

Prevalence and Characteristics of Diagnostic Error in Pediatric Critical Care: A Multicenter Study*

OBJECTIVES: Effective interventions to prevent diagnostic error among critically ill children should be informed by diagnostic error prevalence and etiologies. We aimed to determine the prevalence and characteristics of diagnostic errors and identify factors associated with error in patients admitted to the PICU.

DESIGN: Multicenter retrospective cohort study using structured medical record review by trained clinicians using the Revised Safer Dx instrument to identify diagnostic error (defined as missed opportunities in diagnosis). Cases with potential errors were further reviewed by four pediatric intensivists who made final consensus determinations of diagnostic error occurrence. Demographic, clinical, clinician, and encounter data were also collected.

SETTING: Four academic tertiary-referral PICUs.

PATIENTS: Eight hundred eighty-two randomly selected patients 0–18 years old who were nonelectively admitted to participating PICUs.

INTERVENTIONS: None.

MEASUREMENTS AND MAIN RESULTS: Of 882 patient admissions, 13 (1.5%) had a diagnostic error up to 7 days after PICU admission. Infections (46%) and respiratory conditions (23%) were the most common missed diagnoses. One diagnostic error caused harm with a prolonged hospital stay. Common missed diagnostic opportunities included failure to consider the diagnosis despite a suggestive history (69%) and failure to broaden diagnostic testing (69%). Unadjusted analysis identified more diagnostic errors in patients with atypical presentations (23.1% vs 3.6%, $p = 0.011$), neurologic chief complaints (46.2% vs 18.8%, $p = 0.024$), admitting intensivists greater than or equal to 45 years old (92.3% vs 65.1%, $p = 0.042$), admitting intensivists with more service weeks/year (mean 12.8 vs 10.9 wk, $p = 0.031$), and diagnostic uncertainty on admission (77% vs 25.1%, $p < 0.001$). Generalized linear mixed models determined that atypical presentation (odds ratio [OR] 4.58; 95% CI, 0.94–17.1) and diagnostic uncertainty on admission (OR 9.67; 95% CI, 2.86–44.0) were significantly associated with diagnostic error.

CONCLUSIONS: Among critically ill children, 1.5% had a diagnostic error up to 7 days after PICU admission. Diagnostic errors were associated with atypical presentations and diagnostic uncertainty on admission, suggesting possible targets for intervention.

KEY WORDS: critical care; diagnostic error; patient safety; pediatrics; quality improvement

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Critically ill children are uniquely vulnerable to diagnostic error. Most children in PICUs vary widely in age and development, are dependent on caregivers to articulate symptoms, and suffer from a broad range of problems with varying complexity and severity (1, 2). Pediatric critical care



KEY POINTS

Question: What are the prevalence of and factors associated with diagnostic error among children admitted to the PICU?

Findings: This retrospective cohort study involving structured medical record review found that 13 (1.5%) of 882 patients nonelectively admitted to four academic tertiary-referral PICUs had a diagnostic error up to 7 days after PICU admission. Diagnostic errors were significantly associated with atypical presentation and diagnostic uncertainty on admission.

Meaning: Interventions that help clinicians recognize and manage atypical presentations and diagnostic uncertainty on PICU admission may help reduce the risk of diagnostic error in critically ill children.

teams working in time-pressured environments must continuously make sense of new data to detect and manage physiologic instability, all while coordinating diagnostic evaluations and consultations needed to determine the etiologies of acute disease (3).

Estimates of the prevalence of diagnostic error in pediatric critical care vary from 8% to 25% of admissions (4–8) depending on the study sample and method of detecting error. Although representing a biased sample, autopsies have been the gold standard for determining diagnostic error and have been used to determine diagnostic error rates (4). Other studies have focused on hypothesized high-risk cohorts of PICU patients (e.g., readmissions, admissions after a rapid response) (6, 7) despite lack of empiric evidence that these characteristics are associated with diagnostic error. Because the definitions, populations, and methods used for determining diagnostic error vary, it is difficult to compare the prevalence of diagnostic error between studies (9).

Although diagnostic error can have devastating consequences for patients and their families (10, 11), few coordinated efforts have been implemented to prevent diagnostic error in PICUs (9). Progress has been hampered in part by the absence of robust estimates of diagnostic error prevalence in the general PICU population and by gaps in our knowledge of factors that affect diagnostic performance. In this study, we aimed to determine the prevalence and characteristics of

diagnostic errors and identify factors associated with diagnostic error among critically ill children.

