Issue Brief 16

Current State of Diagnostic Safety: Implications for Research, Practice, and Policy









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Current State of Diagnostic Safety: Implications for Research, Practice, and Policy

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CONTENTS

1. Introduction	3
2. Methods	3
2.1. Rapid Narrative Review	3
2.2. Qualitative Methods	5
3. Results	5
3.1. Incidence and Contributing Factors	7
3.2. Measurement: Data and Methods	
3.3. Cognitive Processes	10
3.4. Culture, Workflow, and Work System Issues	11
3.5. Disparities	
3.6. Health Information Technology	
3.7. Patients and Families	14
3.8. Testing	15
3.9. Interventions	16
3.10. Implementation	
4. Discussion	20
References	

Figures and Tables

Figure 1. Operational framework to understand the state of the science of diagnostic safety	.4
Table 1. Diagnostic safety domains and subdomains	.6
Table 2. Overview of definitions	.8

Appendixes

Appendix A. Search Terms	46
Appendix B. External Experts for Qualitative Interviews	47
Appendix C. Interview Guide	48

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1. Introduction

Diagnostic errors are a major patient safety concern. Research has shown unacceptable rates of diagnostic errors in acute care, ambulatory care, and emergency care.¹⁻⁹ For example, an estimated 5 percent of the U.S. adult population experiences a diagnostic error in the outpatient setting every year,¹ and approximately 0.7 percent of inpatients experience harm from a diagnostic error.² These estimates are consistent with data from the general public about diagnostic errors.^{10,11}

The field of diagnostic safety has developed rapidly over the past decade. The 2015 National Academies of Sciences, Engineering, and Medicine (NASEM) report "*Improving Diagnosis in Health Care*" highlighted the problem and accelerated progress to address diagnostic safety.¹²

Increased funding from multiple sources, such as the Agency for Healthcare Research and Quality (AHRQ) and the Gordon and Betty Moore Foundation,^{13,14} has facilitated scientific progress. Efforts are ongoing to improve medical education and training specific to the diagnostic process, promote cultural changes to facilitate learning and improvement, and support use of information technology by providers and patients.¹² Despite recent advances, diagnostic safety remains understudied and further research is warranted to understand the complexity of the diagnostic process and to devise next steps for research, practice, and policy.^{12,15}

To accelerate progress in diagnostic safety science and improvement activities, we used two methods to identify major themes related to the current state of diagnostic safety and highlight key gaps in knowledge. The first was a rapid narrative review methodology to evaluate multiple resources in the literature and the second included interviews with experts. Findings have several implications for future resource investments to reduce harm from diagnostic errors.

2. Methods

Findings and recommendations are informed by a rapid narrative review and interviews with nine diagnostic safety experts, representing one or more of the following areas: cognitive psychology, social sciences, informatics, clinical medicine, medical education, patient engagement, and implementation. The experts provided feedback on both the methodological approach and initial content, and their input was used to clarify findings or enhance interpretation.

2.1. Rapid Narrative Review

We first convened a team of eight people, including two with extensive expertise and knowledge in diagnostic safety (coauthors Sittig and Singh) and six literature reviewers (coauthors Khan, Cholankeril, Sloane, Bradford, Matin, and Ramisetty). The initial review involved a broad literature search and examination of various reputable sources, including:

- AHRQ's Patient Safety Network and grants website,^{14,16,17}
- National Academy of Medicine (NAM) Diagnostic Excellence Scholars website,¹⁸
- NAM reports,¹²
- Society to Improve Diagnosis in Medicine (SIDM) Foundational Readings in Diagnostic Error and Fellows pages,^{19,20} and
- PubMed (search terms are included in Appendix A).

From this initial review, we developed 10 domains (Figure 1) that broadly represented the main areas of diagnostic safety work, which could then be used to identify gaps in the scientific literature. These 10 domains constituted a pragmatic framework to examine the current state of science and gaps.

Based on the initial review, we created subdomains within each domain to facilitate a more comprehensive review of the literature and to help synthesize findings. For the comprehensive review, we evaluated published literature, grey literature, web-based resources and tools, and ongoing projects related to diagnostic safety, focusing on sources published between 2013 and 2023. While a large volume of foundational work was conducted before this period, we focused on more recent literature that was not included in NASEM's 2015 landmark report.



Figure 1. Operational framework to understand the state of the science of diagnostic safety

2.2. Qualitative Methods

Qualitative interviews with nine experts in the field of diagnostic safety helped ensure the adequacy and appropriateness of the scope and coverage of the 10 domains (Appendix B includes names of external experts). Before the interviews, each expert was provided with an initial outline of the domains to ensure time for reflection and feedback.

We developed a semistructured open-ended interview guide with probes focused on each of the 10 domains. We designed this guide to ensure adequacy of domains and subdomains, identify any gaps not highlighted in our findings, and determine how to address some of the existing gaps we found in each domain. We asked supplemental questions on potential recommendations to promote broad-scale improvement in diagnostic safety.

Three of the coauthors (Khan, Offner, and Shahid) conducted the interviews remotely via video conference between May and June 2023. Participants were recruited through purposive sampling. Each interview lasted approximately 60 minutes, and participants consented to audio recording (Appendix C includes the interview guide).

Interviews were transcribed through a third-party transcription service and subsequently de-identified to maintain confidentiality. A qualitative methodologist conducted a rapid content analysis of interview transcripts to gain an initial understanding of the content. Rapid content analysis provides valuable initial insights and can be an effective option when it is necessary to quickly identify essential trends to inform further research. Each transcript was reviewed to organize the data of participant's feedback and specific suggestions for improvement.

3. Results

Our study team reviewed the literature over the past decade and synthesized findings within each domain, focusing mainly on summarizing findings that reflected advances and gaps. Experts in diagnostic safety provided input to affirm or refine findings within the domains and subdomains and identified several suggestions and recommendations based on these preliminary findings. Their recommendations included basic items, such as rewording or rephrasing domain/subdomain titles, to broader higher level recommendations, such as policy reforms and culture change.

Most of the external experts we interviewed were concerned about a shared understanding of the definitions of certain foundational terms, such as "diagnostic error" and "burden." We scanned leading sources in the literature for a consensus-based definition of key terms and elaborate on this issue in the Incidence and Contributing Factors and Measurement: Data and Methods domains.

Leadership buy-in and institutional commitment often came up during the interviews, emphasizing their importance in achieving diagnostic safety. Experts emphasized work-system-related topics, such as streamlining workflows and enhancing reliability of processes. They also underscored the importance of cross-cutting process improvement work in diagnostic safety.

