Issue Brief 14

Pediatric Diagnostic Safety: State of the Science and Future Directions









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Pediatric Diagnostic Safety: State of the Science and Future Directions

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Introduction

Pediatric clinicians self-report making diagnostic errors resulting in harm at least once or twice annually.^{1,2} National data corroborate pediatric clinicians' experiences. For example, the Child Health Patient Safety Organization reported that missed diagnostic opportunities (MDOs) constituted the greatest proportion of care management errors contributing to serious safety events among their member hospitals.³ Similarly, MDOs represent the most common medical factor contributing to pediatric closed (i.e., settled) malpractice claims.⁴ Given these findings, pediatric patient safety leaders have placed MDOs in the top 10 patient safety research priorities.⁵

The epidemiology of MDOs for specific pediatric diagnoses (e.g., appendicitis, child abuse, cancer) has long been a focus of pediatric research, particularly in tertiary children's hospitals.⁶⁻¹¹ Less exploration has occurred in community hospitals that deliver acute care to the vast majority of children.¹² Hospital-based research into MDOs also focuses on relatively acute presentations.

In contrast, conditions commonly managed in the primary care setting (e.g., hypertension, depression, anemia) have an added challenge in quantifying MDOs for illnesses that evolve over time.¹³ While early efforts to detect and understand MDOs in pediatric medicine are encouraging and necessary, our understanding of the unique issues in pediatric diagnostic safety is embryonic.

This issue brief explores the unique challenges of studying and improving diagnostic safety for children with respect to their overall health, access to care, and unique aspects of diagnostic testing limitations for many pediatric conditions. The issue brief will also highlight approaches to address these challenges across the care delivery spectrum: primary care offices, emergency departments (EDs), inpatient wards, and intensive care units. The brief concludes with recommendations for building capacity to advance pediatric diagnostic safety.

Challenges in Approaching Diagnostic Safety Unique to Children

Low disease burden among children and developmental considerations significantly influences the diagnostic process in pediatric medicine. Pediatric patients' constantly changing anatomy, development, and physiology present distinct challenges related to accurate and timely diagnosis of their health conditions. Limited access to specialized pediatric providers and healthcare facilities with appropriate resources negatively impacts pediatric diagnostic safety. Below, we summarize three specific pediatric challenges.

Low Disease Burden and Implications for Diagnostic Testing

Physician-reported experiential data support that most children with MDOs present for acute care with common undifferentiated symptoms.¹⁴ The primary patient concerns at these encounters frequently involve one of two situations:

- Common time-limited conditions (e.g., mild viral illnesses, minor injuries, bronchiolitis, acute asthma exacerbations), or
- Common symptoms that are far more likely to be associated with benign rather than serious illness (e.g., fever or abdominal pain).¹⁵

While "the chance of serious disease [in children] is low...the consequences of not treating specific illnesses are devastating."¹⁶ The juxtaposition of the risk of missing rare but serious life-limiting illness against a backdrop of a generally healthy population creates tension during the diagnostic process for clinicians treating children.

For example, abdominal pain is one particularly common and challenging chief complaint given its broad differential diagnosis of both self-limited and serious etiologies that drastically vary by age group.¹⁷ One retrospective study of nearly 1,000 primary care patients ages 4-18 years found that 9 percent of patients attended at least one acute care visit for abdominal pain over a 6-month period. Nearly half of those visits ended with diagnoses of acute or chronic constipation.¹⁸ However, studies consistently show that appendicitis is at high risk for misdiagnosis, and symptoms are often attributed to constipation.¹⁹⁻²¹

Pediatricians are aware of pediatric malpractice claims data showing that appendicitis, along with meningitis and pneumonia, are among the most frequent conditions resulting in closed claims.^{22,23} Nonetheless, appendicitis remains a perennial MDO despite the need for accurate and timely recognition to minimize morbidity and mortality.^{24,25}

Providing safe and accurate pediatric care is also complicated by several factors related to diagnostic testing. Pediatric diagnoses such as Kawasaki disease, bronchiolitis, autism spectrum disorder, and juvenile idiopathic arthritis do not have singular criterion standard tests that provide a definitive diagnosis. Instead, providers must synthesize the history of present illness, physical examination, imaging, and less specific laboratory testing to achieve an accurate and timely explanation of their young patients' health problems.

When definitive tests exist, such tests may expose children to greater risks than similar testing in adults. Cumulative ionizing radiation exposure, especially when first exposure occurs in infancy, places children at higher risk of malignancy over their lifetime.^{26,27} Thus, clinicians caring for children must carefully weigh the risks and diagnostic yield associated with computed tomography and fluoroscopy.²⁸⁻³⁰

The risks of testing are not isolated to medical complications. Overtesting, including seemingly benign sample acquisition, can expose children to painful procedures they may not fully understand or accept and negatively affect future responses to procedures or healthcare encounters.^{31,32} Therefore, clinicians treating children may hesitate to order certain tests to avoid adding to their patients' pain and suffering during the diagnostic process or creating fear of undergoing tests at future encounters. Further, overtesting can have significant financial implications as it contributes to wasteful healthcare spending and can burden patients and caregivers with unnecessary costs.^{33,34}

Pediatric diagnostic testing recommendations frequently advise against obtaining low-yield studies for many conditions. For example, all five Choosing Wisely recommendations from the American Academy of Pediatrics (AAP) Section on Emergency Medicine advocate for reducing testing for conditions ranging from lower respiratory tract infections and constipation to febrile seizures and head trauma.³⁵

Tension exists because many conditions that are not dangerous present with similar signs or symptoms as more serious illnesses and injuries. While robust evidence promotes diagnostic test stewardship for patients with certain conditions, clinician risk tolerance contributes significantly to variation in testing practices and can lead to testing that provides little diagnostic value.³⁶⁻³⁸ In addition, parents rarely have knowledge of the evidence supporting diagnostic testing recommendations.