MATERIALS AND METHODS

We conducted a multicenter retrospective cohort study using structured medical record review to identify diagnostic error among patients nonelectively admitted to PICUs. We previously conducted a single-site pilot study ($n = 50$; patients in the pilot were not included in this study) to confirm that this study was feasible (5). The University of Iowa Institutional Review Board (UI IRB) approved this study for all sites (IRB no. 201812777, “Dx PICU: Multi-center Study of Diagnostic Documentation and Diagnostic Errors in the Pediatric Intensive Care Unit—Retrospective Chart Review Study,” approved January 7, 2019). Study procedures were in accordance with the ethical standards of the UI IRB and with the Helsinki Declaration of 1975. We report our work in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (12) (see **Supplement**, <http://links.lww.com/CCM/H355>).

Study Setting and Population

Four tertiary-referral academic PICUs with pediatric critical care fellowship programs participated. Two PICUs serve mainly rural populations with large catchment areas and two serve largely urban populations. Two PICUs are medical-surgical units and two are combined cardiac and medical-surgical units. In total, the four PICUs have 111 beds (range 19–40 beds/unit) and an average of 1,300 (range 1,100–1,900) admissions/unit per year, of which 69% on average are nonelective. The four PICUs are staffed by a total of 51 pediatric intensivists, 33 fellows, 36 advanced practice providers, 21 residents (per rotation), 408 nurses, and 165 respiratory therapists.

Patients admitted from January to December 2018 were randomly selected per season (stratified random sampling of admissions from January to March, from April to June, from July to September, and from October to December) using a validated online computer algorithm (Research Randomizer [13]) and screened for inclusion. We included patients 0–18 years old who were nonelectively admitted to the PICUs. We excluded scheduled admissions (e.g., post-operative), readmissions to the PICU within 30 days of a prior PICU admission, patients who were still

hospitalized at the time of screening for study inclusion, and patients for whom the site principal investigator (PI) was the attending physician during the first 7 days of admission. Clinician reviewers did not review records of patients they admitted.

Data Collection

Clinician Reviewers and Training. At each PICU, 4–5 trained clinician reviewers (pediatric intensivists or advanced practice providers) who had been practicing full-time in the PICU for at least 1 year reviewed patients' electronic health records (EHRs). To standardize the review process, the lead site provided clinician reviewers with standard in-person or online training on data abstraction and use of the Revised Safer Dx instrument. More than one reviewer reviewed 37% of included patient records so that we could calculate inter-reviewer agreement in the determination of diagnostic error.

Determination of Diagnostic Error. The primary outcome for this study is the occurrence of diagnostic error. Records were reviewed for possible diagnostic error occurring between admission and transfer out of the PICU or up to 7 days after PICU admission, whichever came first. We selected a period of 7 days based on literature (14) and because this duration captures the entire length of PICU stay for most patients while limiting review burden.

We used the following criteria to define diagnostic error (15):

- 1) Record review revealed evidence of a missed opportunity to make a correct or timely diagnosis (preventable breakdowns in the diagnostic process).
- 2) The missed opportunity was framed within the context of an evolving diagnostic process, considering information available to PICU clinicians at particular time points.
- 3) The opportunity could have been missed by the provider, care team, system, and/or the patient/family.

These criteria were adapted from Singh's concept of a missed opportunity in diagnosis (MOD), that is, something different could have been done to make the correct diagnosis earlier given information available at that time (15). Diagnostic errors were thus viewed as the result of breakdowns in the diagnostic process, which can be addressed to prevent future errors (**Supplement Box 1**, <http://links.lww.com/CCM/H355>) (15). Consistent with prior chart review studies on diagnostic error (14, 16), we considered the final

diagnosis at hospital discharge as the "correct" diagnosis explaining the clinical presentation on admission.

Reviewers used the Revised Safer Dx Instrument (17), a validated (overall accuracy 84–94%, sensitivity 71%, specificity 90%) (7, 18) 13-item structured medical record review tool, to help identify MODs. Each instrument item is rated on a seven-point Likert scale (1—strongly disagree to 7—strongly agree) and prompts the reviewer to identify MODs (item nos 1–9 in the Revised Safer Dx Instrument which scored ≥ 4) within specific aspects of the diagnostic process including data gathering, information integration, and information interpretation (**Supplement Boxes 2 and 3**, <http://links.lww.com/CCM/H355>). Each case with a potential diagnostic error (Safer Dx item no. 13 scored ≥ 4) was presented at a consensus meeting wherein the lead PI and three site PIs determined if a diagnostic error occurred (**Fig. 1**).