Careful attention to sociotechnical factors, such as ensuring responsibility for closing the loop on abnormal test results in electronic health record (EHR)-based systems was deemed essential, especially when implementing interventions. Additional areas of focus included:

- Understanding patients' and families' psychosocial burden related to diagnostic errors,
- Building knowledge and skills of patients and families through resources and tools such as patient portals, and
- Empowering patients and families to speak up and provide feedback when things are not going well.

The following section synthesizes findings related to each domain and subdomain (Table 1).

Table 1. Diagnostic safety domains and subdomains

Domain	Subdomains
Incidence and Contributing Factors	Incidence Contributing Factors Burden
Measurement: Data and Methods	Defining Diagnostic Error Measurement Frameworks Data and Methods To Operationalize Measurement Reporting Diagnostic Error
Cognitive Processes	Frameworks and Cognitive Biases Cognitive Burden Concepts To Improve Clinical Reasoning
Culture, Workflow, and Work System Issues	Culture: Behavioral Norms Work System Work System: Process Breakdowns
Disparities	Reducing Disparities in Diagnostic Performance Effect of Bias Improving Diagnostic Performance Related to Diagnostic Inequity and Implicit Bias
Health Information Technology	Electronic Health Record in Diagnosis Telehealth/Telemedicine Decision Support Tools and Algorithms
Patients and Families	Patient-Centered Communication and Processes Technology Tools for Patients Families and Caregivers
Testing	Test Ordering and Processing Test Results Management Closing the Loop
Interventions	Educational Interventions Cognitive Interventions Patient and Family Interventions System Interventions
Implementation	Models and Frameworks Organizational Approaches Resources Communities of Practice Policy

3.1. Incidence and Contributing Factors

This domain covers the frequency of diagnostic errors and factors associated with them.

3.1.1. Incidence

Quantifying diagnostic errors through incidence rates and other methodologies helps provide a better understanding of the magnitude of the problem.^{21,22} One study by Singh, et al., which combined estimates from various observational studies, estimated that approximately 12 million outpatient diagnostic errors occur annually within the United States,¹ with half of these errors being potentially harmful.²³ Numerous studies have now demonstrated that diagnostic errors are frequent or harmful in different healthcare settings, underscoring the impact of process breakdowns and various types of cognitive and systems issues.

Studies showcase the need for further research on contributory factors and targeted interventions.^{2,24-33} The heterogeneity of these studies and measurement methods underscores the importance of using a standardized definition of diagnostic error.^{21,34} Progress has been made in determining prevalence of diagnostic error in various clinical settings, including intensive care units,³⁵⁻³⁷ pediatric hospitals,^{38,39} and emergency departments,⁴⁰ and in specific medical conditions.⁴¹

3.1.2. Contributing Factors

Studies show that diagnostic errors nearly always have multifaceted causes and arise from various contributing factors, including issues related to cognition (such as inadequate data gathering, data interpretation, or clinical assessment), systems, patients, and communication.^{25-29,33,42-46} Often, there is an interaction between these factors and cognitive errors that are accompanied by systems problems or process breakdowns. Characterizing the risk factors associated with diagnostic errors can inform the development of appropriate interventions and preventive strategies.²⁹

3.1.3. Burden

The burden of diagnostic errors exists beyond just health outcomes. The burden of diagnostic errors can be determined in many ways, including malpractice claims, physician surveys, patient experience surveys, and economic costs.⁴⁶⁻⁵² Data from malpractice claims indicate that diagnostic errors are one of the most common types of errors, especially for outpatients, and typically result in substantial financial loss to healthcare systems and harm to patients.⁵¹⁻⁵⁴ A study on malpractice claims in hospitalized patients showed that patients with diagnosis-related claims were 2.33 times more likely to die than to have a minor injury compared with other paid claim types. In addition, inpatient diagnostic errors resulted in \$5.7 billion in costs over 12 years.⁴⁹

Additional more rigorous studies are needed to estimate the burden of harm caused by diagnostic errors, especially in ambulatory care settings. Similarly, we did not find additional studies related to economic burden, which would be especially difficult to do given the robustness needed to determine presence or absence of diagnostic error. The literature highlights the need for better methods to quantify their impact in terms of costs and impact of strategies to mitigate related harms.

3.2. Measurement: Data and Methods

This domain included data and methods for tracking and measuring diagnostic error, measurement definitions and frameworks, and tools for measurement, such as e-triggers and reporting.

3.2.1. Defining Diagnostic Error

Use of a standard definition of diagnostic error across studies has remained a major challenge. A shared understanding of what exactly is a diagnostic error has been slow to develop despite a definition proposed by NASEM, building on existing definitions outlined in Table 2, and the understanding of this concept is still evolving. Sources exploring the definition included:

- A review documenting the evolving definition of diagnostic error since the NASEM report,⁵⁵
- A multidisciplinary panel on diagnostic safety,⁵⁶ and
- Most recently, a scoping review on how the literature is operationalizing the NASEM definition with essential components being accuracy and timeliness.⁵⁷

Inclusion of the patient's perspective within the definition remains essential.⁵⁸

Term	Definition	Defined by
Diagnostic Error	A diagnosis that was unintentionally delayed (sufficient information was available earlier), wrong (another diagnosis was made before the correct one), or missed (no diagnosis was ever made), as judged from the eventual appreciation of more definitive information.	Graber, et al. ⁸
Diagnostic Error	Any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis, or a delayed diagnosis. This could include any failure in timely access to care; elicitation or interpretation of symptoms, signs, or laboratory results; formulation and weighing of differential diagnosis; and timely followup and specialty referral or evaluation.	Schiff, et al. ⁷
Diagnostic Error	Missed opportunities to make a correct or timely diagnosis based on the available evidence, regardless of patient harm.	Singh, et al. ⁵⁹
Diagnostic Error	The failure to: (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient.	NASEM report ¹²
Diagnostic Safety Event	One or both of the following occurred, whether or not the patient was harmed: Delayed, Wrong, or Missed Diagnosis: There were one or more missed opportunities to pursue or identify an accurate and timely diagnosis (or other explanation) of the patient's health problem(s) based on the information that existed at the time. Diagnosis Not Communicated to Patient: An accurate diagnosis (or other explanation) of the patient's health problem(s) was available, but it was not communicated to the patient (includes patient's representative or family, as applicable).	AHRQ Common Formats for Event Reporting ⁶⁰

Table 2. Overview of definitions

3.2.2. Measurement Frameworks

Advancing the field of diagnostic safety measurement will depend in part on consensus or standards for measurement, which can be facilitated by conceptual frameworks or theoretical models. The Safer Dx Framework and the NAM framework it informed were frequently used in both conceptual and empirical literature.⁶¹

In 2018, Olson, et al., proposed a framework for identifying "undesirable diagnostic events" by recognizing clinical situations that denote potentially preventable breakdowns in the diagnostic process for which improved diagnostic processes would lead to improved health for patients.⁶² This framework would help in identifying medical conditions prone to error and the care context in which those errors likely occur.

