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Families as Partners in Hospital Error and Adverse Event Surveillance

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Families as Partners in Hospital Error and Adverse Event Surveillance

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Abstract

IMPORTANCE—Medical errors and adverse events (AEs) are common among hospitalized children. While clinician reports are the foundation of operational hospital safety surveillance and a key component of multifaceted research surveillance, patient and family reports are not routinely gathered. We hypothesized that a novel family-reporting mechanism would improve incident detection.

OBJECTIVE—To compare error and AE rates (1) gathered systematically with vs without family reporting, (2) reported by families vs clinicians, and (3) reported by families vs hospital incident reports.

DESIGN, SETTING, AND PARTICIPANTS—We conducted a prospective cohort study including the parents/caregivers of 989 hospitalized patients 17 years and younger (total 3902 patient-days) and their clinicians from December 2014 to July 2015 in 4 US pediatric centers. Clinician abstractors identified potential errors and AEs by reviewing medical records, hospital incident reports, and clinician reports as well as weekly and discharge Family Safety Interviews (FSIs). Two physicians reviewed and independently categorized all incidents, rating severity and preventability (agreement, 68%–90%; κ, 0.50–0.68). Discordant categorizations were reconciled. Rates were generated using Poisson regression estimated via generalized estimating equations to account for repeated measures on the same patient.

MAIN OUTCOMES AND MEASURES—Error and AE rates.

RESULTS—Overall, 746 parents/caregivers consented for the study. Of these, 717 completed FSIs. Their median (interquartile range) age was 32.5 (26–40) years; 380 (53.0%) were nonwhite, 566 (78.9%) were female, 603 (84.1%) were English speaking, and 380 (53.0%) had attended college. Of 717 parents/caregivers completing FSIs, 185 (25.8%) reported a total of 255 incidents, which were classified as 132 safety concerns (51.8%), 102 nonsafety-related quality concerns (40.0%), and 21 other concerns (8.2%). These included 22 preventable AEs (8.6%), 17 nonharmful medical errors (6.7%), and 11 nonpreventable AEs (4.3%) on the study unit. In total, 179 errors and 113 AEs were identified from all sources. Family reports included 8 otherwise unidentified AEs, including 7 preventable AEs. Error rates with family reporting (45.9 per 1000 patient-days) were 1.2-fold (95%CI, 1.1–1.2) higher than rates without family reporting (39.7 per 1000 patient-days). Adverse event rates with family reporting (28.7 per 1000 patient-days) were 1.1-fold (95%CI, 1.0–1.2; P=.006) higher than rates without (26.1 per 1000 patient-days). Families and clinicians reported similar rates of errors (10.0 vs 12.8 per 1000 patient-days; relative rate, 0.8; 95%CI, .5–1.2) and AEs (8.5 vs 6.2 per 1000 patient-days; relative rate, 1.4; 95%CI, 0.8–2.2). Family-reported error rates were 5.0-fold (95%CI, 1.9–13.0) higher and AE rates 2.9-fold (95% CI, 1.2–6.7) higher than hospital incident report rates.

CONCLUSIONS AND RELEVANCE—Families provide unique information about hospital safety and should be included in hospital safety surveillance in order to facilitate better design and assessment of interventions to improve safety.

Between 44 000 and 440 000 patients are estimated to die yearly in the United States due to medical errors,[1–4] making medical errors a leading cause of death. Detecting medical errors is important for identifying causative factors and measuring the effectiveness of prevention strategies. Error detection methodologies have greatly advanced over the past few decades.[5–7] However, implementation of error detection, or safety surveillance, varies across hospitals.

Hospital incident reports, which are voluntary and suffer from underreporting, are commonly used but only capture a small subset of errors and adverse events (AEs), ie, harms due to medical care.[8–12] Trigger tools are higher yield and becoming more sophisticated at identifying events but are not yet widely used.[13] Prospective systematic surveillance, in which trained research staff conduct daily reviews of patient medical records (Figure 1), is the most effective way to measure errors but is expensive and typically limited to research settings.[5,14,15]

Patients and families are absent both from hospital incident reports and systematic surveillance. Limited adult studies suggest that patients are a fruitful source of safety surveillance.[16,17] Small, single-center pediatric studies suggest similar findings; however, the role of patients and families in pediatric safety reporting has not been widely examined.[18–20] Additionally, to our knowledge, a rigorous patient and family error-reporting methodology has not been developed or operationalized.

We sought to fill these gaps by developing a family error reporting methodology and testing its utility and effectiveness in systematic safety surveillance across 4US pediatric hospitals. We hypothesized that families would report errors and AEs not discovered by other methods and that adding a family reporting mechanism to systematic surveillance methodology would increase error and AE detection. If these hypotheses are correct, then adding families to safety surveillance systems would provide an important new way to detect errors, identify their causes, and measure the effectiveness of efforts to prevent them.

Methods

Data, Setting, and Study Population

We conducted a prospective cohort study in 4 pediatric hospitals. Data were collected from December 2014 to July 2015 coincident with data collection for the Patient and Family Centered I-PASS Study, an ongoing multicenter investigation of clinician-family communication and safety built on prior communication and safety research.[21]

Study participants included parents/guardians or caregivers (eg, grandparents living in the home) and clinicians (resident-physicians and nurses) of 989 hospitalized medical patients 17 years and younger on inpatient general pediatric and subspecialty units. We obtained written informed consent from clinicians, verbal consent using an information sheet from parents/caregivers, and a waiver of informed consent to review patient records. The Boston

Children's Hospital Institutional Review Board and each participating institution's institutional review board approved the study.