Clinical Characteristics. We collected data on patients' demographic and clinical/encounter characteristics from the EHR. Additionally, each site PI completed a survey about PICU attending physicians' characteristics. On the basis of their expertise and experience as PICU clinicians, reviewers determined whether the patient's initial presentation at PICU admission was typical of their primary diagnosis at hospital discharge. Reviewers also determined whether diagnostic uncertainty was present at admission, which was defined as the clinician's subjective perception of an inability to accurately explain the patient's health problem (19). We used a published rubric (**Supplement Box 4**, <http://links.lww.com/CCM/H355>) (20) to identify direct and indirect expressions of uncertainty in attending pediatric intensivists' diagnosis narratives and other documentation in admission notes. Similarly, we used a published rubric (**Supplement Box 5**, <http://links.lww.com/CCM/H355>) to identify diagnostic discordance between clinicians or over time (21).

Statistical Analysis

We used the Wilcoxon rank-sum test for continuous variables and Fisher exact test for categorical variables to compare characteristics between patients with and without diagnostic errors. We used a generalized linear mixed model (GLMM) treating site (PICU) as a random effect to estimate the odds of diagnostic error occurrence (dependent variable) given specific

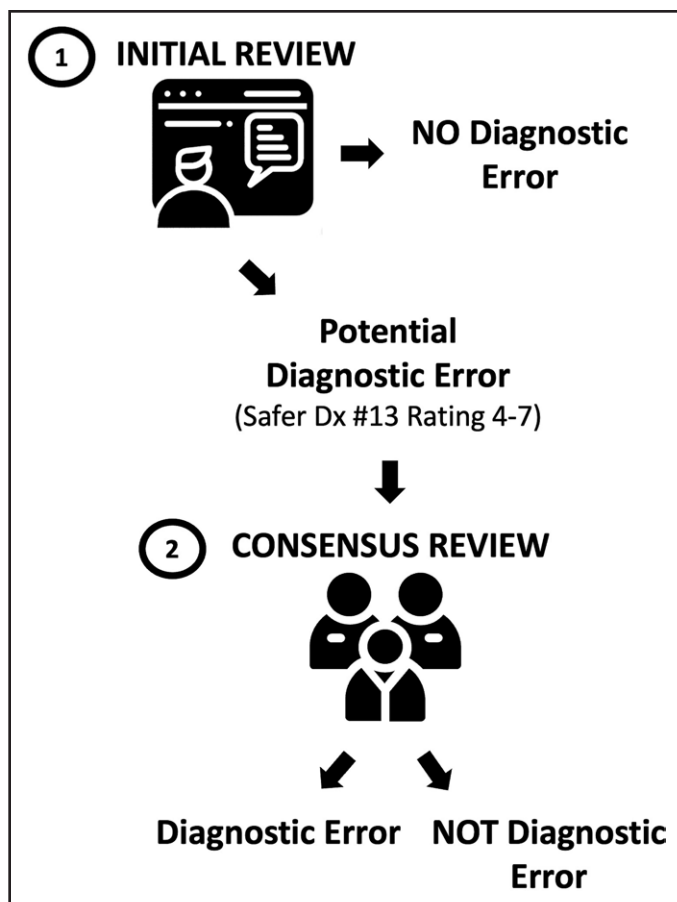


Figure 1. Identification of diagnostic error. A trained clinician reviewer conducted an initial review (1). If the reviewer identified a potential diagnostic error, four pediatric intensivists (lead and site investigators) discussed the case during a consensus meeting (2) and determined whether a diagnostic error occurred.

clinical characteristics (independent variables). The GLMM controlled for positively correlated error variance arising from clustering of clinical characteristics by site. We evaluated all possible models predicting the occurrence of diagnostic error with three or fewer independent variables, and selected the model with the lowest Akaike Information Criterion. We included only three variables in the model given the low prevalence of diagnostic error. We performed a sensitivity analysis by constructing an expanded model which included variables based on the literature, our pilot study, and the results of simple statistical comparisons.

