Received: 26 December 2021 | Accepted: 29 December 2021

DOI: 10.1002/jhm.2777

ORIGINAL RESEARCH

Journal of Hospital Medicine

shm Society of Hospital Medicine

Family Input for Quality and Safety (FIQS): Using mobile technology for in-hospital reporting from families and patients

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Funding information

Eunice Kennedy Shriver National Institute of Child Health and Human Development, Grant/Award Number: R01 HD100393; National Center for Advancing Translational Sciences, Grant/Award Number: KL2TR001870; Agency for Healthcare Research and Quality, Grant/Award Numbers: K08HS028477, R21 HS024553

Abstract

Objective: Despite three decades of effort, ensuring inpatient safety remains elusive. Patients and family members are a potential source of safety observations, but systems gathering these are limited. Our goal was to test a system to gather safety observations from hospitalized patients and their family members via a real-time mobile health tool.

Methods: We developed a mobile-responsive website for reporting safety observations. We piloted the tool during June 2017–April 2018 on the medical–surgical unit of a children's hospital. Participants were English-speaking family members and patients ≥13 years. We sent a daily text with a website link. We assessed: (1) face validity by comparing observations to incident reporting (IR) criteria and to hospital IRs and (2) associations between the number of safety observations/100 patient-days and participant characteristics using Poisson regression.

Results: We enrolled 235 patients (43.8% of 537 reviewed for eligibility), resulting in 8.15 safety reports/100 patient-days, most frequently regarding medications (29% of reports) and communication (20% of reports). Fifty-one (40% of 125) met IR criteria; only one (1.1%) had been reported via the IR system. Latinx participants submitted fewer observations than White participants (3.9 vs. 10.1, $p = .002$); participants with more prior hospitalizations submitted more observations ($p < .001$). In adjusted analyses, including measures of preference in decision making, and patient activation, the difference between Latinx and White participants diminished substantially (6.4 vs. 11.3, $p = .16$).

Conclusions: We demonstrated the feasibility of real-time patient and family-member technology-enabled safety observation reporting and elicited reports not otherwise identified. Variation in reporting may potentially exacerbate disparities in safety if not addressed.

INTRODUCTION

More than two decades after the seminal report, “To Err is Human,” failure rates in inpatient safety remain stubbornly high, with almost 400,000 premature deaths due to preventable harm annually, and adverse events in one-third of hospital admissions.[1–4] Patient safety event rates differ by age, with higher rates among pediatric inpatients than adults,[4,5] and by ethnicity, with recent data from a geographically diverse group of 16 children's hospitals showing almost double the rate of adverse events in Latinx pediatric patients compared to non-Latinx White patients, using a patient safety trigger tool.[6] Our lack of progress may be in part due to limited access to timely safety improvement data.[7–11] Many errors and near-misses remain undetected in incident reporting (IR) systems,[12,13] which are the standard method of gathering patient safety events.

Prior studies have demonstrated that patients and caregivers make safety observations (adverse events, errors, and near misses) that are not identified in medical record review or IR systems.[14–18] In addition, patient and family or caregiver ratings are associated with patient safety indicators such as mortality, readmissions, and infection rates.[19–21] However, some patients may be reluctant to report observed safety issues out of fear of retribution from the hospital team, as Lyndon et al.[22] found when asking NICU parents about willingness to speak-up to staff. The ubiquitous presence of mobile phones may allow us to more effectively gather safety observations anonymously and use them for quality improvement. We hypothesized that patients and families will engage in anonymous, mobile-phone safety reporting but that reports might differ by race, ethnicity, or other patient characteristics.

To test these hypotheses, we developed a mobile phone-based approach, Family Input for Quality and Safety (FIQS), eliciting safety observations daily from patients and families on a pediatric medical–surgical unit. We gathered data on patient demographics, patient activation, health information technology literacy, and patient preference in shared decision-making to assess whether these measures elucidate reasons for differences in reporting.