Caregivers' desire for reassurance may drive demands for testing, even when the tests are unnecessary.³⁹ Thus, evidence-based testing recommendations may be ignored to reduce uncertainty for both providers and

parents. This approach of overtesting, although not an MDO, nonetheless exposes children to possible harm if test results lead to unnecessary treatment or more invasive confirmatory testing.

The generally low likelihood of diagnosing serious illnesses may also lead clinicians toward opposite behavior, forgoing tests that may be warranted. Although it is less well studied, pediatric clinicians warn about the risks of improper reliance on heuristic-driven diagnostic reasoning.^{16,40} When heuristics fail, they are often called cognitive biases.⁴¹

Frequency gambling, the bias of attributing a child's symptoms to a benign common condition rather than a rarer, more serious one, likely contributes to frequent MDOs among children precisely because this strategy often ends without patient harm. Illustratively, Lam, et al., found that multiple clinicians exhibited similar diagnostic reasoning when caring for children presenting to the ED with new-onset headaches.⁹ After the children improved with "migraine cocktails," the clinicians opted for a diagnosis of migraine headache despite indications that more serious intracranial processes may be present.

Suboptimal cognitive acts such as frequency gambling are not unique to pediatrics.⁴² However, pediatric clinicians may unconsciously use heuristics that presume good outcomes based on a preponderance of previous good outcomes (e.g., outcome bias, ascertainment bias) more routinely than other cognitive biases. Further study of these impacts on pediatric diagnostic reasoning holds promise for improving diagnostic calibration.

Limited Access to Specialized Pediatric Care

Another pressing diagnostic safety issue facing children today involves access to providers specialized in the care of children. Every year, many children seek medical care at nonpediatric facilities, such as adult EDs and urgent care centers. According to a national assessment of 4,149 EDs conducted by Gausche-Hill, et al., nearly all (97%) respondents caring for children resided in nonpediatric facilities and accounted for 83 percent of all pediatric ED visits.⁴³

This scenario presents diagnostic challenges for children and their families as nonpediatric healthcare providers may lack the knowledge, procedural skills, and comfort needed to care for this unique patient population. A survey of 375 nonpediatric ED providers (physicians, nurse practitioners, and physician assistants) found that less than half of the respondents felt comfortable caring for a child less than 3 months of age.⁴⁴ This lack of familiarity and comfort with pediatric diagnoses places patients at risk for misdiagnosis, underdiagnosis, and overdiagnosis.

Many organizations, such as AAP and the American College of Emergency Physicians, have long advocated improvements in ED readiness to care for children. These efforts led to the formation of the National Pediatric Readiness Project (NPRP) in 2009. This multiphase quality improvement initiative was founded to help ensure that all U.S. EDs had the necessary clinical guidelines, provider competencies, and material resources to provide optimal care for children.

EDs with high pediatric readiness scores are associated with decreased mortality.^{45,46} As the pediatric readiness score includes assessment of pediatric clinical competency of ED providers, decreased mortality in high-readiness facilities can be partly attributed to improved diagnostic performance in pediatric patients.

Unfortunately, only 55 percent of U.S. children reside within a 30-minute drive of an ED with pediatric readiness above the 90th percentile.⁴⁷ Similar accessibility trends also affect children who require hospital admission. Twenty percent of children and youth have special care needs that require intensive and specialty care in the first two decades of life.⁴⁸ Yet, Cushing, et al., found that from 2008 to 2018, the number of

pediatric inpatient units decreased by 19.1 percent and pediatric inpatient beds decreased by 11.8 percent nationally.⁴⁴ In addition, the percentage of children whose nearest hospital contained a pediatric inpatient unit decreased from 51.6 percent to 41.7 percent.

Another study found that as many as 39 percent of children with one complex chronic condition and 27 percent of children with multiple complex chronic conditions are admitted to nonpediatric hospitals annually.⁴⁹ These facilities often lack staff adequately trained in pediatric care, specialized equipment, supplies, medications, and pediatric-specific care pathways and policies, increasing their risk of misdiagnosis.

Growing Medical Complexity

Given the challenges with access to specialized pediatric care, the rapidly growing subset of children with medical complexity (CMC) represents a population with considerable diagnostic safety risks.^{49,50} This population presents its own potential diagnostic pitfalls given chronic multisystem health issues, technology dependence, functional limitations, and high resource use.⁵¹⁻⁵³

CMC often have increased variation in care, especially related to diagnostic testing.⁵⁴ In addition, this population is more susceptible to adverse events from medical errors.^{55,56} Morse, et al., provide one example of how clinical decision support tools can be used to direct a medical evaluation and enhance differential diagnoses in CMC patients presenting with pain of unknown etiology.⁵⁷

Specialized clinics may also address undiagnosed conditions.^{40,58} However, CMC present numerous challenges for achieving diagnostic excellence. Some patients may be nonverbal or receive care from both in-home providers and numerous specialists, often at multiple institutions, which creates added difficulty in the diagnostic process when new symptoms arise. Therefore, improving diagnosis in CMC must remain a priority.