We calculated inter-rater agreement and inter-rater reliability for selected variables determined using reviewer judgment (diagnostic error, atypical presentation, and diagnostic uncertainty). Inter-rater agreement was defined as the percentage of records wherein all reviewers made the same determination.

To assess inter-rater reliability, we used a method by Fleiss et al (22) to calculate the *kappa* (*k*) coefficient taking into consideration that each record had a varying number of raters (23). We used R version 4.1.2 (RStudio, Boston, MA) and Stata version 14.2 (StataCorp, College Station, TX) for statistical analyses.

RESULTS

Prevalence and Impact of Diagnostic Error

Among 882 randomly selected nonelective patient admissions (24% of all nonelective admissions during the study period), the initial reviews identified 31 (3.5%) as potentially having a diagnostic error. After second (consensus) review, we determined that 13 (1.5%) admissions had a diagnostic error up to 7 days after PICU admission. Diagnostic error rates varied across PICUs with a range of 0.4%–3.2%. Infections (46%) and respiratory conditions (23%) were the most common missed diagnoses (**Table 1**). In 31% of cases with diagnostic error, the admission diagnosis itself was correct, but an additional diagnosis was missed (e.g., pneumonia in a patient with status asthmaticus). Inter-reviewer agreement for diagnostic error was 98.8% among multi-reviewer charts (37% of all reviewed charts) with a $k = 0.27$ ($p < 0.001$).

Forty-six percent of diagnostic errors were discovered greater than 24 hours after PICU admission but within the patient's PICU stay, whereas 38% were discovered after transfer out of the PICU. Diagnostic errors were most commonly discovered because the patient's original signs and symptoms failed to resolve or improve (39%), new data emerged from diagnostic testing (39%), and/or a PICU team member newly assigned to the patient reinterpreted available data (31%). One diagnostic error (8%) harmed a patient due to delayed treatment that prolonged hospitalization.

Missed Opportunities in Diagnosis Contributing to Diagnostic Error

Multiple MODs (range 1–6 per diagnostic error), which could have contributed to error, were recognized in 9 (69%) diagnostic errors. The most common MODs included failure to consider aspects of the history suggestive of an alternative diagnosis (69%), failure to pursue additional diagnostic evaluation given known clinical information (69%), failure to

TABLE 1.
PICU Admission Diagnoses and Corresponding Missed Diagnoses

PICU Admission Diagnosis	Missed Diagnosis
Bronchiolitis with reactive airway disease	Asthma
Shunt malfunction vs progression of brain cyst	Obstructive sleep apnea
Respiratory failure due to rhinovirus/enterovirus	Infantile botulism
Status asthmaticus	Pneumonia ^a
Acute respiratory failure in the setting of pneumonia and sepsis	Urinary tract infection ^a
Acute on chronic respiratory failure secondary to pneumonia	Healing femur fracture ^a
Diabetic ketoacidosis with encephalopathy	Influenza A infection, urinary tract infection ^a
Acute respiratory failure (no etiology documented)	Airway obstruction due to laryngomalacia, subglottic stenosis, micrognathia
Acute respiratory failure possibly from aspiration pneumonia, rule-out status epilepticus	Adenovirus pneumonia
Hypertensive emergency due to posterior reversible encephalopathy syndrome with differential diagnoses of acute tubular necrosis from dehydration, hemolytic-uremic syndrome	Pelvic tumor
Status epilepticus	Status dystonicus
Febrile illness with diarrhea, vomiting, hypotension	Septic shock
Hypernatremia with differential diagnoses of diabetes insipidus, toxic exposure, endocrinopathy, excess salt intake	Chronic malnutrition due to neglect

^aAdditional diagnosis that was missed (the admission diagnosis explaining the primary presenting problem was correct).

consider physical exam findings suggestive of an alternative diagnosis (38%), and the use of inappropriate diagnostic reasoning given the clinical presentation (38%) (**Supplement Table 1**, <http://links.lww.com/CCM/H355>).

