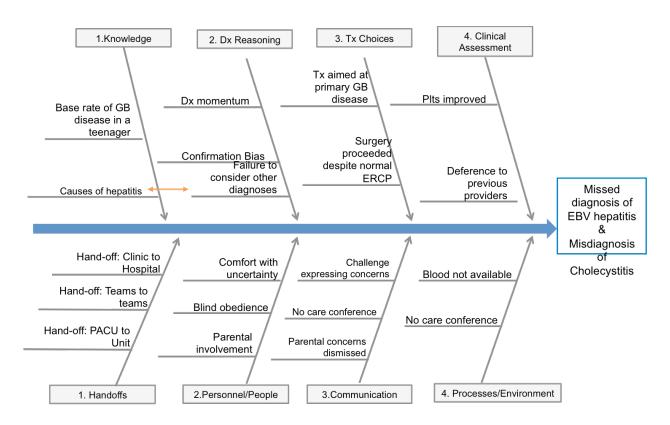
Post-mortem blood tests found elevated levels of Epstein-Barr virus IgM antibody (50 Au, normal 0-19) and negative antibody screens for CMV, and Hepatitis B and C. IgG antibodies to Hepatitis A were elevated but there were normal levels of anti-Hep A IgM.

The autopsy diagnosis was active EBV infection with moderately severe hepatitis and disseminated intravascular coagulation, citing this as an unusual but well described complication of EBV infection.

The discharge coding included all of the procedures and various diagnoses including cholecystitis and choledocholithiasis, but no mention of Ebstein-Barr virus infection. Her death

certificate listed the cause of death as "Complications of disseminated intravascular coagulation and liver failure" and "Fulminant Epstein-Barr Virus Infection".

Normal Range		5-Aug	6-Aug	7-Aug	8-Aug	9-Aug	10-Aug Pre-op	10-Aug Post-op
0.2 - 1 mg/dL	Bili	7.2	7	6.7	7.6		9.6	
0.0 - 0.3 mg/dL	Direct bili	5.2	5.3	5.2	5.7		7.3	
3.5 - 4.9 g/dL	Alb		2.5	2.1			2	
42-168 U/L	Alk Phos	393	431	451	561	604	659	
30-65 U/L	ALT	249	184	161	161	180	179	
23-60 U/L	AST	189	132	130	163	209	211	
20-210 U/L	Gamma GT		290	271	280			
114-286 U/L	Lipase		406	320	321	383	80	
20 - 110 U/L	Amylase	39	85	59	46	45	102	
12 - 16 gm/dL	Hgb		11.9	12.2	12.7	12.3	11.4	5.8
150 - 450 K/uL	Plts		134	134	151	157	147	
4.5 - 11.3 K/uL	WBC		25	28	39.9	47	43.8	
25 - 45%	% lymphs		86%	93%	94%	94%	92%	
		WBC phoned to ward and read back by nurses Aug 8, 9. 10						

Appendix J   19

Delayed diagnosis of Wegener's Granulomatosis

A 54 YO male presented to the ED with a 8 day history of increasing cough, fever, and shortness of breath. Evaluation in the ED showed hypoxemia and infiltrates on chest X-ray. WBC was elevated at 15,000/mm3 with a left shift.

The patient was admitted to the ICU with a Dx of pneumonia and started on appropriate antibiotics. The patients condition deteriorated over the next two days. A Nephrology consult was called because of an elevated creatinine (2.0 mg%). Additional history disclosed sinus congestion for the past month. Red blood cells and RBC casts were seen on urinalysis. The Nephrologist suggested the possibility of Wegener's granulomatosis. An ANCA was ordered. The antibiotics were continued; high dose steroids and cytotoxic agents, the appropriate treatments for severe vasculitis, were help pending the ANCA result.

The ANCA had not returned by the next day. The patient's condition was unchanged. The ANCA had still not returned the day after that or the next day, at which time the patient experienced massive hemolysis and could not be resuscitated.