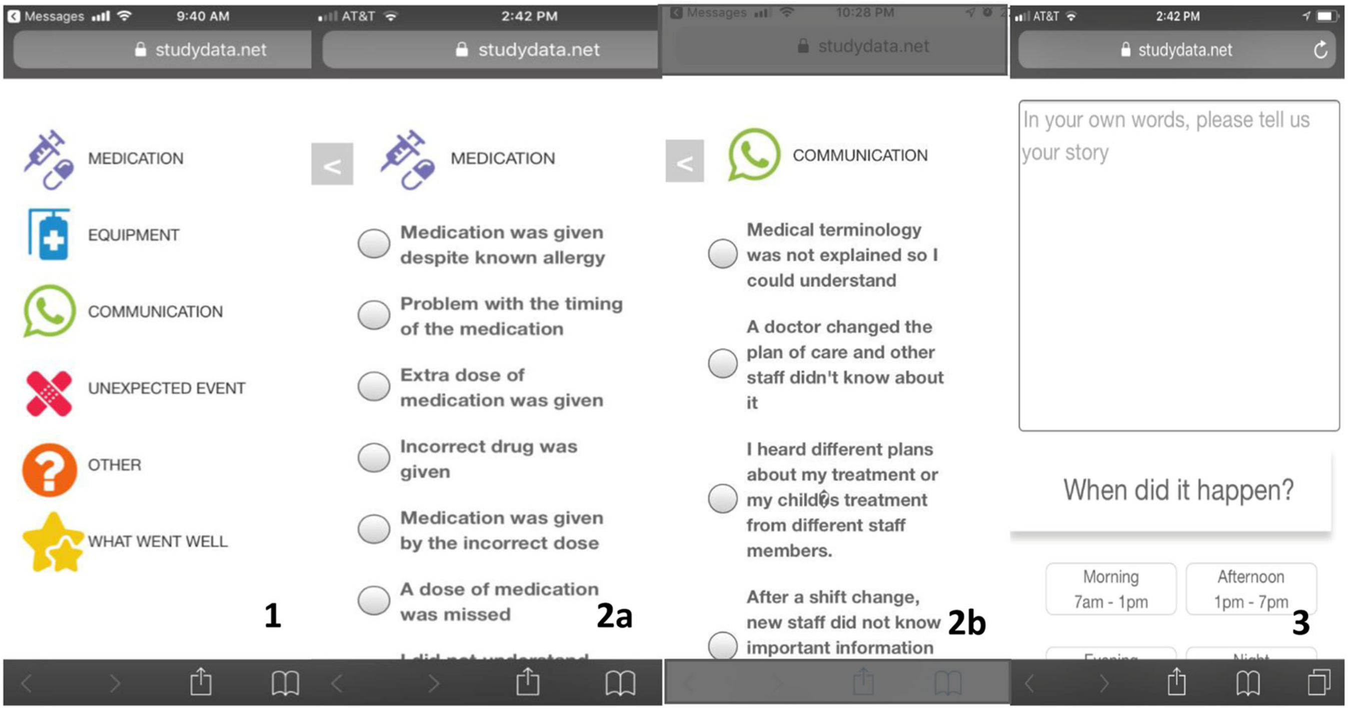
METHODS

Setting

We conducted the study on a medical–surgical unit in a quaternary care children's hospital, staffed by academic pediatric hospitalists (Supporting Information Appendix 1 for unit demographics).

Tool development

We developed an English-language mobile-responsive website (the “FIQS tool”) to gather patient and parent safety reports (Figure 1,



○ Medication was given despite known allergy

○ Problem with the timing of the medication

○ Extra dose of medication was given

○ Incorrect drug was given

○ Medication was given by the incorrect dose

○ A dose of medication was missed

○ Medical terminology was not explained so I could understand

○ A doctor changed the plan of care and other staff didn't know about it

○ I heard different plans about my treatment or my child�s treatment from different staff members.

○ After a shift change, new staff did not know important information

In your own words, please tell us your story

When did it happen?

Morning 7am - 1pm

Afternoon 1pm - 7pm

FIGURE 1 Family Input into Quality and Safety (FIQS) tool selected screenshots. Screenshot 1 shows the categories for event reporting. Screenshots 2a and 2b show the screens subsequent to choosing either the Medication (2a) or Communication (2b) headings. Once a participant selects one of the subcategories, the screen automatically scrolls to the bottom, where the participant can fill out the free text box depicted in screenshot 3. For complete screenshots of the FIQS mobile-responsive website interface, see Supporting Information Appendix 2

Supporting Information Appendix 2). We elicited reports in real time via a daily text message prompt, including a link to the mobile-responsive website. We identified content areas for reports based on a literature review of tools for gathering patient and family feedback.[23–26] We narrowed the topics via an iterative process with the hospital's Family Advisory Council (FAC; ~25 members) and the Pediatric Hospitalist faculty (~15 faculty).[27] Top-level categories and subcategories were: Medication (e.g., timing and dose); Communication (e.g., poor patient–provider communication and team miscommunication); Equipment (e.g., equipment was broken); Unexpected event (e.g., IV blocked; test done incorrectly); Other. Specific language for subcategories (Supporting Information Appendix 2) was adapted from a paper-based tool used in the United Kingdom.[26]

We conducted usability testing in April 2017 with 17 patient/parent dyads on the medical–surgical unit in English, following guidelines from the US Department of Health and Human Services.[28] We tested enrollment scripts and procedures, and opening and navigating the mobile-responsive website.