Inclusions

Given limited translation and interpretation resources, we included parents/caregivers speaking English, Spanish, Arabic, Chinese, or Russian (the most commonly spoken languages across study sites).

Family Safety Interviews

We developed the Family Safety Interview (FSI) using a modified Delphi method with input from experts in survey methodology, patient safety, and health literacy, as well as family partners. Draft versions of the FSI were pilot tested through cognitive interviews with parents/caregivers at Boston Children's Hospital.

To orient families to types of information to report, the FSI began with descriptions, definitions, and examples of safety events related to medications, miscommunications, diagnoses, delays in care, complications of care, and equipment. Using closed-ended and open-ended questions, it then asked parents/caregivers to indicate whether the child's illness worsened or almost worsened because (1) of medical care (ie, an AE), (2) something was not done that should have been (ie, a preventable AE due to an error of omission), or (3) something was done that should not have been (ie, a preventable AE due to an error of commission). It also asked if a mistake occurred that did not result in harm (ie, a nonharmful error) and whether anything else happened or almost happened that was upsetting or could have harmed the child.

Research assistants administered this semistructured interview to parents/caregivers of eligible patients every 7 days while hospitalized and before discharge. Interviews typically lasted 3 to 5 minutes when no concerns were reported and 10 to 15 minutes when concerns were reported. Research clinicians (nurses or physicians) then classified family responses as safety concerns (ie, potential errors and AEs), nonsafety-related quality concerns (eg, an unpleasant interaction with a physician), or other concerns (eg, a difficult intravenous placement). Off-unit (eg, emergency department) safety concerns were subsequently excluded from analyses.

Clinician Event Reporting Surveys

Clinician event reporting was conducted by modifying an instrument used in previous studies.[21,22] This less-than-1-minute survey asked respondents to describe errors and AEs or procedures, medications, fluids, or other therapies that were unnecessary or questionably beneficial, delayed, involved in an error or AE, or ordered erroneously but intercepted before reaching the patient (near-misses). They also asked about resident or nurse sign-out omissions or inaccuracies leading to problems with patient care. Every weekday morning, research clinicians administered the survey (verbally or on paper) to outgoing overnight residents. Surveys were also posted on the study units to allow unit staff, particularly nurses, not enrolled in the study to voluntarily report anonymously.

Error Validation/Classification

To identify potential errors and AEs, research clinicians conducted systematic surveillance using a validated methodology[21–26] (ie, daily review of all study-unit patients' medical records, hospital incident reports, and clinician event reporting surveys) (Figure 1). These data were supplemented with incidents collected during FSIs. For potential errors and AEs, research clinicians recorded reporting source(s) (ie, family, clinician, observation by study personnel, or other), preceding events, patient outcomes, harm level (using modified National Coordinating Council for Medication Error Reporting and Prevention categorization[27]), preventability (if harmful), error category, and follow-up actions.

To validate and categorize events, physician reviewer pairs independently reviewed all research clinician–collected events (including those obtained from FSIs) as AEs (ie, harms), nonharmful errors, or exclusions (preconsensus agreement, 67.6%; κ, 0.50). Physician raters additionally assessed AEs for harm level[27] (preconsensus agreement, 89.5%; κ, 0.68) and preventability (preconsensus agreement, 83.7%; κ, 0.60). Physician reviewer pairs reconciled discordant categorizations through consensus.

Demographic Data

We collected clinician and parent/caregiver demographic information through surveys. We obtained patient clinical and sociodemographic characteristics data from hospital administrative data.

Outcomes and Predictors

Our primary outcome was overall medical error and AE rates per 1000 patient-days (days hospitalized on the study unit) both including and excluding family reporting (ie, FSI data). We also analyzed error and AE rates per 100 admissions. We secondarily analyzed error and AE rates reported by families vs clinicians and by families vs hospital incident reports. We identified the following a priori variables as potential predictors of family reporting: patient age, sex, race/ethnicity, insurance, complex chronic conditions (CCCs, a marker of medical complexity according to *International Classification of Diseases, Ninth Revision, Clinical Modification*[28]), and parent/caregiver age, sex, race/ethnicity, language, education, and household income.

Statistical Analyses

To compare error and AE rates (overall with vs without family data, family vs clinician, and family vs hospital incident report), we used Poisson regression estimated via generalized estimating equations to account for correlation arising from collecting parent/caregiver, clinician, and hospital incident reports on the same patient. All 989 sample patients were used for the overall and family vs clinician analyses. The family vs hospital incident report analysis only included the 3 sites with available hospital incident report data.

In unadjusted and adjusted analyses, we compared family-reported error and AE rates per 1000 patient-days using bias corrected Poisson regression, which has better statistical properties than usual Poisson regression when the total number of events is not large.[29,30] Apriori parent/caregiver-level and patient-level predictors of interest that were significant (*P*

< .05) in unadjusted analyses were fit in an adjusted model. The final adjusted model only included predictors with $P < .05$. Site effects were considered as fixed effects in the adjusted model. For consistency, final adjusted models for errors and AEs contained the same predictors.

Unadjusted and adjusted analyses included only the 717 patients whose parents/caregivers completed FSIs, which we refer to as a complete-case analysis. Because FSIs were not completed for all study-unit patients, we compared patient characteristics among those with and without completed FSIs. Additionally, we conducted a sensitivity analysis using a reweighted estimating equation missing data approach to determine if complete-cases produced biased results. In the reweighted estimating equations approach, we fit a logistic regression model to determine predictors of a parent/caregiver completing an interview (using all nonmissing variables). Then, complete-cases were reweighted by the inverse probability of a parent/caregiver completing an interview. Thus, patients whose parents/caregivers completed interviews despite being less likely to complete them were up-weighted to account for those similar parents/caregivers who did not complete interviews.[31,32] We used REDcap[33] to collect and manage study data and SAS version 9.3 (SAS Institute) for analyses.