The autopsy disclosed a necrotizing vasculitis, consistent with Wegener's granulomatosis. The ANCA had never been sent; the lab had been waiting for the ordering MD to fill out a 'send out' request form and had sent an email to that effect to the resident. House staff generally do not read emails originating from the healthcare organization.
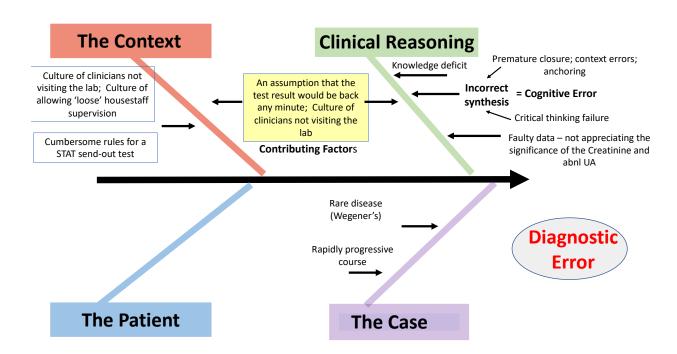
Discussion: The diagnosis of Wegener's granulomatosis was delayed in this case, associated with the patient's death. Regarding cognitive errors, the clinicians involved were aware of the possibility of Wegener's, but were reluctant to start treatment for fear that steroids and cytotoxics might be deleterious in a patient with presumed infectious pneumonia. The data collection step was clearly faulty. The initial analysis, arriving at the diagnosis of pneumonia can be questioned; perhaps vasculitis should have been considered earlier. If the creatinine was elevated on admission, or if a urinalysis had shown features of glomerulonephritis (hematuria, fragmented red cells, red blood cell casts), this would have pointed the diagnosis more towards vasculitis (a more rare condition) and away from the diagnosis of pneumonia (more likely based on pre-tests probability). Vasculitis was not even mentioned as a possibility on the admission notes, and the ICU team was comfortable with the 'pneumonia' diagnosis (premature closure, context error, anchoring).

Regarding system-related elements, the house staff were not aware that the ANCA test was expensive and needed to be sent out to a reference laboratory, which required a physician to complete a justification request. The lab was wrong in assuming that the providers know all the lab rules & that email was an effective communication route. This was too cumbersome a process for a test needed STAT. The providers were under the false assumption that the test results would be back 'any minute'. They also had the opportunity to follow up on the test in a

more timely manner; the lab is located right next to the ICU. Similarly, the lab staff could have walked over to the ICU to get the send-out form completed and advise on when the results would be available.

The Nephrologist could have initiated empiric treatment for vasculitis earlier given the strong clinical suspicion, and could have intervened directly in figuring out why the ANCA result was delayed, instead of relying on the housestaff (too loose supervision).

A root cause analysis of this event might look like this:

Generic Fishbone Diagram of a Lab-Related Error

The diagnostic testing process in the clinical laboratory consists of sequential steps, starting with the clinician thinking about the best test to order, and culminating with the clinician acting upon the test result in the care of the patient. George Lundberg described this as the 'Total Testing Process', and this provides an appropriate framework for analyzing breakdowns\success in laboratory testing.(1)(Figure 1). Mario Plebani et al revived and popularized this concept,(2) and Lubin et al have presented an updated perspective that presents a more integrated vision of lab testing.(3)(Figure 2)

A generic fishbone diagram, based on the domains described by the total testing process concept, is presented in Figure 3.
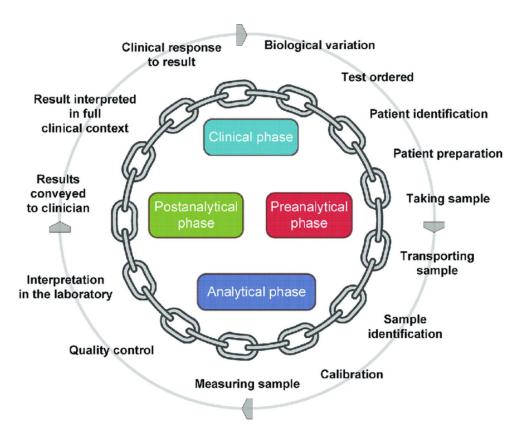