In summary, because of the wide-ranging diagnostic challenges unique to pediatric patients, continued focus on pediatric diagnostic safety is imperative to reduce MDOs and improve patient outcomes.

Pediatric Diagnostic Safety Research and Initiatives Across the Care Continuum

Research and improvement efforts in pediatric diagnostic safety lag behind similar efforts with adult populations. However, pediatric providers and healthcare organizations have made significant contributions to understanding the impact of MDOs in children from primary care offices to the pediatric intensive care unit (PICU). In addition, leading organizations in pediatric safety have begun efforts to educate about, study, and reduce harm from MDOs.

Primary Care

Professional organizations such as AAP strongly advocate that all children have a "medical home" in which patients, their families, and clinicians "develop a partnership of mutual responsibility and trust."⁵⁹ Such partnerships model patient and family inclusion on the diagnostic team as described in Improving Diagnosis in Health Care.⁶⁰ Nonetheless, MDOs occur even in this setting designed to identify new diagnoses well before harm arises from them.

One-third of ambulatory pediatricians surveyed by the AAP Quality Improvement Innovations Network reported making diagnostic errors at least monthly and errors that harmed patients at least annually.⁶¹ Nearly 90 percent indicated interest in reducing diagnostic errors, especially for conditions that evolve over months to years (e.g., hypertension, depression), require subspecialist referral, or may go unnoticed due to systems issues (e.g., not addressing abnormal values).

Responding to this knowledge, primary care diagnostic safety researchers have begun to address common MDOs through a quality improvement collaborative: Reducing Diagnostic Errors in Pediatric Primary Care, or Project RedDE.¹³ Early retrospective work showed more than half of the opportunities to recognize hypertension and depression were missed. When available to the treating clinician, 11 percent of abnormal lab values requiring treatment or additional diagnostic evaluation were not addressed.

Subsequent investigation has started to describe the factors that contribute to these common MDOs.⁶² Project RedDE developed a cluster-randomized, stepped-wedge prospective investigation of a virtual quality improvement collaborative involving 31 pediatric practices.⁶³ Results of the quality improvement initiatives provide actionable steps for other pediatric practices to address these three primary care issues (hypertension, depression, lack of followup on abnormal lab values).⁶⁴⁻⁶⁶

As with other clinical practice environments, Project RedDE focused on specific diagnoses and, in the case of missed lab results, a specific diagnostic process. However, primary care providers are responsible for identifying a wide range of conditions. While most of these conditions may be common pediatric diagnoses, rarer and atypical presentations may go unrecognized, exposing patients to more risk of harm from MDOs.⁴⁰

As more primary care practices adopt electronic health records (EHRs), they may be able to leverage these systems to detect other missed opportunities. Singh, et al., used electronic triggers based on EHR-recorded events to detect episodes of care that might include an MDO. By linking unplanned hospitalizations and ambulatory visits (office, urgent care, ED), they significantly increased identification of cases at risk of containing an MDO.⁶⁷

Another proactive and easily implemented approach leveraged the EHR to prompt diagnostic pauses for primary care clinicians seeing patients in urgent followup within 2 weeks of a prior visit; 13 percent of these encounters contained diagnostic discrepancies.⁶⁸ Clinicians reported that these pauses helped them identify opportunities to improve the diagnostic process at the followup visit.

These investigations reveal two key obstacles for pediatric primary care providers who want to reduce MDOs. First, the best evidence to date comes from one well-funded, centrally coordinated research project. This project included resources not typically available to primary care providers (i.e., statistical, technical, and logistical support from the AAP quality improvement network).

Second, these projects integrated EHRs to aid in building alerts and triggers and tracking data. The resources needed to hire clinical informaticists to support this work may not be feasible for many primary care practices. Thus, primary care practices will probably need to partner with academic medical centers, pediatric hospitals, and patient safety organizations to overcome these obstacles.

Emergency Medicine

The ED, perhaps more than any other clinical location, challenges clinicians with multiple threats to diagnostic performance. Medford-Davis, et al., detail the domains in which these challenges lie:

- Brief, ad hoc patient encounters lacking established rapport;
- Limited clinical information due to alterations in mental status, extremes of age, delirium, or poor information exchange between health systems;
- Time pressures for the recognition and treatment of life-threatening illness as well as those related to patient volume and rapid disposition;
- Frequent interruptions;
- A nearly infinite list of diagnostic possibilities; and
- Resource limitations, especially for pediatric patients.⁶⁹

Unsurprisingly, ED studies consistently indicate that adverse events frequently involve MDOs.⁷⁰⁻⁷² Although specialized for the care of children, pediatric EDs are not immune to MDOs, with diagnostic issues being second only to management concerns as the source of adverse events (19.3% and 52.4%, respectively).⁷³

ED encounters provide limited opportunity to accurately diagnose many of the conditions that patients first bring to medical attention there. Thus, return visits have received considerable attention as possible MDOs,^{74,75} although return visits resulting in admission are more likely to involve MDOs.^{71,76}

Fewer data exist for children but their experiences parallel data in adult populations. Nearly 10 percent of unplanned ED 48-hour return visits in children involved a change in diagnosis; however, the presence of MDOs was not assessed.⁷⁷ Another single-center study evaluated unplanned admission within 14 days of an ED or urgent care visit to identify discrepancies between ED index encounter and subsequent hospital discharge summary diagnoses.⁹ Twenty percent of cases reviewed involved MDOs. This method allowed researchers to aggregate similar MDOs that were not identified through traditional incident reporting structures.