Results

Sample Characteristics

Of 1024 patients on the study units, 989 met study criteria (eFigure in the Supplement). Parents/caregivers of 782 eligible patients (79.1%) were available and therefore approached. Most parents/caregivers (746 [95.4%]) who were approached consented for the study. Of these, 717 parents/caregivers completed 763 interviews (35 parents/caregivers completed more than 1 interview). Among clinicians, 146 nurses (98.6%) and 207 resident-physicians (95.4%) consented for the study. A total of 717 of 782 eligible parents/caregivers (91.7%) completed FSIs. Overall, 77 residents completed a total of 284 of 327 (86.9%) solicited post shift event reporting surveys, with residents completing0–11 surveys each.

Patient, parent/caregiver, and clinician demographic data are reported in Table 1. Patients and parents/caregivers were from varied racial/ethnic and socioeconomic backgrounds. Overall, 243 of 989 patients (24.6%) had 1 or more CCCs. Patients without completed FSIs (primarily because parents/caregivers were not present) were similar to patients with completed FSIs in terms of age, CCCs, race/ethnicity, insurance, and error and AE rates. Patient sex was the only statistically significant difference between these 2 groups.

Errors and AEs

We found a total of 179 errors and 113 AEs on our study units through all sources. Families reported 39 of 179 total errors (21.8%; 19[10.6%] uniquely and 20[11.2%] in combination with another source) and 33 of 113 total AEs (29.2%; 8[7.1%] uniquely and 25 [22.1%] in combination with another source) (Figure 2).

Family Reports

Overall, 185 parents/caregivers (25.8%) reported 255 total incidents, of which we classified 132 (51.8%) as safety concerns, 102 (40.0%) as nonsafety-related quality concerns, and 21 (8.2%) as other concerns. Of reported safety concerns, 35 occurred off-unit and were excluded from further analyses; 97 (73.5%) occurred on-unit. On 2-step review, 50 family-reported on-unit errors and/or AEs were confirmed, including 22 preventable AEs, 17 nonharmful medical errors, and 11 nonpreventable AEs.

Family reports included 8 otherwise unidentified AEs, including 7 preventable AEs. Unique family-reported AEs included multiple needle sticks, inadequate suctioning, and adverse effects from medication (Table 2). Of 39 validated family-reported errors (ie, preventable AEs and nonharmful errors), 20 were also detected through research clinician medical record review, 3 through resident report, 2 through nurse report, and 1 through hospital incident report. Of 33 validated family-reported AEs, 25 were also detected through medical record review, 3 through nurse report, 2 through resident report, and 2 through hospital incident report.

Family-reported AEs most commonly involved temporary patient harm requiring intervention (28 [84.9%]) or prolonging hospitalization (5 [15.2%]). Both family-reported and nonfamily-reported errors and AEs were primarily medication related.

Overall Error and AE Rates With vs Without Family-Reporting

Overall error rates with family reporting were 15.5%(95% CI, 9.0%–22.3%) higher than without. Overall AE rates with family reporting were 9.8%(95% CI, 3.1%–16.9%) higher than without (Table 3).

Family-Reported vs Clinician-Reported Errors and AEs

Family-reported error rates were equivalent to clinician-reported rates (relative rate [RR], 0.8; 95% CI, 0.5–1.2). Family-reported AE rates were also equivalent to clinician-reported rates (RR, 1.4; 95% CI, 0.8–2.2) (Table 4).

Family-Reported vs Hospital Incident Report Rates of Errors and AEs

Among the 3 sites with available hospital incident report data, of 111 errors detected through all sources, hospital incident reports detected 5 errors (4.5%) and family reports detected 25 errors (22.5%). Of 71 AEs detected through all sources, hospital incident reports detected 7 AEs (9.9%) and family reports detected 20 AEs (28.2%).

Family-reported error rates were 5.0-fold (95% CI, 1.9–13.0) higher than hospital incident report rates across these sites. Family-reported AE rates were 2.9-fold (95% CI, 1.2–6.7) higher than hospital incident report rates (Table 5).

Predictors of Family-Reported Errors and AEs

Results of the weighted estimated approach accounting for missing data were similar to unweighted results; for simplicity, we report only unweighted results. Unadjusted predictors of family-reported errors included patient age, 1 or more CCCs, parent/caregiver proficiency

in written and spoken English, and higher parent/caregiver education (eTable 1 in the Supplement). Adjusted predictors of family-reported errors included younger patient age (RR, 0.9 per 1-year increment; 95% CI, 0.9–1.0), 1 or more CCCs (RR, 2.4; 95% CI, 1.2–4.8), older parent/caregiver age (RR, 1.0; 95% CI, 1.0–1.1), and higher parent/caregiver education (less than high school vs college education: RR, 0.2; 95% CI, 0.1–0.3) (eTable 2 in the Supplement).

Unadjusted predictors of family-reported AEs include 1 or more CCCs, higher parent/caregiver education, and greater family presence during hospitalization. Adjusted predictors of family-reported AEs included 1 or more CCCs (RR, 2.3; 95% CI, 1.1–4.8) and higher parent/caregiver education (less than high school vs college education: RR, 0.3; 95% CI, 0.2–0.4).