Figure 1. The total testing process (the 'brain to brain loop') from: Elvar Theodorsson.(4)
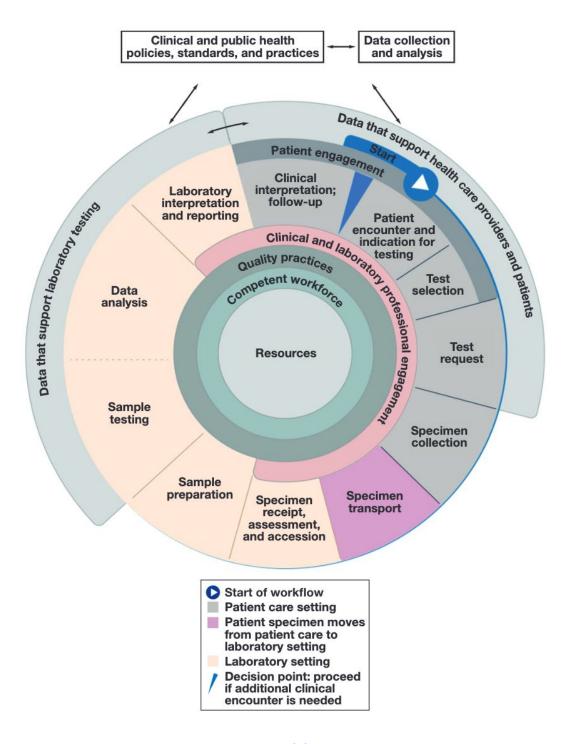
Figure 2. The total testing process, in context.(3)
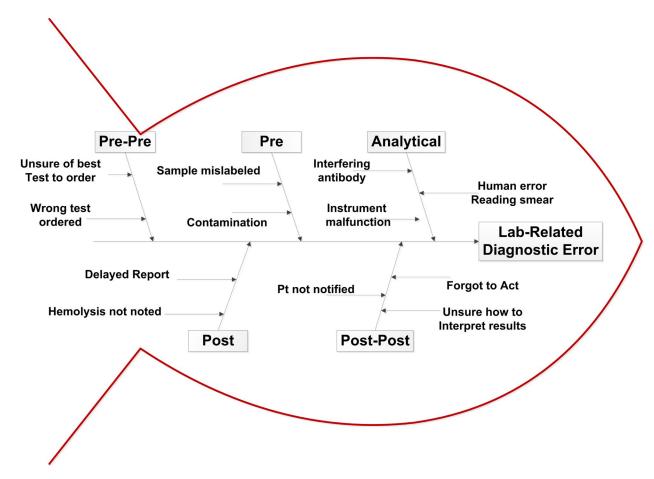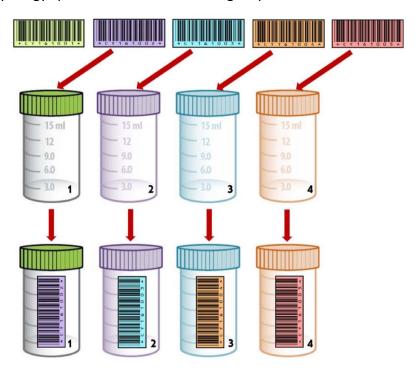
Figure 3. A generic fishbone diagram for considering contributions to lab-related diagnostic errors

REFERENCES
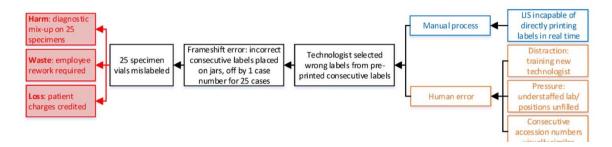
1.   Lundberg GD. Acting on significant laboratory results. JAMA. 1981;245:2.

2.   Plebani M, Laposata M, Lundberg GD. The Brain-to-Brain Loop Concept for Laboratory Testing 40 Years After Its Introduction. Am J Clin Pathol. 2011;136(6):829-33.