Aggregating cases with similar diagnostic process failures may allow patient safety leaders to implement or modify clinical decision support resources (e.g., clinical care pathways) to mitigate the risks to future patients. Evaluating ED return visits with admission may augment hospital systems' ability to identify diagnostic improvement opportunities.

A less labor-intensive way to identify MDOs leverages administrative data to identify patterns of recurrent MDOs in pediatric ED encounters. For example, administrative data collected in four states showed that 8.1 percent of children admitted for sepsis within 7 days of an ED encounter experienced a probable MDO.⁷⁸ This approach also holds promise for nonpediatric hospitals interested in reducing MDOs.⁷⁹

Other data indicate that methods for detecting MDOs using administrative data will likely require different time horizons depending on the specific condition of interest.⁸⁰ Further, attempts to quantify MDOs in the ED must account for return visits to a different ED or risk missing approximately one in six return visits.⁸¹ Overall, the existing literature suggests that identifying, learning from, and reducing harm associated with MDOs in the ED will require multiple measurement strategies.

Hospital Medicine

Few studies have examined the epidemiology of MDOs among hospitalized children. One preliminary investigation that used a structured chart review to describe the prevalence of MDOs in pediatric patients admitted to a community hospital over a 90-day period showed that they affect approximately 5 percent of hospitalized children.¹² Similarly, 6.3 percent of children readmitted within 15 days at a single freestanding children's hospital within 15 days of discharge experienced an MDO.⁸²

More recently, a quality improvement initiative successfully increased physician reporting of "diagnostic learning opportunities." The project coupled a simple, dedicated reporting mechanism for suspected MDOs while patients were still hospitalized with a systematic review process to confirm the presence of a diagnostic learning opportunity.⁸ This approach consistently identified MDOs; 66 percent of reported events were determined to be MDOs. Further, the reports also generated insights about where in the diagnostic process errors often occur, which highlighted that most identified MDOs were multifactorial.

Nationwide Children's Hospital has leveraged a combination of data streams, including physician event reporting, an abdominal pain-related electronic chart review trigger, morbidity and mortality conferences, and autopsy results, to build a diagnostic error index.¹¹ This approach allowed a more thorough and nuanced view of the incidence of MDOs and was used to identify targets for quality improvement initiatives. It also enabled consistent tracking of progress made toward improved diagnostic safety.

Relatively few published studies in pediatric hospital medicine (PHM) describe interventions or approaches to reduce MDOs. Recognition and open discussion of diagnostic uncertainty has been proposed as a strategy to prevent MDOs due to inappropriately applied heuristics (see box below), such as premature closure.

A group of eight PHM providers developed and piloted diagnostic timeout over a 12-month period.⁸³ In general, the diagnostic pause was well received. Notably, in half of cases studied, the timeout did not confirm the initial diagnosis, often led to new actions being taken, and was rarely seen as a time burden. It also engaged learners in diagnostic reasoning.

Terms Used To Describe Decision-Making Processes

Improving Diagnosis in Health Care, published by the National Academy of Medicine (NAM), dedicated a chapter to the science of decision making as it pertains to the diagnostic process.⁶⁰ The discussion centers on dual-process theory developed by cognitive psychologists Daniel Kahneman and Amos Tversky. The theory includes two types of decision-making processes. System 1 relies on heuristics or mental shortcuts to make rapid, intuitive, almost subconscious decisions while System 2 uses a more analytical, deliberate approach.

As described in NAM's report,⁶⁰ when heuristics result in suboptimal (i.e., erroneous) decisions, they are labeled cognitive biases, which carry a negative connotation. This connotation may arise from the general description of the "heuristics and biases" approach to intuitive judgments as skeptical of expert judgment or intuition.⁸⁴ An alternate theory describing intuitive judgments by experts, including diagnosticians, known as naturalistic decision making, focuses on the real-world successes of intuition.⁸⁵

As both correct and incorrect decisions can arise from the application of intuition in the diagnostic process, some have suggested avoiding the term "cognitive bias" in favor of "heuristics." Cognitive psychologist and emergency physician Patrick Croskerry has proposed the term "cognitive dispositions to respond (CDRs)."⁴¹

An important component of CDRs, claims Croskerry, is that they can fail in predictable ways. For example, clinicians with varying credentials across time and clinical locations may make similar reasoning errors.⁸⁶ Such predictable failures present the possibility of avoiding them through debiasing strategies such as cognitive forcing functions.⁸⁷

Where proponents of dual process theory and naturalistic decision making align is that heuristicdriven, intuitive judgment can be improved through deliberate practice and feedback.^{84,88} Croskerry describes the importance of addressing the heuristic of feedback sanction (discouraging or inhibiting feedback during ED encounters), which directly impairs the feedback process.⁸⁹ AHRQ has developed a tool to support clinicians in refining and improving their intuition.⁹⁰

Engaging clinicians in improvement efforts related to diagnostic safety is challenging because "diagnostic errors" detrimentally impact psychological safety² and the term "cognitive bias" does little to improve that psychological safety. Promoting the use of terms such as "heuristics" or "cognitive dispositions to respond" might help clinicians focus on the cognitive science of decision making that affects all clinicians rather than perceiving personal failure.