Discussion

In a study of 4US hospitals, solicited family reporting yielded 5-fold more errors and 3-fold more AEs than the voluntary hospital incident reports that most hospitals use as their primary patient safety surveillance tool. Additionally, we found that family reporting substantively enhanced rigorous multifaceted patient safety surveillance methods, with families reporting patient safety incidents that were not otherwise detected. Our finding that family reporting increased overall error detection by 16% and AE detection by 10%—compared with what is typically considered the highest-yield methodology in safety surveillance research—supports our hypothesis that including families in safety surveillance improves safety detection. This represents an important patient safety innovation. By including families in safety reporting, we can identify otherwise unrecognized errors and AEs, providing new opportunities to prevent them from occurring.

Our study's family-reported error and AE rates are far higher than rates detected through clinician-only, voluntary hospital incident reports, which typically only detect 1% to 14% of AEs.[8,14] We similarly found that hospital incident reports only captured 5% of errors and 10% of AEs. In contrast, our family-reporting methodology was much higher yield, detecting 22% of errors and 29% of AEs. This may be because families are available to provide patient safety information and may in fact have more opportunity to provide such reports than clinicians, who might be prevented from reporting by competing time demands.[34,35] We additionally found that 49% of family reported errors and 24% of family-reported AEs were not present in the medical record, consistent with prior studies.[14,16–18]

Based on other studies, patient and family safety-reporting rates are variable and appear related to mode of reporting. The percentage of families in our study reporting incidents (26%) was approximately 3-foldhigher than in our prior single-center study (9%),[18] in which we used written family discharge experience surveys (vs the active semi structured family interviews used in our current study). Additionally, our current study's reporting rate is more than 600-foldhigher than that of a voluntary prototype consumer-reporting hotline that was tested with funding from the Agency for Healthcare Research and Quality in 2 hospital institutions in a single state and administered via the web and telephone (0.04%; Denise Quigley, PhD, email communication, June 2016).[36]

Prior studies using active patient and family reporting similarly found that 23% to 49% of patients and families reported safety concerns.[16,17,19] These studies used various methods, including post discharge patient telephone interviews,[16] computer-based safety-reporting parent discharge surveys,[17] and in-person patient/caregiver interviews 2 to 3 times per week.[19] An important difference between our study and these is that we subsequently validated family safety reporting using a rigorous 2-step methodology. Our validation step represents an important advance in medical error and AE reporting methodology.

Further research is needed to determine the best process for operationalizing patient and family reporting in hospitals and to assess its feasibility, success, and safety implications. While less intensive than systematic surveillance, gathering patient and family safety reports requires hospital personnel time and effort. Time and effort may vary depending on whether post discharge interviews or in-hospital surveys are used, for instance. Further research is required to compare and weigh yield and costs of different approaches. While we employed research assistants for this purpose in our study, it is plausible that, if they felt it worthwhile, hospitals might use existing quality improvement staff to administer family safety surveys or interviews. Hospitals might additionally consider incorporating safety reporting into their existing family surveys, thereby leveraging existing resources, although the sensitivity of this approach would need to be further evaluated.

The effects of patient and family safety reporting on outcomes, such as malpractice risk, parent experience, and subsequent hospital improvement efforts, are unknown. Research suggests that disclosing errors of which patients are unaware does not lead to more malpractice cases.[37–40] It seems unlikely that gathering patient and family reports of errors of which patients are already aware would increase malpractice risk. Moreover, engaging patients and families may drive hospitals to bridge the gap between safety reporting and improvement. Involving patients and families may increase transparency and accountability of safety reporting and there by address criticisms that safety reports are not consistently acted on.[41]

Given our finding that families of children with 1 or more CCCs were more likely to report errors and AEs, actively partnering with families of patients with CCCs may be a high-yield approach to detecting and perhaps preventing medical errors and AEs. Patients with CCCs experience higher rates of errors and AEs owing to increased illness complexity and length of stay.[17,18,42,43] Their families may also be more activated or better understand the medical system,[44] making them particularly high-yield reporters. However, it is also important for hospitals to make concerted efforts to actively engage all families in safety reporting and, in particular, to engage less educated and other vulnerable populations.

Limitations

Our study had several limitations. We included patients from general pediatric and subspecialty services, not surgical services, at 4 hospitals. Therefore, our reporting rates may not be generalizable to all hospitals or services. However, family and caregiver reporting may be broadly applicable to other patient populations (eg, adult, surgical, and geriatric). Although we used a rigorous methodology using a well established 2-step review process with kappas similar to or higher than prior studies,[21] rating errors and AEs is complex.

Additionally, families reported a number of off-unit (eg, emergency department) safety concerns beyond our study's scope to further investigate. Our rates of validated family-reported errors and AEs may have been even higher had we done so.