Another widely used framework is the Diagnosis Error Evaluation and Research taxonomy to evaluate errors in the diagnostic process.⁶³ The Tripartite Framework of Diagnostic Process Safety proposed to measure quality and safety of the diagnostic process focused on three practices: considering "don't miss" diagnoses, looking for red flags, and avoiding common diagnostic pitfalls.⁶⁴

A patient-centered framework, the process-related breakdowns framework, was codeveloped by a multidisciplinary team to aid in the detection of breakdowns in the diagnostic process.⁶⁵ Conceptual models have been developed not just for the overall diagnostic process,⁶⁶ but also for individual components of the diagnostic process, such as closing the loop on referral communication^{67,68} and the testing process.⁶⁹

3.2.3. Data and Methods To Operationalize Measurement

Approaches to measuring diagnostic errors were initially developed in research settings but have been increasingly adopted for use in healthcare quality and safety programs. For example, teams have developed approaches to creating mechanisms for clinicians and staff to report suspected errors, and some organizations are trialing use of EHR queries to detect events suspicious for diagnostic error.⁷⁰

An AHRQ issue brief on operational measurement of diagnostic errors reviews the literature and provides recommendations for leveraging various data sources to systematically identify diagnostic errors.⁷¹ Use of electronic triggers (e-triggers) and review instruments are proposed strategies covered here.

E-Triggers

E-triggers are algorithms applied to the EHR to identify patients with red-flag signals or symptoms who are at risk of misdiagnosis. E-triggers have now been applied to emergency departments⁷² and cancer diagnosis⁷³ but are applicable to many settings. To streamline the process of e-trigger development, the Safer Dx Trigger Tools Framework has been proposed to guide health systems in identifying and measuring diagnostic errors.⁷⁴ E-trigger tools that have been developed using this framework can detect potential diagnostic events, which can allow health systems to monitor event rates, study contributing factors, and identify targets for improving diagnostic safety.

Notably, this new approach is needed because other e-trigger tools, including the Institute for Healthcare Improvement's Global Trigger Tool (GTT), do not yield an adequate number of diagnostic errors.⁷⁵ However, they may be more beneficial if they can be modified. For example, to increase the yield for preventable diagnostic safety events, Bhise, et al., leveraged EHR data, modified the GTT algorithm to focus on a specific patient population, and used chart reviews to validate diagnosis-related events.⁷⁶

Review Instruments

The Revised Safer Dx Instrument has 12 questions to evaluate the diagnostic process and has been applied in multiple care settings,⁷⁷ including inpatient medical units⁷⁸ and intensive care units,⁷⁹ and is being increasingly used to measure diagnostic error in other clinical settings.⁸⁰

3.2.4. Reporting Diagnostic Error

Reporting tools aid in capturing the details of diagnostic safety events to prompt further investigation or to collect data for later analysis of aggregate trends and patterns. Recently, AHRQ released Common Formats for Event Reporting for Diagnostic Safety Events to provide standards for external reporting of diagnostic safety events.⁸¹ To enhance reporting and learning, the Primary-Care Research in Diagnosis Errors Learning Network allows users to upload de-identified case studies, which are reviewed and shared to help build clinician awareness programs to ultimately improve patient care.⁸²

Additional reporting mechanisms have been used by healthcare systems to increase the number of safety events reported for internal quality and safety initiatives.⁸³⁻⁸⁶ An AHRQ-funded project is developing and testing an electronic diagnostic error-reporting system for patients to report diagnostic error experiences.⁸⁷ In a recent study, three common barriers for reporting errors were lack of time, complexity of the reporting system, and lack of feedback to the reporting clinician on analysis and action-related outcomes.⁸⁸

3.3. Cognitive Processes

Cognitive processes encompass mental processes related to medical decision making.

3.3.1. Frameworks and Cognitive Biases

Several frameworks of clinical reasoning have been suggested to help understand specific cognitive processes. The most well-known model is the dual process theory, which suggests two types of cognitive processing: intuitive and automatic (Type 1) and analytic and effortful (Type 2).⁸⁹⁻⁹² Clinicians often resort to Type 1 thinking, which can sometimes lead to cognitive biases.

Several cognitive biases are associated with diagnostic errors; some of the most relevant ones include premature closure, confirmation bias, base rate neglect, and the availability heuristic.^{90,91,93,94} However, new frameworks are emerging that are shifting the focus from "diagnosis in the head" to "diagnosis in the world" (e.g., situativity theories).⁹⁵⁻⁹⁷ Thus, the emphasis is now on considering context and environmental factors and acknowledging that diagnosis is not an individual phenomenon. Rather, it is a sociotechnical systems-based effort requiring a large team to work together effectively to collect needed data and synthesize information to make a diagnosis. This shift is significant because it encourages conceptualizing even the cognitive aspects of the diagnostic process at a systems level.

3.3.2. Cognitive Burden

The International Classification of Diseases, 9th Revision (ICD-9) has more than 12,000 codes, and the current ICD-10 has more than 68,000 codes to which more than 1,000 codes were added in 2023.⁹⁸ One study suggests that medical knowledge doubles every few months.⁹⁹ Coupled with the vast amount of clinical and administrative data collected and stored in EHRs, this information places ever greater cognitive demands on clinicians.^{100,101}

Research has also shown that increasing documentation demands linked with clinical quality measures, accompanied by poorly designed EHRs, are associated with increased cognitive load and burden.^{102,103}

Moreover, uncertainty is inherent to clinical decision making,^{104,105} adding to the cognitive burden of clinicians who need to make a correct and timely diagnosis.