Diagnostic uncertainty, especially when inadequately communicated within the healthcare team and to patients and families, may contribute to MDOs.^{91,92} A quality improvement initiative to increase shared situational awareness among the healthcare team about diagnostic uncertainty for children admitted to the PHM service resulted in a novel "uncertain diagnosis" or UD label added to the EHR.⁹³ The UD label was built on existing situational awareness infrastructure at this institution to identify risk for clinical deterioration. It included communication strategies to facilitate contingency planning for patients with uncertain diagnoses.⁹⁴

Building on this work regarding prospectively identifying diagnostic uncertainty in hospitalized children, additional studies have sought to better identify patients with uncertain diagnoses using EHR data such as diagnosis codes and clinical documentation.^{95,96} Despite promising results for improving identification and situational awareness about diagnostic uncertainty, reductions in patient harm have yet to be clearly linked to these intermediate outcomes.

Feedback on diagnostic accuracy is often inconsistent or lacking in clinical practice. Without consistent feedback on diagnostic outcomes, physicians cannot calibrate their clinical reasoning for future, similar cases.⁹⁷ To address this gap, a prospective educational study sought to provide structured feedback to residents on subsequent diagnostic changes for patients admitted overnight. The goal was to facilitate learning and diagnostic calibration.⁹⁸ Notably, they found that 12.7 percent of all cases had major diagnostic changes. In addition, residents reported that this approach increased their comfort with giving feedback and improved self-efficacy in identifying and mitigating cognitive biases.

Critical Care

Focused attention on diagnostic safety has resulted in increased knowledge on the epidemiology of MDOs in pediatric critical care over the past few years.⁹⁹ Autopsy studies have historically served as the primary source of information on the prevalence of pediatric intensive care unit (PICU) MDOs¹⁰⁰ despite pediatric autopsy rates being below 50 percent and autopsies providing a limited and biased sample.⁹⁹

Recognizing these limitations, more recent investigations have attempted to determine MDO frequency, causes, and impact across the larger PICU population beyond the small percentage of critically ill children who die. These epidemiologic studies have used a variety of methods and sources to characterize MDOs, including clinician surveys,¹⁰¹ morbidity and mortality conference reviews,^{102,103} incident reports,¹⁰⁴ and structured medical record review.^{7,105,106}

In contrast, research to understand the pediatric critical care diagnostic process remains underdeveloped. Early efforts using qualitative, quasi-experimental, and mixed methods studies have provided interesting insights into vulnerabilities of the PICU diagnostic process, including investigations of:

- Team cognition for diagnosis in daily PICU work,¹⁰⁷
- Impact of PICU transfer communication on the diagnostic process,¹⁰⁸
- Effect of hierarchy and professionalism on diagnosis during operating room-to-PICU handoffs,¹⁰⁹
- Quality and meaning of pediatric intensivists' diagnosis narratives in clinical notes,¹¹⁰ and
- Impact of subspecialty consulting services on PICU diagnosis.¹¹¹

Much work is still needed to translate these observations into effective and feasible interventions that can prevent misdiagnosis-related harm in critically ill children.

Since most research on diagnostic performance in the PICU has been disease oriented, almost all of the current interventions promoting diagnostic safety in daily PICU practice are disease specific, such as electronic sepsis alerts and clinical pathways.¹¹²⁻¹¹⁴ However, momentum is building for more disease-agnostic systems interventions, with early investigations of:

- Clinical decision support tools to detect patients at high risk for clinical deterioration,¹¹⁵
- PICU feedback systems to referring clinicians,¹¹⁶
- Communication of diagnostic uncertainty,^{93,117} and
- Standardization of referral communication for PICU transfer.^{118,119}

Despite these early achievements in primary and acute care, the achievements have been relatively isolated to specific practice locations. Integrated study of the impact of care transitions from the office to the ED to the hospital wards and ICUs on the diagnostic process has received little attention. In addition, outpatient subspecialty clinics have pursued little research on MDOs in children.

Diagnostic Safety Research Priorities and Opportunities

As the field of diagnostic safety research has evolved rapidly over the past decade, several attempts have been made to identify foundational research priorities both broadly and more specifically within pediatrics. The 2015 NAM report *Improving Diagnosis in Healthcare* highlighted the critical deficiencies in diagnostic error research compared with other patient safety events. The report identified four broad priority research topics related to diagnostic error⁶⁰:

- 1. Patient and family engagement in the diagnostic process¹²⁰;
- 2. Healthcare professional education and training¹²¹;
- 3. Health information technology¹²²; and
- 4. Identification, analysis, and reduction in diagnostic errors.

The priorities laid out within the NAM report have been echoed in more recent attempts to delineate priority research topics and questions. While the recommendations within the NAM report apply to pediatrics, the report does not call out any research priorities specific to pediatrics. This lack of attention to pediatrics is true of much of the available literature focused on diagnostic safety research priorities.