Usability testing informed the timing of text messages to occur daily in the afternoon, the decision to make the reports anonymous to the hospital team, and the inclusion of a category for “What went well” in response to requests to be able to give positive feedback. FAC members, presented with the option of anonymous versus identified reports, preferred anonymous reporting, to decrease potential family concerns of retribution for negative reports. Hospitalists preferred anonymous reports also to prevent mis-set service recovery expectations.

Patients and recruitment

Eligible participants were patients aged ≥ 13 years, admitted to the medical–surgical unit during July 2017–April 2018, and parents or caregivers of admitted patients 0–21 years. Exclusions: no smartphone, no legal guardian available, non-English speaking (English-speaking patients with Spanish-speaking parents could participate), patient temporarily off-unit, or patient with an active medical or social concern (e.g., difficult medical news that day). Written consent for Health Insurance Portability and Accountability Act (HIPAA) release for medical records review and electronic consent to participate were gathered.

During recruitment, research staff oriented participants to the FIQS tool, familiarizing participants with the user interface and creating a shared mental model of safety through a review of the tool categories and subcategories. Staff reinforced that the tool was not for emergencies and that reports were only shared with hospital staff without patient or parent identifiers. After enrollment, during the admission, automated daily text messages were sent to participants, soliciting safety reports (or an “N” for no report), including a link to the FIQS tool to make the report. Participants did not need to download a mobile health application or remember a specific website independently.

Safety reports were reviewed without patient identifiers during the weekly unit quality huddle and in aggregate at the end of the pilot, to inform safety efforts. Reports were subsequently linked with patient characteristics from medical records using medical record numbers and visit dates.

Covariates

We obtained patient diagnoses from medical record review to assess chronic disease status, using the patient medical complexity algorithm (PMCA).[29,30] We reviewed medical records for the number of admissions in 2017 prior to a patient's enrollment, as prior inpatient experience may lead to greater patient activation and safety awareness.[31]

We gathered demographic and social factors in patient- and caregiver-facing enrollment surveys. Items included patient's race, ethnicity, employment status, education,[32] preference in shared decision-making,[33] health information technology readiness,[34] and the parent–patient activation measure (P-PAM) or the patient activation measure (PAM). The P-PAM and PAM are validated 13-item surveys regarding confidence in the management of a child's disease (P-PAM),[35–37] or in self-management of disease (PAM),[38–40] providing four-level activation scores.

Outcome

Our primary outcome was the number of safety reports/100 patient-days (days in the study). For our primary analysis, we did not include safety reports from the category “What went well,” as the content of most was non-specific.

We reviewed narrative comments to assess whether the reports were safety-related and whether they would meet the criteria for an incident report (see “Narrative comment analysis” for definitions). We compared the reports to those in the IR system to assess whether the IR system had captured any of the FIQS-reported events.

Analysis

We assessed the cross-sectional relationships between patient and caregiver characteristics and the primary outcome using Poisson regression. Observations were at the patient level, assessing the count of reports per patient. We considered negative binomial regression but chose Poisson to maximize power in our data set. All models included “number of days in the study” as an exposure term, to account for differential follow-up times. Adjusted analyses used observations with non-missing values for model variables. We obtained adjusted rates for multivariable analyses using the post-estimation margins command,[41,42] which have more intuitive interpretations than β coefficients from regression modeling. We used these methods in both bivariate and multivariable models. Multivariable models included variables with a $p < .2$ in testing to assess for overall statistical significance across categories (testparm command) in bivariate analyses.

We used multivariable analyses with a step-wise approach to test whether relationships between race/ethnicity and reports/100 patient-days might be further explained by social determinants of health (education, employment) and caregiver preferences. We first tested the association only including race/ethnicity, prior hospitalizations, and education and employment variables, then added covariates for caregiver activation and preference for decision-making.

Narrative comment analysis

Three research team members reviewed the comments to assess: whether reports were safety concerns, using the safety rubric from the Healthcare Performance Improvement White Paper Series[43]; and whether comments met criteria for an IR, using the hospital's IR policy guidelines. Reviewing team members were a pediatrician and health services researcher (NSB), the patient safety officer at the hospital (JRS), and the research coordinator who enrolled patients (CPN). The patient safety officer (JRS) reviewed narrative comments and compared them to patient IRs.

Sensitivity analyses

We repeated the quantitative analyses including the safety reports from the "What went well" category.