Interest is growing in the topic of diagnostic uncertainty, which has recently been defined as the "subjective perception of an inability to provide an accurate explanation of the patient's health problem."¹⁰⁵⁻¹⁰⁸ Defining diagnostic uncertainty allows better measurement of this cognitive construct.^{105,109,110} In addition, there is more of an emphasis to clearly communicate uncertainty with patients and families.^{105,109}

External factors within the environment can also increase cognitive burden and lead to mistakes.^{111,112} For example, interruptions are a common occurrence in the diagnostic process and have been associated with increased medical errors and stress, anxiety, and burnout.^{113,114} Time pressure and clinician burnout may also be associated with poorer diagnostic performance.¹¹¹ However, a recent paper on identifying research topics to advance the field of diagnostic safety found the need to prioritize research on system factors, such as workload, time pressure, and interruptions, to better understand how these factors affect diagnostic decision making.¹⁵

3.3.3. Concepts To Improve Clinical Reasoning

Several potential solutions can improve clinical reasoning. For example, cognitive debiasing strategies can help mitigate the risks of cognitive biases.⁹⁰ Additional strategies include considering alternative diagnoses, taking a diagnostic timeout to pause and reflect, and minimizing time pressures.^{93,115,116}

Several experts have called for feedback on diagnostic performance as a step to improve clinical reasoning.^{20,117-119} Feedback is particularly important because it can help clinicians recalibrate their performance to minimize both overconfidence and underconfidence.^{108,120-122} Although pilot studies have tested the feasibility of these approaches, data are limited on their effectiveness in preventing and reducing diagnostic error.^{123,124}

Strategies are also available to help reduce the negative impact of interruptions, such as managing mobile devices, using checklists, and taking a moment to prepare before switching tasks.¹²⁵ However, research is limited on these strategies within diagnosis specifically. For example, although checklists and cognitive forcing strategies seem promising, results are mixed on their impact on the diagnostic process, so further research is needed before implementation.^{126,127} Finally, it is essential for all clinicians and future trainees to have the necessary training and skills in diagnostic reasoning and uncertainty to reduce the risk of diagnostic error.^{20,107,128-132}

3.4. Culture, Workflow, and Work System Issues

This domain encompasses behaviors and practices in the workplace that affect diagnostic safety.

3.4.1. Culture: Behavioral Norms

Behavioral norms in the workplace may affect diagnostic safety. In a randomized controlled study, the effects of rude behavior on wrong diagnosis during handoff were assessed in a standardized simulation trial. Findings showed that rudeness hindered the diagnostic performance of less experienced physicians versus more experienced physicians.¹³³

3.4.2. Work System

Several barriers to achieving diagnostic safety have been identified in the work system. Studies and models analyzing the relationship of the work environment and diagnostic quality have noted higher burnout scores in physicians where key elements of the diagnostic process were missing from the physicians' clinical notes.^{111,113,134} Another recent study recognized communication barriers and transfer of accountability as contributing factors to diagnostic error.¹³⁵

To overcome barriers to reporting safety events, one study noted a benefit from a closed-loop feedback system between safety management and frontline staff on filed safety reports.¹³⁶ In an observational study, Chopra, et al., identified key themes of the diagnostic process, including diagnosis as a social phenomenon and distractions and time pressures impeding the decision-making process.¹³⁷

3.4.3. Work System: Process Breakdowns

Vulnerabilities in the work system can lead to breakdowns in the diagnostic process. In one study, inadequate followup of patients due to a lack of health information technology (IT) implementation in medical offices was a barrier to timely review of test results.¹³⁸ Several additional reasons for inadequate followup include physician-patient miscommunication, information overload, absence of record retrieval systems, and lack of coordination.^{139,140}

3.5. Disparities

Disparities are differences in healthcare and health status based on various social factors, including age, gender, and race, that may affect diagnosis.

3.5.1. Reducing Disparities in Diagnostic Performance

Diagnostic errors are closely interconnected to and exacerbated by health disparities, leading to unequal access to healthcare and disparate outcomes for vulnerable populations.¹⁴¹⁻¹⁴³ The lack of inclusive representation presents challenges to addressing health disparities in diagnosis.¹⁴⁴ For instance, racial disparities in diagnosis have been observed in numerous studies, particularly among non-White patients, including prolonged diagnostic delays and misdiagnosis.¹⁴⁵⁻¹⁴⁸

Recently, a study observed diagnostic delays for breast cancer detected through screening that was associated with increased breast cancer mortality for Black female patients.¹⁴⁸ Despite advances in patient safety, substantial challenges and areas of improvement are evident in diagnosis-related disparities that need to be addressed.^{143,147,149}

3.5.2. Effect of Bias

Beyond societal and social constraints within the healthcare system, implicit biases on the part of the clinician can manifest as contributors to diagnostic inequities.^{117,150} Implicit biases and attitudes can perpetuate health disparities that may influence clinical decision making and diagnostic accuracy. The literature documents multiple studies and systematic reviews highlighting racial diagnostic inequality in the United States.¹⁵¹⁻¹⁵⁸

Several studies noted racial diagnostic disparities.¹⁵⁶⁻¹⁵⁸ For example, even after controlling for clinical and behavioral risk factors, Black patients were more likely to be diagnosed with schizophrenia compared with White patients.¹⁵⁸

In addition, implicit clinician bias in patient diagnosis was associated with gender and socioeconomic status.¹⁵⁹⁻¹⁶² For instance, one study explored how gender biases among physicians may influence clinical decision making for type 2 diabetes, emphasizing associations with diagnostic uncertainty for female patients.¹⁶²

Overall, these studies lend support to the role of bias in contributing to diagnostic disparities. Further evaluation is needed to assess the impact of bias and identify potential areas of improvement within the scope of the diagnostic process.

3.5.3. Improving Diagnostic Performance Related to Diagnostic Inequity and Implicit Bias

Aside from establishing evidence on inequity, efforts are being made to try to improve diagnostic performance in this space. The current research suggests various strategies to reduce clinicians' sensitivity to diagnostic biases, including mindfulness training, use of segmented data to identify patterns, and diagnostic checklists.^{150,163-166}

To address disparities, Wiegand, et al., conducted a series of multistakeholder sessions involving patients, clinicians, and researchers, using human-centered design principles. These workshop sessions generated potential solutions and prototypes to mitigate diagnostic disparities, highlighting a holistic, people-centric approach that prioritizes patients and could be further replicated in different healthcare settings.¹⁶⁶ While strategies are needed to reduce clinician implicit bias and enhance diagnostic accuracy among marginalized groups, they are currently either underdeveloped or untested in terms of implementation and effectiveness.

3.6. Health Information Technology

Given that the scope of health IT is broad, this domain is focused on health IT that is used to assist physicians with the diagnostic process.

3.6.1. Electronic Health Record in Diagnosis

In the past decade, healthcare organizations have made significant progress in implementing information technology and EHRs that improve access to patient information, provide decision support, notify providers of potential medication errors, and enhance communication and coordination.^{167,168}

While EHRs have supported the diagnostic process, several limitations and challenges remain that contribute to diagnostic error. These include interoperability and usability issues, information overload, absence of face-to-face communication for certain high-risk communications, and lack of systematic feedback related to patients' diagnostic outcomes.¹⁶⁸⁻¹⁷² Furthermore, a recent systematic review found limited research on the impact of EHR on diagnostic error and clinicians' cognitive processes,¹⁷³ highlighting the need for continued work to develop and optimize EHRs.