This section highlights high-quality papers that also apply to pediatrics, even if not providing pediatricspecific recommendations. Notably, a systematic review of MDOs in pediatrics highlighted the continued need to build foundational knowledge around the epidemiology of diagnostic safety events in children and to identify patient scenarios and populations at high risk for an MDO.¹²³

Recently, a project bringing together various stakeholders in the diagnostic process attempted to delineate clear diagnostic safety research priorities in the form of specific, focused research questions. A systematic approach to gathering and ranking research questions submitted by a broad range of researchers, including experts across several disciplines and in 10 different countries, identified high-priority research questions to advance diagnostic safety research.¹²⁴

A panel of subject matter experts reviewed and ranked 177 research questions on five criteria (usefulness, answerability, effectiveness, potential for translation, and maximal potential effect on diagnostic safety). This process resulted in 20 priority questions for advancing diagnostic safety research. As these priority topics were not specific to pediatrics, several require thoughtful design when considering children in diagnostic safety research (Table 1).

Table 1. Exai safety	nples of pedia	ric considerations when setting research priorities in diagnostic

Priority Research Question	Possible Pediatric Considerations
How can we best bring expert knowledge about diagnostic test selection and result interpretation to ordering providers at the point of care?	Reference ranges for tests often vary by age. Less familiarity with pediatric values among emergency physicians, general surgeons, and anesthesiologists may require unique methods to support proper interpretation.
How do we develop and evaluate performance of diagnostic trigger tools that can be used to identify or prevent diagnostic errors across the care continuum?	Trigger methodologies based on symptom-disease pairs may be harder to adapt to relatively healthy or nonverbal pediatric populations. ¹²⁵ For example, fever is a high-volume childhood complaint, but sepsis is a comparatively rare event. While meningitis is an important target for diagnostic safety research, the infants most at risk cannot report a headache.
What types of EHR design and functionality can effectively and efficiently summarize important historical patient context and new clinical findings to facilitate making an otherwise unrecognized diagnosis?	Parents are the first stewards of their children's EHR information when those children may be incapable of managing its accuracy independently. As children become developmentally capable of assuming more of their own health care responsibilities, EHRs will need to address this transition as well as new diagnoses that present in adulthood related to congenital and childhood-acquired conditions.
Can we improve diagnostic safety by facilitating shared decision making in the diagnostic process, i.e., by discussing the risks and benefits of watchful waiting vs. additional diagnostic testing and treatment options?	Parents may be less willing to accept diagnostic uncertainty or delays for their children's conditions compared with their own. ³⁹ Partnership with parents in preventing diagnostic error will likely require particular focus on addressing overdiagnosis and avoiding unnecessary testing.

Note: Priority research questions were adapted from Zwaan, El-Kareh R, Meyer AND, Hooftman J, Singh H. Advancing diagnostic safety research: results of a systematic research priority setting exercise. J Gen Intern Med. 2021;36:2943-2951. https://doi.org/10.1007/s11606-020-06428-3.

Within pediatrics, a growing number of stakeholders such as clinicians and healthcare leaders recognize that diagnostic safety is a priority topic in patient safety research.⁵ A narrative review of MDOs in pediatrics highlighted persistent gaps in the epidemiology of MDOs across pediatric disciplines compared with the literature on diagnostic safety in adult populations.¹⁰ This review also proposed several key research questions that focus on better establishing the causes and epidemiology of MDOs and developing evidence-based interventions to improve diagnostic safety specific to pediatrics. The importance of equity in the diagnostic process and in diagnostic safety research has also been highlighted by the Society to Improve Diagnosis in Medicine (SIDM).¹²⁶

There is also an increasing focus on the concept of safety II or resilience engineering.¹²⁷ Traditional patient safety approaches, or safety I, focus on creating standard processes and systems that limit the opportunity for things to go wrong. In contrast, safety II assumes that everyday performance variability provides the necessary adaptation to respond appropriately to inevitable variations in even the most well-designed systems.

Resilience at the individual, team, or systems level can be the reason things go right. For example, Ramnarayan and colleagues have demonstrated that less experienced clinicians will be alerted to important and "must-not-miss" diagnoses more often when using a web-based differential diagnosis support tool.¹²⁸ Limited evidence suggests that such tools may even decrease the likelihood of pursuing unsafe diagnostic evaluations at the risk of missing important conditions.¹²⁹

As diagnostic safety research advances, we should not only focus on learning from failures in the diagnostic process but also try to learn from cases where, despite its complexity, the diagnostic process or journey goes well and correct, timely diagnoses are achieved.

To date, diagnostic safety research funding has largely relied on federal agencies, such as AHRQ, and private entities, primarily the Gordon and Betty Moore Foundation. However, research and funding to improve diagnosis remain disproportionately focused on adults. In a brief query of the National Institutes of Health (NIH) RePORTER, the authors found that only 10 percent of AHRQ and NIH funding in diagnostic safety specifically focused on pediatric care. To overcome this disparity, future efforts should include:

- Heightened advocacy efforts focused on improving the diagnostic process for pediatric patients,
- Training and mentoring pediatric diagnostic safety researchers, and
- Dedicated funding allocated to pediatric-specific initiatives.

The Future of Pediatric Diagnostic Safety Research

Research To Understand the Diagnostic Process and Missed Diagnostic Opportunities in Pediatric Care Settings

We have only just started to develop an understanding of the extent of the problem of MDOs, much less a comprehensive theory of the diagnostic process and its vulnerabilities in pediatric care. Additional work is needed to create conceptual models of the diagnostic process specific to the clinical settings where pediatric care is provided (ambulatory care, EDs, general inpatient wards, intensive care units).