3.   Lubin I, Astles J, Bunn J, Cornish N, Lazaro G, Marshall A, et al. The Clinical Laboratory Is an Integral Component to Health Care Delivery; An expanded representation of the total testing process. Am J Clin Pathol. 2023;160(2):124-9.

4.   Theodorsson E. Uncertainty in measurement and total error: Tools for coping with diagnostic uncertainty. Clinics in Laboratory Medicine. 2017;37(1):15-34.

RCA of a Pre-Analytical Laboratory Error
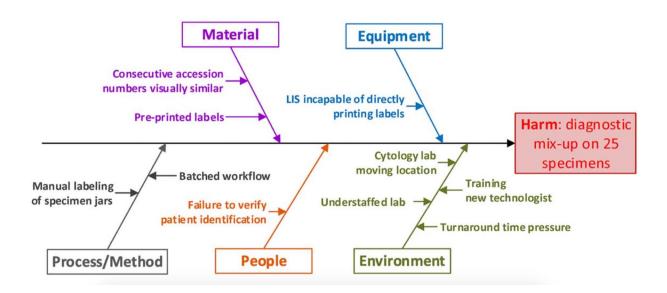
The incident: A close call where numerous cytology specimens were mislabeled and diagnoses would have been issued to the wrong patients if a conscientious cytotechnologist had not picked up on the error by chance. The incident involved the mislabeling of more than 25 cytology specimens because of a single upstream frameshift error:

The cause map (below) is a visual explanation of why an event occurred. A coherent and cohesive story is created by moving from left to right and asking "why" or by inserting "because" between boxes. 3 For example, a diagnostic mix-up occurred in 25 specimens (why?) because 25 jars were mislabeled (why?) because there was a frameshift error (why?) because a technologist selected the incorrect labels (why?) because of human error and a manual process, and so on. A cause map creates connections between individual cause-and-effect relationships to help build a narrative via the building blocks of the map. It can be basic or it can be detailed, with as few as 2 and as many as hundreds of boxes. A cause map also has the capacity to have more than 1 adverse outcome for any given event (in this case, potential patient harm, wasted employee time, and lost revenue).

The RCA fishbone can then be constructed, identifying factors that may have played a role in the specimen mis-labeling:

REFERENCE:

Yael Heher, MD MPH FRCPC.   A Brief Guide to Root Cause Analysis. Cancer Cytopathology. February 2017. Pages79-82

Delayed diagnosis of adrenal insufficiency in a Type 1 diabetic

A 47 yo man with Type I DM presents to Emergency Department with several days fatigue, abdominal pain, and vomiting. He was unable to tolerate oral intake for 3 days. He held his insulin for 2 days to avoid "going low".

Past history: Type I Diabetes Mellitus, diagnosed in childhood; history of inconsistent control of sugars.

Medications: Basal Glargine Insulin and Prandial Aspart Insulin

Physical Exam: Alert, thin, very uncomfortable; Afebrile, Pulse 70, BP 96/58, normal oxygen sat; Cardiorespiratory Exam is normal; Abdominal exam: Soft, diffusely mildy tender, without rebound tenderness of guarding: Remainder of exam documented as normal

Laboratory Studies: Mildly elevated WBC count with normal differential; Glucose 197; Creatinine 1.2 (from normal baseline 0.8); Potassium 5.8; Bicarb 16; Elevated Anion Gap (=22)

Infectious and cardiac testing unrevealing; Abdominal CT performed showing no pathology;