3.6.2. Telehealth/Telemedicine

Although use of telemedicine has been slowly increasing over the past decade, at the start of the COVID-19 pandemic, Congress passed several regulations allowing telemedicine to rapidly expand.¹⁷⁴ A national study reported a 766 percent increase in telemedicine use in the first 3 months of the pandemic.¹⁷⁵ Importantly, telemedicine can provide access to specialist care and reduce barriers to improved quality of care for individuals in rural areas.¹⁷⁶

Telemedicine has been found to be reliable for a range of medical specialties and specific conditions, including providing emergency care,^{177,178} diagnosing patients with dementia,¹⁷⁹ and diagnosing children with febrile and respiratory distress,¹⁸⁰ to name a few. However, results are mixed. For example, some research suggests patients may be more likely to receive inappropriate antibiotics from a telemedicine provider.¹⁸¹

Other telemedicine barriers include the social and geographic divide regarding access to telehealthcare. There is also a need for further research on the costs, utilization, and outcome differences for patients who get diagnostic care via telemedicine.¹⁷⁵ While telemedicine plays a valuable role in health IT, it should be used as a complement to, rather than a replacement for, in-person care.¹⁷⁴

3.6.3. Decision Support Tools and Algorithms

In addition to EHRs and telehealth, numerous clinical decision support tools are being developed and implemented to aid with diagnostic decision making, including machine learning and artificial intelligence (AI) algorithms¹⁸²⁻¹⁸⁵ and deep learning models.¹⁸⁶ For example, a recent study found the primary computer-aided system for managing clinical knowledge, UpToDate, was significantly associated with diagnostic error reduction,¹⁸⁷ emphasizing the availability and use of basic information resources to make a diagnosis. Furthermore, machine learning algorithms can help in classifying certain conditions,¹⁸² predicting whether individuals may be at risk for specific diseases,¹⁸⁴ and providing accurate differential diagnoses for difficult-to-diagnose cases.¹⁸⁵

Much of the current work in AI is around visual diagnosis (radiology, pathology, etc.) and large language models, such as ChatGPT.¹⁸⁸ Many challenges and opportunities arise with use of AI for real-world clinical diagnosis, where processes such as history, exam, and communication are essential and involve a lot of uncertainty.¹⁸⁸ Since many of these tools and algorithms are still in their infancy, more research is needed in this field to test and validate these emerging AI technologies to ensure their effectiveness and optimization.^{189,190} Furthermore, it is essential to have effective implementation strategies in place.

3.7. Patients and Families

Over recent years, the traditional paternalistic relationship between clinicians and patients has shifted to a more collaborative one, where the patient has a greater role in their health and wellness. The following subdomains discuss the patient's and caregivers' roles in diagnostic activities.

3.7.1. Patient-Centered Communication and Processes

Awareness has grown of the impact patient engagement can have on diagnostic error reduction.^{57,191-193} Several studies and reviews have investigated the role of patients and their families or caregivers on diagnosis and have evaluated the quality of interactions between healthcare providers and patients during clinical encounters.

One study found that while clinicians in U.S. hospitals largely used the physical exam and patient history to reach their clinical diagnosis, they spent only 12 percent of their time directly engaging with the patient and their family during the encounter.¹⁹⁴ Breakdown of the patient-provider encounter has been identified as a significant contributor to cases of diagnostic error.¹⁹⁵ As such, efforts to reduce diagnostic errors have led to increased investigations into patient perspectives. These have been in the form of both analysis of patients' complaints^{192,196,197} and methods to capture patients' views and preferences.^{105,198-200}

Involving the patient in the diagnostic process is becoming recognized as necessary,^{201,202} and efforts are growing to promote the adoption of patient-centered communication strategies.^{193,200,203} These include strategies for improving the interaction^{193,194} and ensuring patients' health literacy and language needs are considered.^{161,204,205} Several publicly available tools and resources also facilitate better communication between patients and clinicians.^{12,206-208}

3.7.2. Technology Tools for Patients

The 21st Century Cures Act mandates patients' access to their electronic health information, including clinical notes and test results in EHRs.²⁰⁹ Most large health systems provide their patients with access to patient portals, allowing them to review their test results and communicate asynchronously with their primary care providers and the practice staff.²⁰⁰ While development of health IT tools that facilitate diagnosis for patients has been limited, some electronic tools are available to facilitate patient-provider conversations around clinical and health information.^{202,210}

The ease of access and consumer-friendly interfaces of mobile health (mhealth) apps have boosted their rapid adoption by patients for tasks such as recording medical history, ordering tests, and supporting diagnostic decisions for both self-diagnosis and discussions with their physician.^{211,212} Among the more than 250,000 mhealth diagnostic apps available through the major app stores,²¹³ several have become well known for facilitating self-diagnosis by laypeople (e.g., Diagnose Yourself, WebMD-Symptoms, Ada – check your health).

While patients may feel comfortable checking on symptoms such as cough, fever, or skin symptoms, few digital health apps have undergone rigorous evaluation for accuracy and effectiveness.^{211,214} In addition, their impact on unintended outcomes, such as diagnostic error, needs further study,²¹³ particularly as one recent study reviewing symptom checkers found on average no improvement in triage performance over the last 5 years.²¹⁵

3.7.3. Families and Caregivers

Although the patient is the primary focus for clinicians in developing a clinical diagnosis and care plan, patients' family members or caregivers are often aware of or can provide valuable information about the patient during the clinical encounter. While engaging families and caregivers in clinical encounters and diagnostic processes is often beneficial in preventing potential diagnostic errors, little effort has investigated and promoted this strategy.^{161,210}

3.8. Testing

Diagnostic testing is complex, involves multiple disciplines, and is known to be a contributing factor for diagnostic error. Previous studies suggest that 6.8 to 62 percent of abnormal laboratory tests and 1.0 to 35.7 percent of abnormal imaging test results are not followed up.²¹⁶ Abnormal test results frequently are not communicated to the patient, leading to missed and delayed diagnoses, sometimes of life-threatening conditions.^{217,218}

From the perspective of the total testing process, three principal areas to consider in terms of diagnostic error are:

- Ordering and processing tests,
- Interpreting and managing test results, and
- Closing the loop on followup and communication of test results.