Although NAM's conceptual model of the diagnostic process is useful in many ways, adapting it to develop more tailored models will be essential to identify the barriers and facilitators of accurate and timely diagnosis unique to each setting. One example is the recent operational framework put forth by Mahajan, et al., to study the diagnostic process in the ED.¹³⁰

It is also essential that investigators study and learn from diagnostic process successes despite considerable variation in disease presentation and healthcare delivery (safety-II) in addition to understanding failure in the diagnostic process (safety-I).¹³¹ Within such conceptual models, potentially high-risk areas and factors investigators have started to address include:

- Pediatric transitions of care,¹³²
- Clinicians' cognitive load,¹³³
- The role of diagnostic uncertainty,¹³⁴
- Teamwork and communication,¹³⁵
- The clinical work environment and culture,² and
- Disparities in diagnostic testing and outcomes.¹³⁶⁻¹³⁸

Research on Interventions To Improve Pediatric Diagnosis

In tandem with biomedical discovery fueling the more precise diagnosis of new types and subtypes of pediatric disease, interventions addressing the sociotechnical aspects of pediatric diagnosis that cut across diseases must also be developed, implemented, and evaluated. Because diagnostic efforts cannot be extricated from the systems, circumstances, and environments within which patient care is delivered and healthcare teams must work,¹³⁹ an intense focus on the diagnostic process is needed. Such focus could target high-yield systems-based interventions for diagnostic safety and excellence.

Using a modified Delphi process to reach consensus, Singh, et al., determined 10 practical approaches that healthcare systems and organizations could implement to identify and support opportunities to improve diagnostic safety.¹⁴⁰ These include:

- Ensuring appropriate leadership engagement,
- Building a diagnostic safety culture that supports event reporting and learning,
- Developing infrastructure for MDO measurement and improvement activities, and
- Engaging patients.

Teamwork, team cognition, safety culture, communication, and patient/family-centeredness are some of the important aspects of the sociotechnical milieu of pediatric diagnosis that will likely receive more attention in the future as diagnosis-focused interventions are developed and tested.

Promising advances that address these aspects of diagnosis have been developed initially in adult clinical settings, many of which have been translated effectively for use in pediatrics. These include interventions to improve clinicians' calibration through feedback^{98,116}; tools to adjust how healthcare teams think about diagnosis, such as diagnostic timeouts¹⁴¹; and programs to improve communication about diagnostic uncertainty.⁹³

Interventions focused on clinicians likely apply across adult and pediatric settings because of the many similarities in clinician workflows regardless of the patient population. However, an important challenge for pediatrics would be to determine the applicability and adaptability of interventions that involve patient-centeredness and family involvement in the diagnostic process.^{120,142} Patient-focused interventions in pediatrics require more emphasis on family partnerships because of the inherent universal involvement of parents and caregivers in the diagnostic process.¹⁴³

Many potential resources that can be translated into tools to improve these various aspects of the diagnostic process are now available. Technological innovations in health information technology have historically been powerful allies in making healthcare safer in pediatrics, but they are not without pitfalls,¹⁴⁴ as noted in the discussion of artificial intelligence (AI) later in this section.

Existing technology, such as the EHR and telemedicine, can be redesigned or redeployed in the service of diagnostic safety. For example, efforts to identify patients with diagnostic uncertainty and provide clinician feedback to improve calibration have made clever use of the EHR to serve both as an information source and information delivery vehicle.^{96,98,145}

The use of telemedicine in pediatrics has expanded during the COVID-19 pandemic.¹⁴⁶⁻¹⁴⁸ Telemedicine has provided more equitable access to pediatric subspecialists for children who are underserved or living in remote locations.^{149,150}

New technology such as clinical decision support powered by AI can have a powerful impact on pediatric diagnosis.¹⁵¹ For example, recent work showing how AI can be used for pediatric diagnosis includes:

- Studies on AI's ability to diagnose common pediatric conditions after being trained on large medical record-derived datasets,^{152,153}
- Web-based AI systems that can provide advice to parents of sick children (including whether their child requires a doctor's visit),^{46,154}
- AI-driven vital sign parameters to prevent alert fatigue in pediatric acute care units,¹⁵⁵ and
- AI methodologies to automate or augment pediatric biomedical image interpretation.^{156,157}

However, as impressive as these initial forays are, AI-powered applications for pediatric diagnosis are still very much in their infancy. Similar to other new technologies, AI's thoughtful implementation into complex clinical workflows must be carefully considered just as much as its intended functions. In addition, we must consider challenges such as developing clinician trust and mitigating possible adverse outcomes, including inaccuracy due to shortcomings in training datasets and propagation of harmful healthcare disparities and bias.^{158,159}

Partnerships for Pediatric Diagnostic Safety

Developing a deep understanding of the diagnostic process and implementing interventions to promote diagnostic safety will require the inclusion of diagnostic excellence-focused goals and programs within and strong partnerships across a multitude of stakeholder organizations.