He was admitted to Medicine service with diagnosis of diabetic ketoacidosis triggered by viral gastroenteritis and insulin non-adherence. No beds available so treatment initiated in ED with an Insulin drip and IV fluids. Repeat lab studies showed improvement in most lab parameters, so he was re-admitted to floor team. The potassium level was still elevated but improved. He was signed out to the Medicine night float resident who performed a chart review:
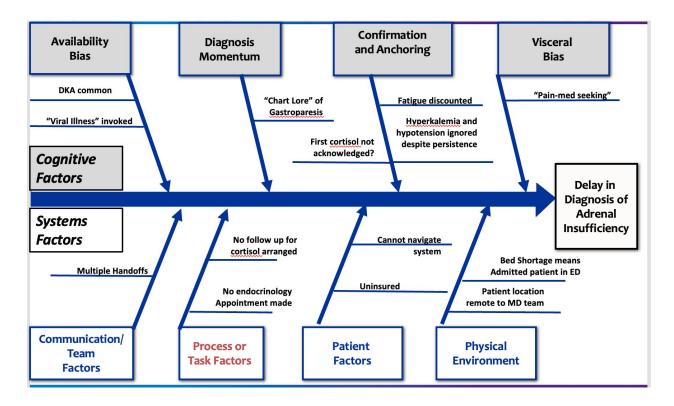
The patient had four previous admissions in the past year for similar complaints. He been previously diagnosed with "gastroparesis" by nuclear gastric emptying study.

The management plant was adjusted to begin metoclopromide (promotility) and limit opioid pain meds as they could exacerbate gastroparesis and related pain. Due to a busy call night, this was not communicated to patient.   The night float hands off the patient to the morning team. The patient is still in the ED awaiting a bed. Morning rounds are truncated due to other sick patients and team does not round in the ED. Multiple requests from the ED nurse for pain medicine are declined by the intern over phone. The patient becomes frustrated, signs out against medical advice.

Three days later the patient returns to the ED with dizziness and persistent fatigue. He is afebrile, Pulse 70, BP 92/60, normal oxygen saturation. His physical examination is normal. His potassium is again elevated at 5.9, other parameters are normal. He is readmitted to medicine for "presyncope" and "failure to thrive". Upon questioning, patient emphasizes that most concerning symptom has been fatigue. This had contributed to poor job performance leading

to termination (and loss of health insurance). The lack of insurance prevented him from following up with his endocrinologist "for that other test". A second review of past records showed baseline high potassium and an equivocal baseline morning cortisol.

An inpatient adrenal stimulation test confirmed the diagnosis of primary adrenal insufficiency.

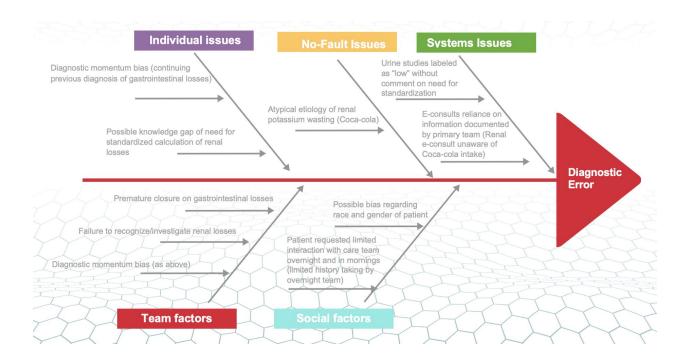**James B. Reilly, MD MS FACP.   Analysis of a Diagnostic Error Using a Fishbone Diagram**

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West Penn Hospital Educational Consortium
Assistant Professor of Medicine, Temple University School of Medicine

Presented on a Webcast during Patient Safety Awareness Week, 2014

Delayed diagnosis of hypokalema (due to excessive consumption of Coca-Cola)

Case: A thirty-three-year old male patient presented with leg pain to the emergency department. He had no trauma, existing disease or past operation history. In his history of illness there were no fever, recent infection, diarrhea, extreme physical activity, or exposure to any drug or herbal medicine that could reveal his pain. He consumed at least one liter of all kinds of cola-based drinks(diet, zero, normal etc) for several months. Vital signs were as follows: 36.7°C, sp02:100%, pulse:91 beats per minute, blood pressure: 134/81 mmHg . His physical examination was normal. The patient's electrocardiography (ECG) showed normal sinus rhythm (NSR) and no ischemic changes with a 88 of heart rate. Biochemical tests include CBC, electrolytes, renal and liver functions, creatine phosphokinase and arterial blood gase analysis showed that patient's values were within the normal limits except potassium 2.3 mEq/L (normal limit 3.5-5.1 mEql/L) and creatine phosphokinase (CPK) 1001 U/L (normal limit 30-200 U/L). His 24-hour urine potassium level was 23.4 (normal limit 25-125 g/hr) and urine osmalility was 221 mosm/kg. The results of plasma renin activity (PRA; 4.8 ng/mL/h; reference range 1.9-6.0 upright and aldosterone (312 pg/mL; reference range 38–313), available the day after his presentation. There were nothing for the etiology hypokalemia and high levels of CPK other than cola-based drink consumption. After potassium and fluid replacement, patient was discharged from the hospital with diet recommendations. One week later after cessation of cola-based drink consumption, patient's potassium value was 3.9 mmol/L and creatine phosphokinase value was 166 U/L.