3.8.1. Test Ordering and Processing

Multiple factors are involved in errors at the test ordering and processing stage. One study showed that more than 5 percent of test-related encounters contained at least one error, including failure of the clinician to order the correct test.⁵ Another problem area was the manual entry of orders and transcription of patient data by someone other than the clinician who ordered the test.²¹⁹ This study outlines the risk of not using closed-loop technologies, such as computerized provider order entry (CPOE) systems.²¹⁹

Experts and research studies propose that integration of CPOE with laboratory information systems could effectively replace and support the human parts of the testing process that may be more vulnerable to error.²¹⁹⁻²²¹ Diagnostic stewardship related to test ordering has been suggested as one way to reduce excessive testing²²² given the high unwarranted variation in test ordering patterns across clinicians and practices.²²³

3.8.2. Test Results Management

The followup and management of test results has been identified as an area of persistent safety concerns (e.g., providers missing abnormal test results, failure to effectively route and track test results).¹⁷⁰ Studies investigating barriers and risks to test results management have elucidated causes such as:

- Variations in followup practices,
- Breakdowns in teamwork and coordination,
- Transitions of care,
- Communication failures,
- System factors, and
- Poorly designed human-computer-interfaces.²²⁴⁻²²⁷

Health IT is considered to hold the promise of safer test results management by delivering better tracking of test results, improved communication via patient portals, and support for interpretation of results.^{220,228,229} Followup has been shown to improve when health IT systems provide alerts for abnormal results and support clinician and patient interactions.^{170,200,230}

3.8.3. Closing the Loop

Closing the loop is when every test result is sent, received, acknowledged, and acted on without failure, including communicating with patients in a language they understand. Failure to close the loop can occur due to failures in timely followup of abnormal laboratory results or ineffective communication of results to patients.^{230,231}

Closing the loop remains a challenge despite EHR use in integrated health systems. Several studies have highlighted breakdowns in followup of test results.^{218,230-233} One study evaluating followup for patients with kidney disease found 58 percent lacked timely followup of their abnormal test result.²⁰⁰

3.9. Interventions

For this brief, interventions refer to specific actions or initiatives to prevent or reduce diagnostic errors and increase safe, timely, and appropriately communicated diagnosis. Several recent systematic reviews describe the growing evidence base for interventions to decrease diagnostic errors.²³⁴⁻²³⁶ We outline these interventions in four broad categories as detailed below.

3.9.1. Educational Interventions

Educational interventions focus on transfer of knowledge and skills to various groups of learners. While diagnostic reasoning is an essential clinical competency, we focus on activities explicitly intended to address diagnostic error. Some of these focus on specific skill domains, such as critical thinking and cognitive biases,²³⁷ physical examination,²³⁸ and diagnostic efficiency.²³⁹ More comprehensive longitudinal curricula focused on diagnostic reasoning and diagnostic error have also been described.²⁴⁰⁻²⁴² Nondidactic approaches currently in development include simulation-based training in diagnostic reasoning and error reduction.^{18,20}

An important recent advance is the development of proposed competencies for diagnostic quality and safety in education and training programs for health professionals. These competencies, developed by a panel of experts in diagnostic quality and safety, include:

- Diagnostic reasoning (e.g., differential diagnosis, use of decision support tools for diagnostic reasoning),
- Teamwork (e.g., engagement of all team members, including patients), and
- System-related aspects of diagnosis (e.g., human factors, safety culture).²⁴³

3.9.2. Cognitive Interventions

Cognitive interventions provide support to reduce clinicians' cognitive burden and enhance diagnostic reasoning. Checklists have long been proposed as a cognitive aid to reduce diagnostic error,²⁴⁴ although empirical evaluation has yielded mixed results on diagnostic quality.²⁴⁵⁻²⁴⁸ Relatedly, clinical decision support systems have shown modest but positive effects on differential diagnosis and other aspects of diagnostic decision making.²⁴⁹⁻²⁵⁴ Most studies have focused on algorithmic decision support tools, although crowd-sourced intelligence from multiple physicians may also improve diagnostic accuracy.²⁵⁵

More recently, interventions have been developed to encourage reflection and mindful practice during the diagnostic process^{116,256-258}; a specific example is the "diagnostic timeout."²⁵⁹ Finally, an emerging group of interventions focuses on providing timely retrospective feedback to clinicians on their diagnostic performance.^{20,105}

3.9.3. Patient and Family Interventions

Interventions to engage patients in error prevention, detection, and mitigation have become more prominent in recent years. Broadly, these interventions include strategies to enhance transparency and collaboration in patient-clinician communication during the diagnostic process.¹⁹³

For example, recent developments include structured approaches to help patients contribute to diagnostic encounters,^{87,210,260} strategies to better communicate diagnostic uncertainty to patients,²⁰⁴ and approaches to address diagnostic disparities due to language barriers.²⁰ A recent AHRQ issue brief provides a comprehensive review of strategies to solicit and use patient experience data for diagnostic safety improvement.²⁶¹

3.9.4. System Interventions

System interventions aim to improve one or more factors at the team or system level to reduce diagnostic error. Efforts to make diagnostic processes safer include enhancing interprofessional communication and teamwork.^{262,263} One proposed approach includes reorganizing resources to create "diagnostic management teams." Such teams include experts in diagnostic specialties such as laboratory medicine and are available

for consultation on test selection and interpretation to improve the timeliness and accuracy of challenging diagnoses.²⁶⁴ Other system interventions address barriers to timely and accurate diagnosis, such as access to testing.²⁶⁵

Finally, two recently tested approaches in primary care settings used multimodal interventions that included educational content for clinicians and staff, quality/process improvement activities, and detailed reviews of diagnostic errors to identify improvement opportunities.^{266,267} Methods to monitor and audit records for potential diagnostic safety events²³⁵ may inform intervention targets; these are described in more detail in the "Implementation" section.

3.10. Implementation

The Implementation domain includes enacting and sustaining practices to improve diagnostic safety through use of operational frameworks, guides, and other resources.

3.10.1. Models and Frameworks

Strategies to improve diagnostic safety are gradually moving from research settings into operational settings. However, dedicated programs and activities to address diagnostic error remain uncommon in healthcare organizations. Diagnostic safety activities have been described in the context of existing quality and safety frameworks, such as learning health systems²⁶⁸ and high-reliability organizations.²⁶⁹

Singh, et al., suggested a diagnostic safety-specific action plan for organizations, termed "learning and exploration of diagnostic excellence."²⁷⁰ This plan recommends that organizations establish a central coordinating "virtual hub" for diagnostic safety activities that includes:

- Scientific initiatives to translate research into practice,
- Measurement for improvement purposes,
- Engagement of clinicians in diagnostic safety improvement activities, and
- Engagement of patients and learning from them about their diagnostic concerns.

3.10.2. Organizational Approaches

Barriers to diagnostic safety improvement in healthcare organizations include low awareness of the problem, lack of infrastructure and resources to address diagnostic safety, lack of leadership commitment, and low prioritization in the context of other quality goals.^{150,271} Once organizations have committed to implementing diagnostic safety activities, they must further overcome several practical obstacles. These include adopting a useful working definition of diagnostic safety events, developing ways to identify and learn from vulnerabilities in diagnostic processes, and conducting appropriate response and prevention activities.