Conclusions

We developed and studied a novel family-reporting methodology that suggests families may be useful partners in hospital safety reporting. They report events not otherwise detected or documented, including preventable AEs. Family reporting increases error and AE rates detected through voluntary hospital incident reporting systems used by most hospitals and systematic safety surveillance used in research—both of which typically exclude patients and families. Actively surveying families about safety may be a fruitful way to gather errors and AEs—for both hospital safety improvement and research.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Levinson, DR. Office of Inspector General. [Accessed July 28, 2016] Adverse events in hospitals: national incidence among Medicare beneficiaries. https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf
2. Kohn, L., Corrigan, J., Donaldson, MS. Institute of Medicine. [Accessed July 18, 2016] To err is human: building a safer health system. Nov. http://iom.nationalacademies.org/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf
3. Makary MA, Daniel M. Medical error: the third leading cause of death in the US. BMJ. 2016; 353:i2139. [PubMed: 27143499]
4. James JT. A new, evidence-based estimate of patient harms associated with hospital care. J Patient Saf. 2013; 9(3):122–128. [PubMed: 23860193]
5. Classen DC, Lloyd RC, Provost L, Griffin FA, Resar R. Development and evaluation of the Institute for Healthcare Improvement Global Trigger Tool. J Patient Saf. 2008; 4(3):169–177. DOI: 10.1097/PTS.0b013e318183a475
6. Sharek PJ, Parry G, Goldmann D, et al. Performance characteristics of a methodology to quantify adverse events over time in hospitalized patients. Health Serv Res. 2011; 46(2):654–678. [PubMed: 20722749]
7. National Patient Safety Foundation. [Accessed July 30, 2016] Free from harm: accelerating patient safety improvement fifteen years after To Err is Human. http://www.npsf.org/?freefromharm
8. Levinson, DR. Office of Inspector General. [Accessed September 18, 2016] Hospital incident reporting systems do not capture most patient harm. http://oig.hhs.gov/oei/reports/oei-06-09-00091.pdf
9. Sari AB-A, Sheldon TA, Cracknell A, Turnbull A. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. BMJ. 2007; 334(7584): 79. [PubMed: 17175566]

10. Farley DO, Haviland A, Champagne S, et al. Adverse-event-reporting practices by US hospitals: results of a national survey. Qual Saf Health Care. 2008; 17(6):416–423. [PubMed: 19064656]
11. Evans SM, Berry JG, Smith BJ, et al. Attitudes and barriers to incident reporting: a collaborative hospital study. Qual Saf Health Care. 2006; 15(1):39–43. [PubMed: 16456208]
12. Uribe CL, Schweikhart SB, Pathak DS, Dow M, Marsh GB. Perceived barriers to medical-error reporting: an exploratory investigation. J Healthc Manag. 2002; 47(4):263–279. [PubMed: 12221747]
13. Landrigan CP, Stockwell D, Toomey SL, et al. Performance of the Global Assessment of Pediatric Patient Safety (GAPPS) Tool [published online May 21, 2016]. Pediatrics. 2016; 137(6):e20154076.doi: 10.1542/peds.2015-4076 [PubMed: 27221286]
14. Classen DC, Resar R, Griffin F, et al. 'Global trigger tool' shows that adverse events in hospitals ay be ten times greater than previously measured. Health Aff (Millwood). 2011; 30(4):581–589. [PubMed: 21471476]
15. Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm. Qual Saf Health Care. 2003; 12(3):194–200. [PubMed: 12792009]
16. Weingart SN, Pagovich O, Sands DZ, et al. What can hospitalized patients tell us about adverse events? learning from patient-reported incidents. J Gen Intern Med. 2005; 20(9):830–836. [PubMed: 16117751]
17. Weissman JS, Schneider EC, Weingart SN, et al. Comparing patient-reported hospital adverse events with medical record review: do patients know something that hospitals do not? Ann Intern Med. 2008; 149(2):100–108. [PubMed: 18626049]
18. Khan A, Furtak SL, Melvin P, Rogers JE, Schuster MA, Landrigan CP. Parent-reported errors and adverse events in hospitalized children. JAMA Pediatr. 2016; 170(4):e154608. [PubMed: 26928413]
19. Daniels JP, Hunc K, Cochrane DD, et al. Identification by families of pediatric adverse events and near misses overlooked by health care providers. CMAJ. 2012; 184(1):29–34. [PubMed: 22105750]
20. Matlow AG, Baker GR, Flintoft V, et al. Adverse events among children in Canadian hospitals: the Canadian Paediatric Adverse Events Study. CMAJ. 2012; 184(13):E709–E718. [PubMed: 22847964]
21. Starmer AJ, Spector ND, Srivastava R, et al. I-PASS Study Group. Changes in medical errors after implementation of a handoff program. N Engl J Med. 2014; 371(19):1803–1812. [PubMed: 25372088]
22. Starmer AJ, Sectish TC, Simon DW, et al. Rates of medical errors and preventable adverse events among hospitalized children following implementation of a resident handoff bundle. JAMA. 2013; 310(21):2262–2270. [PubMed: 24302089]
23. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. N Engl J Med. 1991; 324(6): 370–376. [PubMed: 1987460]
24. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. N Engl J Med. 1991; 324(6):377–384. [PubMed: 1824793]
25. Bates DW, Boyle DL, Vander Vliet MB, Schneider J, Leape L. Relationship between medication errors and adverse drug events. J Gen Intern Med. 1995; 10(4):199–205. [PubMed: 7790981]
26. Kaushal R, Bates DW, Landrigan C, et al. Medication errors and adverse drug events in pediatric inpatients. JAMA. 2001; 285(16):2114–2120. [PubMed: 11311101]
27. National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). [Accessed July 18, 2016] NCC MERP index for categorizing medication errors. http://www.nccmerp.org/sites/default/files/algorColor2001-06-12.pdf
28. Feudtner C, Christakis DA, Connell FA. Pediatric deaths attributable to complex chronic conditions: a population-based study of Washington State, 1980–1997. Pediatrics. 2000; 106 suppl 1(1 pt 2):205–209. [PubMed: 10888693]