Active efforts must be made to include diagnosis-focused clinical and health services research in the portfolios of pediatric research collaborative groups to ensure robust multicenter research. For example, the international Pediatric Emergency Research Network¹⁶⁰ served as the primary platform for a recent study delineating the types of MDOs reported by pediatric emergency providers.¹⁴

In tandem, pediatric patient safety and quality collaboratives must include diagnostic excellence as a key patient safety goal to prioritize projects that improve diagnosis. To illustrate, the Children's Hospital Association, a national collaborative aimed at improving the safety and quality of pediatric hospital care, has developed a Diagnostic Safety Toolkit, which guides organizations in improving communication to prevent MDOs.

Likewise, subspecialty-specific pediatric professional societies and medical journals should ensure that their projects, programming, and publications appropriately include work focused on diagnostic excellence. In recent years, AAP, the Society of Critical Care Medicine, and their corresponding official journals, *Hospital Pediatrics* and *Pediatric Critical Care Medicine*, have prominently featured work on pediatric diagnostic safety.

Strong partnerships must be forged between investigators, pediatric research and professional networks, and pediatric patient safety collaboratives to ensure a throughline across discovery, implementation, and dissemination, resulting in more timely translation of findings to broadly benefit pediatric diagnosis.

Multistakeholder organizations, such as SIDM and the Society for Medical Decision Making, must continue to provide resources and support for a wide range of research and quality improvement initiatives to improve diagnosis. They must also ensure that pediatric-specific projects are well represented.

These societies are especially relevant when they provide venues for stakeholder engagement and collaboration. Engaged patients, families, and frontline clinicians are particularly important in pediatric diagnostic safety work. Thus, their input must be integrated into all initiatives aiming to improve diagnosis. One example is SIDM's Patients Improving Research in Diagnosis (PAIRED) program. This program trains and connects patient partners (many of whom are parents and family members of children affected by diagnostic error) with investigators to ensure that patients' and families' voices are integrated into diagnostic safety research.

Funding organizations such as AHRQ and the Gordon and Betty Moore Foundation have been significant champions of projects to improve pediatric diagnosis. For example, AHRQ's Measure Dx pilot implementation project designed to develop capacity for diagnostic safety recruited health systems to participate; nearly half of these systems were freestanding children's hospitals.¹⁶¹

The Moore Foundation, through its diagnostic excellence initiative, has funded numerous fellowships, quality improvement projects, and clinical education through various organizations, including:

- SIDM,
- NAM,
- Society of Bedside Medicine,
- American Board of Medical Specialties,
- Council of Medical Specialty Societies (CMSS), and
- Institute for Healthcare Improvement.

These grants and partnerships support researchers and clinicians (many of whom work in pediatric settings) in implementing a variety of initiatives to improve pediatric diagnosis. They also support efforts to expand the pediatric diagnostic safety research and quality improvement workforce. For example, CMSS awarded one of 11 grants funded by the Moore Foundation to AAP to promote diagnostic excellence in ambulatory pediatrics.¹⁶² These collaborations ensure that pediatric healthcare priorities align with and benefit from the rapidly expanding expertise in diagnostic safety.

Finally, to ensure the continued growth and development of the field, investments are needed in research, including the research workforce, and programs that will develop future leaders in pediatric diagnostic safety research and improvement. Diagnostic reasoning curricula must be incorporated not only into medical school education but also into allied healthcare professions' education.

Pediatric-specific graduate medical training programs must include didactic and practical education on diagnostic safety, which can be incorporated into standard patient safety and quality improvement education. Postgraduate fellowships in diagnostic safety research and quality improvement must also be offered by academic institutions, professional societies, and nonprofit organizations and agencies. Priority should go to healthcare professionals interested in improving diagnosis.

Consistently achieving pediatric diagnostic excellence will involve marshaling and coordinating resources from a broad array of disciplines, stakeholders, and institutions. Increased pediatric advocacy efforts and research funding focused on diagnostic safety are also needed.

Interdisciplinary research is needed to elucidate vulnerabilities in the diagnostic process specific to pediatric clinical settings and to rigorously investigate corresponding interventions that can improve diagnostic outcomes for children. At the same time, targeted efforts at the frontlines of pediatric care are needed to efficiently translate evidence-based interventions into measurable ways of improving diagnosis and, most importantly, reducing harm.

To accomplish this goal effectively and equitably, partnerships will need to be forged with patients, families, and frontline clinicians. Resources will also need to be shared among existing national and international pediatric research networks, pediatric patient safety collaboratives, professional societies, institutions of higher learning, and federal and private funding agencies. Finally, ensuring continuity and growth of the field requires that programs be established to develop and support learners at all stages to become future leaders in pediatric diagnostic safety research and improvement.

Conclusion

While pediatric diagnostic safety faces many unique challenges, it is imperative that focus remains on reducing harm attributable to misdiagnosis while continuing to optimize the diagnostic process for patients and families. Recent research and collaborative partnerships across the pediatric care delivery spectrum have increased understanding of the epidemiology of MDOs, potential interventions needed to reduce these errors, and efforts needed to improve patient and caregiver engagement in the diagnostic process.

Pediatric diagnostic safety quality improvement and research efforts with well-defined patient-level measures and outcomes remain behind adult diagnostic safety. But promising initiatives and a growing cadre of researchers are dedicated to advancing this important field in pediatrics. Increased pediatric advocacy, dedicated pediatric diagnostic safety funding, and enhanced training of pediatric-specific providers and researchers are needed to ensure future generations of children receive accurate, timely, and patient-centered diagnoses.

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