Errors in Knowledge Management: The Ellen Roche Case

The events leading to and following Roche's death in June 2001 are summarized in Table 2. If Roche had completed the study, she would have received up to $365 — $25 for each of the first-phase visits and $60 for each of the second-phase visits. In the consent form, hexamethonium was described as "a medication that has been used during surgery, as
a part of anesthesia; this is capable of stopping some nerves in your airways from functioning for a short period." The section on risks stated that hexamethonium "may reduce your blood pressure and may make you feel dizzy especially when you stand up." Pulmonary or other potential toxic effects were not mentioned. The consent document was later criticized as having "failed to indicate that inhaled hexamethonium was experimental and not approved by the FDA" and because it referred to hexamethonium as a "medication."

Roche received hexamethonium on May 4; she was the third subject who received it (Table 2). Mild shortness of breath and a cough had developed in the first subject, resolving over a period of about eight days. The second subject, who received hexamethonium while the first subject still had symptoms, did not report any symptoms. The day after Roche inhaled about 1 g of hexamethonium, a cough developed. She was hospitalized on May 9 and died on June 2. An autopsy showed diffuse alveolar damage but established no specific etiologic diagnosis. An internal review committee concluded that although the cause will never be certain, "the inhaled hexamethonium phase of the experiment was either solely responsible for [her] illness or played an important contributory role."

TABLE 2. EVENTS LEADING U P TO AND F OLLOWING THE DEATH OF ELLEN ROCHE

DATE EVENT
September 18, 2000 The institutional review board (IRB) at the Johns Hopkins Bayview Medical Center approves a study, "Mechanisms of Deep Inspiration–Induced Airway Relaxation." The study is a part of the research plan funded by a grant from the
National Institutes of Health, entitled "Lung Inflation in Airways Hyper-Responsiveness."
April 16, 2001 Ellen Roche, a 24-year-old healthy volunteer and a technician at the Johns Hopkins Asthma and Allergy Center, provides consent to participate inthe study and begins the protocol.

April 23, 2001 Subject 1 [another healthy volunteer] receives about 1 g of hexamethonium by inhalation. The base-line values for forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) are 2.68 and 3.23, respectively.

April 25, 2001 Subject 1 reports mild shortness of breath and a nonproductive cough. The values for FEV1 and FVC are reduced to 2.33 and 2.74, respectively.

May 3, 2001 Subject 1 reports complete resolution of symptoms. The values for FEV1 and FVC are 2.41 and 2.91, respectively — somewhat reduced, as compared with the values on April 23 but similar to those obtained when the subject entered the study.

May 4, 2001 Roche (Subject 3 in the study) receives about 1 g of hexamethonium by inhalation.

May 5, 2001 A dry cough develops in Roche.

May 9, 2001 Roche is hospitalized at Bayview Medical Center with fever, hypoxemia, and abnormalities on a chest film. The IRB is notified of adverse events in Subject 1 and Roche; the study is placed on hold.

May 12, 2001 Progressive dyspnea develops in Roche, and she is transferred to the intensive care unit.

June 2, 2001 Roche dies as a result of progressive hypotension and multiorgan failure.

July 16, 2001 An internal review committee at Johns Hopkins reports that Roche's death "was most likely the result of participation in the hexamethonium phase of the experiment."

October 11, 2001 Johns Hopkins announces a financial settlement
with the Roche family.