29. Firth D. Bias reduction of maximum likelihood estimates. Biometrika. 1993; 80(1):27–38. DOI: 10.1093/biomet/80.1.27
30. Lipsitz SR, Fitzmaurice GM, Regenbogen SE, Sinha D, Ibrahim JG, Gawande AA. Bias correction for the proportional odds logistic regression model with application to a study of surgical complications. J R Stat Soc Ser C Appl Stat. 2013; 62(2):233–250.
31. Moore CG, Lipsitz SR, Addy CL, Hussey JR, Fitzmaurice G, Natarajan S. Logistic regression with incomplete covariate data in complex survey sampling: application of reweighted estimating equations. Epidemiology. 2009; 20(3):382–390. [PubMed: 19289959]
32. Henry AJ, Hevelone ND, Lipsitz S, Nguyen LL. Comparative methods for handling missing data in large databases. J Vasc Surg. 2013; 58(5):1353–1359. e6. [PubMed: 23830314]
33. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap): a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009; 42(2):377–381. [PubMed: 18929686]
34. Jeffe DB, Dunagan WC, Garbutt J, et al. Using focus groups to understand physicians' and nurses' perspectives on error reporting in hospitals. Jt Comm J Qual Saf. 2004; 30(9):471–479. [PubMed: 15469124]
35. Elder NC, Graham D, Brandt E, Hickner J. Barriers and motivators for making error reports from family medicine offices: a report from the American Academy of Family Physicians National Research Network (AAFP NRN). J Am Board Fam Med. 2007; 20(2):115–123. [PubMed: 17341747]
36. Agency for Healthcare Research and Quality. [Accessed July 18, 2016] Developing and testing the Health Care Safety Hotline: a prototype consumer reporting system for patient safety events. http://www.ahrq.gov/professionals/quality-patient-safety/patient-family-engagement/hotline/index.html
37. Kraman SS, Hamm G. Risk management: extreme honesty may be the best policy. Ann Intern Med. 1999; 131(12):963–967. [PubMed: 10610649]
38. Kachalia A, Kaufman SR, Boothman R, et al. Liability claims and costs before and after implementation of a medical error disclosure program. Ann Intern Med. 2010; 153(4):213–221. [PubMed: 20713789]
39. Stewart RM, Corneille MG, Johnston J, et al. Transparent and open discussion of errors does not increase malpractice risk in trauma patients. Ann Surg. 2006; 243(5):645–649. [PubMed: 16632999]
40. Painter LM, Kidwell KM, Kidwell RP, et al. Do written disclosures of serious events increase risk of malpractice claims? one health care system's experience [published online March 31, 2015]. J Patient Saf.
41. Macrae C. The problem with incident reporting. BMJ Qual Saf. 2016; 25(2):71–75.
42. Edwards JD, Houtrow AJ, Vasilevskis EE, et al. Chronic conditions among children admitted to U.S. pediatric intensive care units: their prevalence and impact on risk for mortality and prolonged length of stay. Crit Care Med. 2012; 40(7):2196–2203. [PubMed: 22564961]
43. Feinstein JA, Feudtner C, Kempe A. Adverse drug event-related emergency department visits associated with complex chronic conditions. Pediatrics. 2014; 133(6):e1575–e1585. [PubMed: 24843054]
44. Pennarola BW, Rodday AM, Mayer DK, et al. HSCT-CHESS Study. Factors associated with parental activation in pediatric hematopoietic stem cell transplant. Med Care Res Rev. 2012; 69(2): 194–214. [PubMed: 22203645]

Key Points

Question

How do rates of family-reported errors and adverse events (AEs) compare with those detected by other sources of hospital safety reporting that do not typically include families?

Findings

In this cohort study including 746 parents/caregivers of 989 hospitalized pediatric patients, families reported similar rates of errors and AEs as clinicians, and families reported 5-fold more errors and 3-fold more AEs than hospital incident reports. Including families in prospective systematic surveillance increased overall error detection rates by 16%and AE detection rates by 10%.

Meaning

Families provide unique safety information and have the potential to be valuable partners in safety surveillance conducted by both hospitals and researchers.

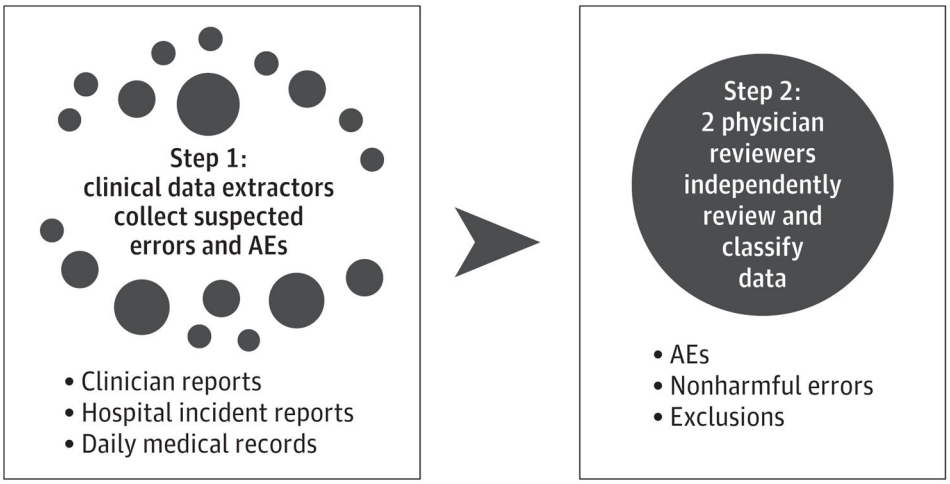

Figure 1. Systematic Surveillance of Errors and Adverse Events (AEs)

The established 2-step, prospective, systematic surveillance methodology currently considered highest yield for detecting errors and AEs in safety surveillance research.[5,14,15] Notably, patients and families are absent from this process. Our study integrated family safety reports into the first step of this process.