Clinical Characteristics Associated With Diagnostic Error

Patients' age, gender, race/ethnicity, presence of complex chronic conditions, illness severity, and admission source did not differ significantly among patients with versus without diagnostic error. Compared with patients without diagnostic error, more patients with diagnostic error had an atypical presentation at admission ($k = 0.36$, $p < 0.001$) (23% vs 4%, $p = 0.011$) and neurologic chief complaints (46% vs 19%, $p = 0.024$). Admission during off hours (nights, weekends, and holidays) and admitting intensivists' gender and years in practice did not differ. However, patients with diagnostic error were admitted more frequently by intensivists who were 45 years old or older (92% vs 65%, $p = 0.042$) and intensivists with more clinical service

weeks in the year (mean 12.8 vs 10.9 wk, $p = 0.031$) than were patients without diagnostic errors. Overall, clinicians had diagnostic uncertainty for 26% of patients on admission ($k = 0.50$, $p < 0.001$), which was consistent across sites (range 22%-29%). Diagnostic uncertainty was more common among patients with diagnostic error than among those with no error (77% vs 25%, $p < 0.001$). Patients with diagnostic error had more laboratory tests, imaging, and subspecialty consultations on admission. The documented primary diagnosis was also more frequently discordant between admission and PICU discharge among patients with diagnostic error than those without errors (67% vs 5%, $p < 0.001$). PICU length of stay and mortality did not differ between patients with and without diagnostic error. However, patients with diagnostic error had longer hospital stays (median 14 vs 4 d, $p = 0.002$) (**Supplement Table 2**, <http://links.lww.com/CCM/H355>).

Multivariable analysis using a GLMM specifying site (PICU) as a random effect found that an atypical presentation on admission (OR 4.58; 95% CI, 0.94–17.1, $p = 0.034$) and the presence of diagnostic

uncertainty on admission (OR 9.67; 95% CI, 2.86–44.0, $p < 0.001$) were significantly associated with diagnostic error (Table 2). Sensitivity analysis using an expanded model which included variables based on the literature, our pilot study, and results of simple statistical comparisons found that these factors remained significantly associated with diagnostic error (Supplement Table 3, <http://links.lww.com/CCM/H355>).

DISCUSSION

Diagnostic error occurred in 1.5% of critically ill children admitted to the PICU, which is markedly lower than the 8%–25% prevalence of diagnostic error reported by prior studies (9). The observed lower rate may have been due to a more rigorous definition of diagnostic error, a conservative method of adjudicating the occurrence of diagnostic error, and reluctance by reviewers to identify colleagues' MODs (see limitations). Moreover, almost all prior studies reporting PICU diagnostic error rates had selected populations and may have overestimated prevalence. Our study is the first to determine the prevalence of diagnostic error among randomly selected nonelective PICU admissions, thus estimating a baseline rate of diagnostic error in the pediatric critical care setting.

Similar to the results of a study among readmitted adult patients (24) and that of our pilot (5), one-third of the misdiagnosed conditions we observed pertained to diagnoses other than the admission diagnosis. These errors emphasize the complexity of

critically ill children who often present with multiple interrelated conditions that need to be accurately identified and addressed. Additionally, such errors could have been the result of clinicians attributing clinical changes to a known diagnosis rather than considering alternative explanations (i.e., confirmation bias) (25). These results also reveal a major limitation to using discordance between admission and discharge diagnoses as a signal for diagnostic error because admission and discharge diagnoses may not be discordant in patients where secondary diagnoses were missed (26).

Diagnostic errors were discovered mostly through passive means (e.g., when the patient's original symptoms failed to resolve or after a new PICU team member reviewed the clinical findings), rather than by active surveillance as performed for other types of medical errors (27–29). We identified only one patient harmed by diagnostic error, which, given the study's reliance on clinical documentation and possible reluctance of reviewers to attribute harm directly to diagnostic error, may be an underestimate of the overall harm caused by diagnostic error.

Nine of 13 identified diagnostic errors had multiple associated MODs. Although MODs do not always lead to harmful diagnostic errors, they can identify potentially high-yield areas for intervention within the diagnostic process. MODs illustrate the complexity of collaborative diagnosis, which involves gathering, integrating, and interpreting information across the entire diagnostic team, including clinicians, patients, and patients' families (30). Diagnostic reasoning is further

TABLE 2.
Logistic Regression Model of Clinical Characteristics Associated with Diagnostic Error^a

Characteristic ($n = 864$)	Odds Ratio	95% CI		p
		LCL	UCL	
Atypical presentation on admission ^b	4.58	0.94	17.10	0.034
Admitting intensivist's age				
< 45 yr		Reference		
≥ 45 yr ^b	6.61	1.26	122.0	0.072
Presence of diagnostic uncertainty on admission	9.67	2.86	44.0	<0.001

LCL = lower confidence limit, UCL = upper confidence limit.