Several publications describe how organizations have implemented diagnostic safety monitoring and improvement activities, and these reports reflect the importance of adapting to local contexts and resources.^{4,270,272-275} For instance, Perry, et al., reported creation of a hospitalwide "diagnostic error index" using five well-established data sources within the organization, including autopsy findings, root cause analyses, and morbidity and mortality conferences.²⁷⁴ Others have focused improvement efforts on specific care settings (e.g., primary care²⁷⁶) or presenting problems (e.g., abdominal pain,⁴ suspected cancer²⁷⁵).

3.10.3. Resources

Despite variations in focus and approach, broadly generalizable principles and recommendations have now emerged; these are summarized in recent publicly available resources to support implementation of diagnostic safety practices. In addition to the resources already mentioned, examples of resources developed for a broad audience of healthcare leaders, clinicians, and quality and safety professionals include:

- Safer Dx Checklist (Institute for Healthcare Improvement; Singh, et al., 2021). This resource lists 10 organization-level practices to advance diagnostic excellence. Each item is rated as fully, partially, or not implemented. https://www.ihi.org/resources/tools/safer-dx-checklist-10-high-priority-practices-diagnostic-excellence.
- Recognizing Excellence in Diagnosis: Recommended Practices for Hospitals (Leapfrog Group). This report describes 29 evidence-based practices hospitals can use to prevent diagnostic harm to patients. https://www.leapfroggroup.org/recognizing-excellence-diagnosis-recommended-practices-hospitals.
- Improving Diagnosis in Medicine: Diagnostic Error Change Package (SIDM and Health Research & Educational Trust). This toolkit describes a variety of possible strategies for improving the diagnostic process and engaging a variety of team members, including patients and families, in improvement efforts. https://www.improvediagnosis.org/wp-content/uploads/2018/11/improving-diagnosis-in-medicine-change-package-11-8.pdf.
- Measure Dx: A Resource To Detect, Analyze, and Learn From Diagnostic Safety Events (AHRQ). This resource describes how organizations can convene a diagnostic safety team and use a variety of data sources to identify, and subsequently learn from, diagnostic safety events. https://www.ahrq.gov/ patient-safety/settings/multiple/measure-dx.html.
- Calibrate Dx: A Resource To Improve Diagnostic Decisions (AHRQ). This clinician-oriented resource provides step-by-step guidance for self-assessing one's diagnostic reasoning based on a systematic case review process. https://www.ahrq.gov/patient-safety/settings/multiple/calibrate-dx.html.
- GoodDx (University of California-San Francisco). This web-based compendium of diagnostic performance feedback and data gathering tools includes, but is not limited to, the resources described above. https://gooddx.org.

3.10.4. Communities of Practice

In addition to publicly available resources, multi-institutional learning collaboratives show promise as a way to disseminate and facilitate implementation of diagnostic safety practices. Among the first such collaboratives was the AHRQ-funded PROMISES project. This randomized trial engaged 16 primary care practices in a shared learning initiative to improve care processes, including management of test results and referrals (http://www.macoalition.org/promises.shtml).

SIDM has hosted multiple virtual learning collaboratives in partnership with the Institute for Healthcare Improvement (https://www.improvediagnosis.org/improvedx-march-2019/learning-collaborative-applies-qi-to-diagnostic-error/) and, more recently, with Constellation Mutual (https://constellationmutual.com/blog/ how-to-close-the-loop-on-diagnostic-error/).

In 2023, the Washington State Hospital Association launched a regional collaborative focused on shared learning and pursuit of diagnostic excellence (https://www.wsha.org/diagnostic-excellence/). Finally, NAM, in partnership with the Council of Medical Specialty Societies, provides support for scholarship and leadership development for a yearlong cohort of professionals interested in diagnostic excellence (https://dxexscholars.nam.edu).

3.10.5. Policy

Few external incentives encourage healthcare organizations to engage in diagnostic safety improvement work. The NAM report suggests potential policy and payment levers to drive improvements in this area, including the recommendation that accrediting organizations (such as the Joint Commission) require organizations to systematically monitor, identify, and learn from diagnostic errors.¹² Toward this goal, the Leapfrog Group's Recognizing Excellence in Diagnosis program is a current effort to build national consensus on recommended practices for hospitals to improve diagnosis.²⁷⁷

Additional reforms include revising payment models to incentivize diagnostic safety measurement and improvement activities; more appropriately reimbursing the cognitive effort and teamwork needed to achieve diagnostic safety; and demonstrating diagnostic accuracy for condition-based alternative payment models.^{278,279}

4. Discussion

Findings from this review suggest scientific progress in nearly all the diagnostic domains, but progress has varied across domains. Certain domains, such as incidence, measurement, and health IT use, have experienced significant scientific progress. However, application of the research to clinical practice and operational safety improvement is lagging. Research is inadequate on cross-cutting systems and processes of care issues related to diagnostic safety, as well as research focused on closing implementation gaps.

We identified several gaps related to both science and practice that need progress. For instance, specific gaps identified in the measurement data and methods domain included low rates of operationalizing reporting tools clinicians can use and limited monitoring of diagnostic error incidence in actual practice. Clinicians have a lot of information about diagnostic errors that can be leveraged by organizations thinking of databased improvement strategies.

We also found inadequate use of electronic data (such as data available in EHR repositories) to both measure and improve diagnostic safety. Another domain that needs further development was that of cognition, where we found that studies in the field of cognitive processes were mostly experimental and missing real-world context.

In addition, we found gaps in the culture, workflow, and work system issues domain, where studies related to how culture, behavior, and work system influence diagnostic safety were limited. Data on disparities was limited but suggested the need to address diagnostic equity and ensure collection of segmented data to see how various underrepresented groups are affected.

Progress in certain domains, such as patient/family engagement and interventions, was mostly from published perspectives and thought pieces with fewer empirical or evaluation studies. The domains of intervention and implementation are still emerging, with inadequate ways to close the implementation research to practice gaps. Real-world studies that involved health systems as partners for learning and improvement activities are also lacking. Gaps in the health IT domain included limited application or effectiveness studies of computer algorithms and decision support to specifically augment diagnostic accuracy.

The domains were not mutually exclusive, and we found several overlapping themes that cut across the various domains. This overlap underscores the need to develop a more multidisciplinary approach to diagnostic safety that would cut across domains. For example, while a body of literature exists related to cognitive science, we did not find it very well integrated into clinical practice or with other fields. Similarly, while emerging use of health IT is improving diagnosis, we did not find adequate studies that used human factors and cognitive science approaches to optimize cognitive support to clinicians and to inform technology design.