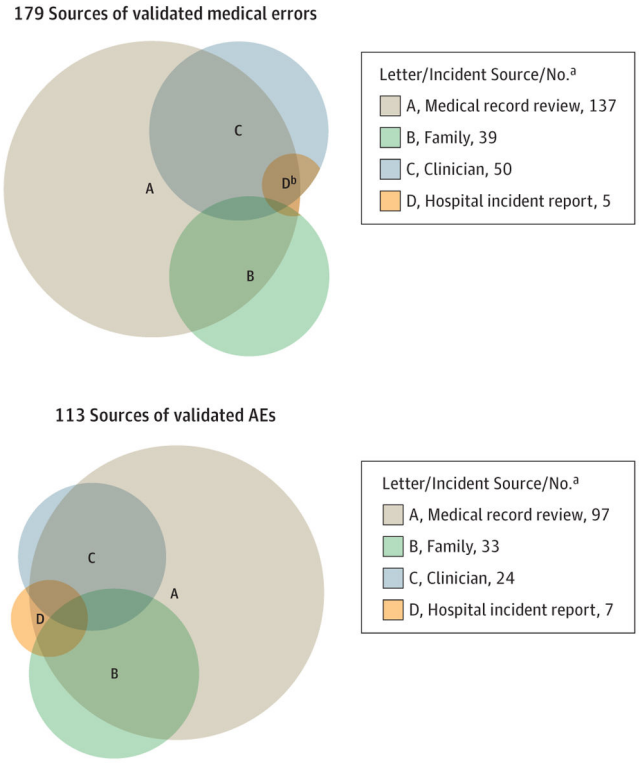

Figure 2. Sources of Errors and Adverse Events (AEs)

Sources of medical errors as validated through 2-step methodology (research clinician review followed by review by 2 physicians) across all 4 sites. Additional sources of medical errors included observation (eg, by study nurse while on unit; n = 12) and other (n = 8). Additional sources of AEs included observation (n = 7) and other (n = 4).

[a]Categories are not mutually exclusive, so numbers do not sum to 179 errors and 113 AEs.

[b]There were 0 unique medical errors reported through hospital incident reports.

Table 1

Patient, Parent/Caregiver, and Clinician Characteristics

Characteristic	No. (%)
Patients (n = 989)	
Age, median (IQR), y[a]	3 (0.75–10)
Sex	
Male	488 (49.3)
Female	473 (47.8)
Missing	28 (2.8)
Race/ethnicity	
White	418 (42.3)
Black	223 (22.5)
Asian	64 (6.5)
Other	211 (21.3)
Missing	73 (7.4)
CCC count[b]	
0	746 (75.4)
1	125 (12.6)
≥2	118 (11.9)
Insurance	
Public	645 (65.2)
Nonpublic	312 (31.5)
Missing	32 (3.2)
Length of stay, mean (SD), d	
Hospital	4.6 (6.2)
Unit	4.0 (3.7)
Parents/caregivers (n = 717)	
Age, median (IQR), y[c]	32.5 (26–40)
sex	
Male	111 (15.5)
Female	566 (78.9)
Declined	2 (0.3)
Missing	38 (5.3)
Race/ethnicity	
White, non-Hispanic	302 (42.1)
Black, non-Hispanic	135 (18.8)
Hispanic	164 (22.9)
Asian	35 (4.9)
Other	46 (6.4)

Characteristic	No. (%)
Missing	35 (4.9)
Relationship to patient	
Parent	638 (90.0)
Grandparent	19 (2.6)
Guardian	4 (0.6)
Other	13 (1.8)
Missing	43 (6.0)
Language most comfortable speaking with clinicians	
English	603 (84.1)
Spanish	40 (5.6)
Other	15 (2.1)
Declined	2 (0.3)
Missing	57 (7.9)
Ability to speak English	
Not at all	16 (2.2)
Not well	18 (2.5)
Well	48 (6.7)
Very well	592 (82.6)
Declined	4 (0.6)
Missing	39 (5.4)
Satisfaction with ability to read English	
Very dissatisfied	28 (3.9)
Somewhat dissatisfied	7 (1.0)
Somewhat satisfied	14 (2.0)
Satisfied	72 (10.0)
Very satisfied	549 (76.6)
Missing	47 (6.6)
Income, median (IQR), $	30 000–49 999 (15 000–29 999 to 75 000–99 999)
Education level	
Less than high school	26 (3.6)
Some or all of high school	262 (36.5)
Some college or more	380 (53.0)
Missing	49 (6.8)
Clinicians (n = 378)	
Age, mean (SD), y[d]	31.0(7.1)
Sex	
Male	76 (20.1)
Female	288 (76.2)
Declined	1 (0.3)

Characteristic	No. (%)
Missing	13(3.4)
Race/ethnicity	
White, non-Hispanic	236 (62.4)
Black, non-Hispanic	10 (2.6)
Hispanic	24 (6.3)
Asian	70 (18.5)
Other	16 (4.2)
Missing	22 (5.8)
Position	
Resident	199 (52.6)
Nurse	131 (34.7)
Medical student	32 (8.5)
PA student	3 (0.8)
Missing	13 (3.4)

Abbreviations: CCC, complex chronic condition; IQR, interquartile range; PA, physician's assistant.

[a] 28 missing.

[b] The CCC system uses *International Classification of Diseases, Ninth Revision, Clinical Modification* codes to capture medically complex children, namely those with medical conditions expected to last 12 or more months that involve several different organ systems or 1 organ system severely enough to require specialty pediatric care and hospitalization in a tertiary care center.[28]

[c] 51 missing.