^aA generalized linear mixed model was used with site (institution) as a random effect.

^bThe Wald method was used for calculating the p value, whereas profile likelihood was used to calculate the 95% CI, thus the two assessments may differ (e.g., $p < 0.05$ with 95% CI crossing 1 or vice versa).

complicated by the fact that cognition is distributed among members of the multidisciplinary PICU team (31) (distributed cognition describes how information processing is dispersed across people, their workplace, technologies, social organization, and over time (32)). Thus, current efforts to improve diagnostic reasoning that focus primarily on individual clinician-learners (33, 34) may not be as effective as team-based approaches, such as TeamSTEPPS for Diagnosis Improvement (35), which can potentially improve diagnostic thinking of PICU teams.

We found that an atypical presentation and the presence of diagnostic uncertainty on admission were significantly associated with diagnostic error. Although this finding seems intuitive, the opposite can be argued—that patients with atypical presentations and diagnostic uncertainty may elicit substantially more attention from clinicians, which could lead to fewer, not more diagnostic errors. Moreover, few studies have empirically evaluated the association of these factors with diagnostic error, although we know that atypical presentations make the diagnostic process more difficult and fraught (36), and that poor management of diagnostic uncertainty can lead to inappropriate resource utilization and adverse events (37–39). Our study shows that an atypical presentation (clinical findings that do not easily fit a known illness script) and diagnostic uncertainty on admission can potentially be used as markers to identify critically ill children at risk for diagnostic error at the start of the diagnostic process, where diagnostic decision-making may be more amenable to intervention. This finding also supports efforts to improve diagnosis focusing on helping clinicians better recognize, communicate, and address diagnostic uncertainty (40–42).

Given our findings, we suggest interventions for further study that can potentially prevent diagnostic error in the PICU: 1) active surveillance for patients at risk for diagnostic error (e.g., an atypical presentation or with diagnostic uncertainty on admission) (43); 2) standard methods for communicating diagnostic uncertainty among PICU team members and to patients/families (42, 44); 3) cognitive support for clinicians encountering significant diagnostic uncertainty (e.g., automatic second opinion, mandatory case conference) (45, 46); and 4) communication protocols related to gathering, integration, and interpretation of clinical data to improve PICU team functioning with

regards to diagnosis (47). Future work should determine the impact of these interventions on patient outcomes.

Our study has strengths and limitations. This is a retrospective study; thus our findings may have been limited by documentation quality. Our sample was restricted to patients at tertiary-referral academic PICUs, thus our findings may be less applicable to smaller units. We may have underestimated the true prevalence of diagnostic error because of heterogeneity in review, which can partially explain the difference in diagnostic error rates across sites. Variation may be due to reviewer inexperience in using the Revised Safer Dx Instrument despite training (especially for those not at the lead site), diagnostic errors missed in records reviewed by only one reviewer, and reviewers' reluctance to identify colleagues' MODs. We also had a two-tier review process resulting in more conservative error adjudication given that we considered the hospital discharge diagnosis as the final "correct" diagnosis, thus we may have missed diagnostic errors discovered postdischarge. Although inter-reviewer agreement was high, the low inter-rater reliability for diagnostic error determination was low, likely due to kappa's adjustment for "agreement by chance," which would be high given the very low diagnostic error prevalence. Last, because the diagnostic error prevalence was low, we could not include many variables in our multivariable analysis, hampering our ability to identify factors associated with diagnostic error. However, sensitivity analysis with an expanded model found the same associations to be significant. Our study mitigated these limitations by including a random sample of patients across PICUs in different geographic locations. We used a validated instrument and a structured process of record review performed by trained clinician reviewers to standardize reviews as much as possible. Finally, we used a parsimonious multivariable model and conducted a sensitivity analysis with an expanded model that found similar results.

CONCLUSIONS

Among critically ill children, 1.5% had a diagnostic error up to 7 days after PICU admission. Diagnostic errors were associated with atypical presentations and diagnostic uncertainty on admission. These factors can

help clinicians identify patients at risk for missed diagnostic opportunities and should be considered when developing interventions to prevent diagnostic error.

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