Source: Steinbrook R. Protecting research subjects - the crisis at John's Hopkins. *N Engl J Med* 2002;346: 716-20.
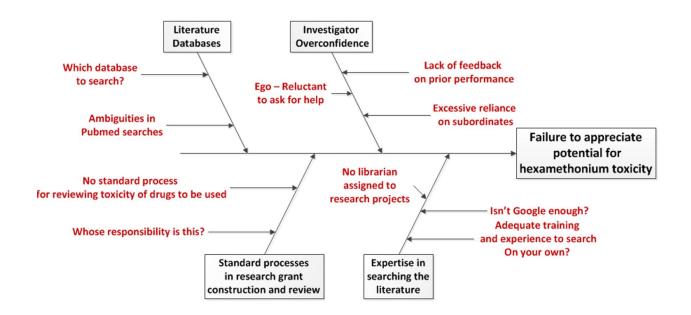
Source of RCA:

Clinicians, librarians and patient safety: opportunities for partnership
L Zipperer
Qual Saf Health Care 2004;13:218–222. doi: 10.1136/qshc.2002.003103
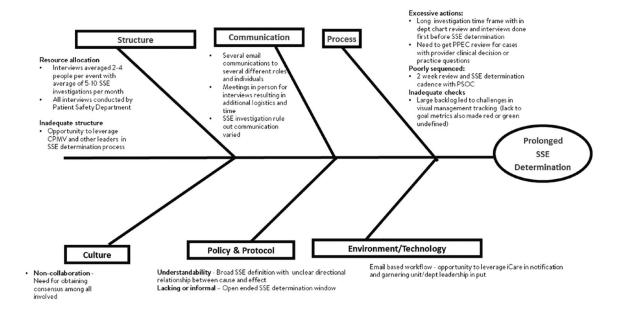
edited by Lorri Zipperer

Chapter 14: Analyzing breakdowns in the EIK pathway. Barbara Jones, Mark L Graber, Elaine Alligood. In: Patient Safety: Perspectives on Evidence, Information and Knowledge Transfer. L Zipperer, Editor. Taylor Francis, 2016

Failure to appreciate potential for hexamethonium toxicity — fishbone (Ishikawa) diagram

- Literature Databases
  - Which database to search?
  - Ambiguities in Pubmed searches
- Investigator Overconfidence
  - Ego – Reluctant to ask for help
  - Lack of feedback on prior performance
  - Excessive reliance on subordinates
- Standard processes in research grant construction and review
  - No standard process for reviewing toxicity of drugs to be used
  - Whose responsibility is this?
- Expertise in searching the literature
  - No librarian assigned to research projects
  - Isn't Google enough?
  - Adequate training and experience to search On your own?

Delays in Conducting an RCA

Structure
Resource allocation
- Interviews averaged 2-4 people per event with average of 5-10 SSE investigations per month
- All interviews conducted by Patient Safety Department

Inadequate structure
- Opportunity to leverage CPMV and other leaders in SSE determination process

Communication
- Several email communications to several different roles and individuals
- Meetings in person for interviews resulting in additional logistics and time
- SSE investigation rule out communication varied

Process
Excessive actions:
- Long investigation time frame with in dept chart review and interviews done first before SSE determination
- Need to get PPEC review for cases with provider clinical decision or practice questions

Poorly sequenced:
- 2 week review and SSE determination cadence with PSOC

Inadequate checks
- Large backlog led to challenges in visual management tracking (lack to goal metrics also made red or green undefined)

Prolonged SSE Determination

Culture
- **Non-collaboration** - Need for obtaining consensus among all involved

Policy & Protocol
Understandability - Broad SSE definition with unclear directional relationship between cause and effect
Lacking or informal – Open ended SSE determination window

Environment/Technology
Email based workflow - opportunity to leverage iCare in notification and garnering unit/dept leadership in put

REFERENCE:(1)

1.   Donnelly L, Palangyo T, Bargmann-Losche J, Rogers K, Wood M, Shin A. Creating a Defined Process to Improve the Timeliness of Serious Safety Event Determination and Root Cause Analysis. Pediatr Qual Saf. 2019;4:e200.