In addition, there has been rapid development of resources and tools while implementation work that focuses on strengthening systems and processes of care is lacking. We also found minimal use of learning health systems approaches and embedded research models that could accelerate practice transformation. Our findings suggest the need to approach diagnostic safety research from multiple lenses and use of multidisciplinary scientific teams to accelerate progress.

To promote broad-scale improvement in diagnostic safety, we recommend research efforts to address the identified gaps within each domain. We also recommend approaches for better dissemination of this work. For example, engaging boards of different specialties and their associated professional organizations to promote diagnostic safety in a more consistent and uniform way could lead to better uptake of emerging research findings.

Another important step would be to engage policymakers who could promote uptake of resources that have been developed and consider policy and payment reforms to incentivize health systems to promote diagnostic safety. As AI becomes more integrated into clinical care and population health, studies are needed to observe how clinicians interact with generative AI to formulate a correct and timely clinical diagnosis, including asking patients the right questions.

This issue brief has several limitations. We used a rapid narrative review methodology to scan diagnostic safety materials that was not systematic, so we likely missed some publications. We addressed this limitation by performing a second search with the domains and subdomains as search terms as well as incorporating input from experts.

Another limitation was including search materials mostly since 2013 onward, so we missed certain key items published just prior to 2013. However, our focus was the current state of diagnostic safety and because many of these publications built on prior work and because we included external experts, this choice had minimal impact on findings. The 10 domains had overlap, so certain papers ideally belonged in more than one category. Finally, the field of diagnostic safety is broad and emerging, so this issue brief may not cover all areas.

We summarized the state of the science of diagnostic safety for the past decade. Despite progress in various domains of diagnostic safety, several research gaps remain. Our findings and recommendations have implications for future investments and research funding for diagnostic safety.

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Appendix A. Search Terms

diagnostic safety/error + incidence diagnostic safety/error + contributing factors diagnostic safety/error + burden diagnostic safety/error + measurement data and methods diagnostic safety/error + e-triggers diagnostic safety/error + measurement frameworks diagnostic safety/error + defining diagnostic error diagnostic safety/error + reporting diagnostic error diagnostic safety/error + cognitive process diagnostic safety/error + cognitive biases diagnostic safety/error + cognitive burden diagnostic safety/error + culture, workflow, and work system issues diagnostic safety/error + culture behavioral norms diagnostic safety/error + culture barriers identified by staff diagnostic safety/error + work system diagnostic safety/error + work system process breakdowns diagnostic safety/error + disparities diagnostic safety/error + disparities diagnostic performance diagnostic safety/error + effect of bias diagnostic safety/error + implicit bias diagnostic safety/error + health information technology diagnostic safety/error + electronic health record diagnostic safety/error + telehealth diagnostic safety/error + telemedicine diagnostic safety/error + decision support tools diagnostic safety/error + patient families caregivers diagnostic safety/error + patient centered communication diagnostic safety/error + technology tools diagnostic safety/error + testing diagnostic safety/error + test order diagnostic safety/error + test results management diagnostic safety/error + close the loop diagnostic safety/error + interventions diagnostic safety/error + interventions educational diagnostic safety/error + interventions cognitive diagnostic safety/error + interventions patient and family diagnostic safety/error + interventions system diagnostic safety/error + implementation diagnostic safety/error + organizational approaches diagnostic safety/error + resources diagnostic safety/error + communities of practice diagnostic safety/error + policy

Appendix B. External Experts for Qualitative Interviews

Experts	Area of Expertise in Diagnostic Safety
Laura Zwaan, Ph.D.	Cognitive psychology and reasoning
Christina Cifra, M.D., M.S.	Pediatrics/ICU diagnostic error research
Kelly Smith, Ph.D.	Patient-focused research/social scientist
Joe Grubenhoff, M.D.	Pediatric emergency medicine
Kelly Gleason, RN, Ph.D.	Nursing research
Andrew Olson, M.D.	Hospitalist with expertise in diagnostic error-related education
Andrew Auerbach, M.D.	Hospitalist with diagnostic error and patient safety expertise
Gordon Schiff, M.D.	Primary care and overall expertise in diagnostic error
Mark Graber, M.D.	Founder of SIDM and expertise in diagnostic error

Appendix C. Interview Guide

We will be presenting our preliminary findings on the current state of diagnostic safety. As we present the findings, we will pause to ask about your thoughts on any major themes or gaps in knowledge.

[Introduce team members]

We are reviewing the state of the science of diagnostic safety to identify gaps and outline next steps for research, policy, and practice.

After scanning numerous leading sources in diagnostic safety, including the Institute of Medicine reports, AHRQ PSNet, Society to Improve Diagnosis in Medicine, NAM Scholars in Diagnostic Excellence, etc., we identified themes that encompass the current state of diagnostic safety.

With these themes in mind, we conducted a rapid narrative review. Our search duration was from 2013 to 2023. Our review included published literature, grey literature, projects, and, lastly, tools, resources, and guides on diagnostic safety.

The initial rapid narrative review led us to 10 domains of diagnostic safety [read through list]. We then identified subdomains. We will review these domains, subdomains, and provide an example of a gap within each of the domains in the following slides. A note of caution is that the gap is for the entire domain and not linked to a particular subdomain. Also wanted to note, the 10 domains may not be inclusive, and some domains are overlapping.

Based on the previously sent figure of the domains, feel free to let us know if any of the listed domains is out of your field of expertise. We would appreciate your comments on the domains you are comfortable and familiar with. [Pause for feedback]

The interviewee will list the domain on the slide and ask the following questions after each domain.

[Pause for feedback] Does this domain adequately represent the field? Do the subdomains encompass the domain? Are there additional subdomains needed?

Then the interviewer will list out some gaps.

[Pause for feedback] Do these gaps make sense? Are there additional gaps in this domain that should be included? Do you have any suggestions or recommendations on how to address these gaps? What are some of the imminent next steps in moving forward in this domain?

We know that we are covering a wide range of topics and ideas here, and so next we want to share a framework we're working on to try to visualize how all these domains are connected to one another and how they relate to the diagnostic process. As you can see, our framework is based on the NAM model. We'd love to hear your thoughts on this framework. Do you think anything is missing? Do you think anything should be moved?

[Pause for feedback]

To wrap up, we want to know your overall thoughts about our methodological approach to address the state of diagnostic safety. Do you think it is comprehensive? Any last-minute refinement that you would suggest?

Lastly, can you share what are your perspectives on how we can promote broad-scale improvements in diagnostic safety and at the same time making sure not to duplicate any activity already taking place?