[d] 22 missing.

Table 2

Examples of Errors and Adverse Events (AEs) by Reporting Source

Error	AE
Family-Report Only	
Toddler with Kawasaki disease whose diagnosis of pleural effusion and pulmonary edema and treatment with furosemide was delayed by 12 h despite parent reporting rapid breathing and an unusual sound coming from the chest much earlier in the day.	Infant with bronchiolitis requiring intensive care admission for high flow nasal cannula who, on transfer back to the unit, was found by mother to have swaddler wrapped around her neck, vomiting, choking, and having difficulty breathing. Nurse did not suction the patient as requested by mother.
Clinician-Reported Only	
Teenaged patient with cystic fibrosis exacerbation admitted with elevated creatinine level who received a bolus of D5 NS + 20KCl despite nurse raising concerns with overnight resident that the patient had an elevated creatinine level and that the nurse had never administered this solution as a bolus before.	School-aged child with a metabolic disorder admitted for pancreatitis whose pain medication was delayed because an inappropriate rate of hydromorphone was ordered for the patient-controlled analgesia (PCA).
Reported by Both Family and Clinician	
Teenaged patient with inflammatory bowel disease on ketamine drip for pain control whose pump settings were incorrectly entered, resulting in patient receiving 3-fold the appropriate rate overnight.	Toddler admitted with fever and dehydration in the setting of *Streptococcus*, adenovirus, and coronavirus infection who experienced a 10-h delay in ordering maintenance IV fluids after parent alerted nurse about decreased oral intake and urination. Later that evening, patient experienced an IV infiltrate, after which there was another 10-h delay before IV fluids were restarted. This resulted in symptomatic dehydration, including tachycardia and dry mucus membranes, requiring need for additional IV fluid boluses.
Medical Record Review Only	
Teenaged patient with migraines admitted for dihydroergotamine infusion who was ordered for an incorrect dose of medication by overnight resident, who had not examined the patient or conferred with neurology. Dose was corrected before reaching patient.	Neonate admitted with a brief resolved unexplained event (BRUE) and cough in the setting of rhinovirus and respiratory syncytial virus infection who began to worsen and have desaturations and apneas. A chest radiograph was ordered (but not obtained), and the patient was transferred to the ICU for 4 d. Two d after being transferred from the ICU back to the general pediatric unit, the patient again developed apnea and desaturations, prompting septic workup and a chest radiograph, which revealed a right upper lobe pneumonia, for which the patient was subsequently treated with IV antibiotics.
Hospital Incident Report Only	
NA	Toddler with Kawasaki disease who fell and hit head during playtime. Patient required additional monitoring for changes in mental status.

Abbreviations: D5 NS + 20KCL, potassium chloride in 5% dextrose and sodium chloride injection; ICU, intensive care unit; IV, intravenous; NA, not applicable.

Table 3

Overall Error and AE Rates Without vs With Family Reporting[a]

Frequency	Rate (95% CI)		Relative Rate (95% CI)
	Without Family Reporting	With Family Reporting	
Per 1000 patient-d			
Errors	39.8 (33.6–46.9)	45.9 (39.2–53.7)	1.2 (1.1–1.2)
AEs	26.1 (21.3–32.1)	28.7 (23.6–35.0)	1.1 (1.0–1.2)[b]
Per 100 admissions			
Errors	15.7 (13.1–18.8)	18.1 (15.3–21.5)	1.2 (1.1–1.2)
AEs	10.3 (8.3–12.9)	11.3 (9.1–14.0)	1.1 (1.0–1.2)[b]

Abbreviation: AE, adverse event.

[a] Including families in error reporting led to significantly higher rates of overall errors and AEs.

[b] $P = .006$.

Table 4

Clinician vs Family Contributions to Overall Error and AE Rates[a]

Frequency	Rate (95% CI)		Relative Rate (95% CI)
	Clinician Reporting	Family Reporting	
Per 1000 patient-d			
Errors	12.8 (9.6–17.1)	10.0 (7.0–14.2)	0.8 (0.5–1.2)
AEs	6.2 (4.0–9.4)	8.5 (5.9–12.1)	1.4 (0.8–2.2)
Per 100 admissions			
Errors	5.1 (3.8–6.8)	3.9 (2.8–5.6)	0.8 (0.5–1.2)
AEs	2.4 (1.6–3.7)	3.3 (2.3–4.8)	1.4 (0.8–2.2)

Abbreviation: AE, adverse event.

[a]Families reported equal rates of errors and AEs as clinicians.

Table 5

Hospital Incident Report vs Family Contributions to Overall Error and AE Rates[a,b]

Frequency	Rate (95% CI)		Relative Rate (95% CI)
	Hospital Incident Report	Family Reporting	
Per 1000 patient-d			
Errors	1.7 (0.7–4.2)	8.7 (5.5–13.6)	5.0 (1.9–13.0)
AEs	2.4 (1.0–5.6)	6.9 (4.2–11.4)	2.9 (1.2–6.7)
Per 100 admissions			
Errors	0.6 (0.3–1.5)	3.1 (2.0–4.9)	5.0 (1.9–13.0)
AEs	0.9 (0.4–2.0)	2.5 (1.5–4.1)	2.9 (1.2–6.7)

Abbreviation: AE, adverse event.

[a] Families reported errors and AEs at rates 5 and 3 times, respectively, greater than hospital incident reports.

[b] Results from sites with available hospital incident report data (3 of 4 study sites).