We used STATA 13 for data management and all analyses. The University of California San Francisco Institutional Review Board approved this study.

RESULTS

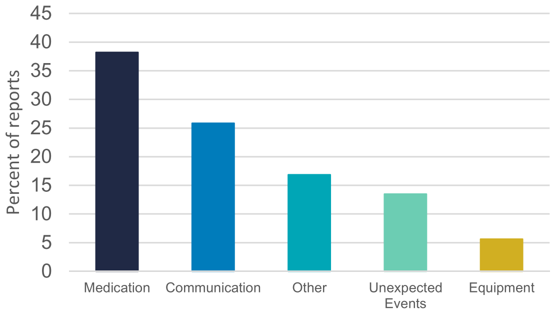


FIGURE 2 Percent of reports by category made at the point of care by hospitalized patients and family members ($N = 89$ non-duplicate reports, not including "What went well"). Categories: medication (e.g., timing and dose); communication (e.g., poor patient-provider communication and team miscommunication); equipment (e.g., equipment was broken); unexpected event (e.g., test done incorrectly). Missed care was not included as a separate category, but could have been reported as an "Other"

We enrolled 248 participants (69.9% were mothers, 19.7% fathers, 7.5% adolescents, and 2.9% others). They were associated with 235 patients (some patients had more than one associated participant, e.g., two parents, or patient and parent) of 537 (43.8%) reviewed for eligibility (Supporting Information Appendix 3). Median length of stay (LOS) was 2 days (interquartile range: 1–5), and the mean was 4.6 (standard deviation: 7.5). Fifty-eight participants (50 parents; eight patients) submitted at least one report. Twenty-nine patients had only one report submitted; a maximum of six reports were submitted for one patient. Most (80.7%) participants replied to ≥1 daily text ($n = 2026$ texts), with either a report ($n = 125$) or "No reports" ($n = 633$) for a 37.4% (758/2026) response rate. The most common categories were Medication ($n = 34$, 29%), What went well ($n = 28$, 24%), and Communication ($n = 23$, 20%, Figure 2). Almost all reports included a narrative comment, providing rich data on safety events (e.g., "Amount of infusion was incorrect. I was told by a nurse that I need to tell the doctor what the amount should be before it started. The doctor blamed the pharmacy but did change the order. I should not have to or be expected to correct doctors"). On expert review, 69 (55%) of the comments were considered safety concerns using the Healthcare Performance Improvement rubric and 51 (40%) met the criteria for an IR entry; only one (1.1%) was found in the IR system. Full qualitative analysis of the narrative comments will be reported elsewhere.

After excluding "What went well" reports, the overall rate of safety reports was 8.15 reports/100 patient-days. In bivariate testing, there were no statistically significant differences in reporting rates by patient gender, age group, or chronic condition status. Hispanic (henceforth Latinx) patients had lower reporting rates than White patients (3.9 vs. 10.1 reports/100 patient-days, $p = .002$). Patients with Medicaid insurance had lower report rates compared to those with commercial insurance (3.7 vs. 12.8, $p < .001$), and the number of hospitalizations in 2017 prior to study enrollment was associated with increased reporting (Table 1). Longer LOS was associated with more reports but was not statistically significant (LOS 0–2 days: mean 0.35 reports; 3–5 days: mean 0.32 reports; ≥6 days: mean 0.50 reports, $p = .18$).

Education, employment, and caregiver decision-making preference were associated with reporting rates, while relationship (mother, father, other), activation level, and mobile phone use were not, though these three variables showed limited variation, and the latter two indicate a ceiling effect (Table 2). Specifically, those with a graduate degree had a higher reporting rate compared to those with a 4-year college degree (20.0 reports/100 patient-days vs. 6.1, $p = .001$). Those who were unemployed had lower rates than those employed full time (2.6 vs. 10.1, $p = .004$). Those who strongly (1.9 reports/100 patient-days) or moderately (4.5 reports/100 patient-days) agreed with the statement: "I prefer to rely on my doctor's knowledge and not try to find out about my condition on my own" had lower report rates than those who strongly disagreed (16.7, $p < .001$ for both comparisons).

TABLE 1 Patient characteristics and rate of safety reporting bivariate analyses

Patient characteristics	*N* (%)	# Reports/100 patient-days	*p* Value[b]
Overall	235 (100)	8.15 (6.46 to 9.84)	–
Age group (years)			
0–2	46 (19.6)	5.4 (2.1 to 8.8)	Ref.
3–6	46 (19.6)	11.5 (6.0 to 16.9)	.06
7–11	49 (20.9)	9.1 (4.6 to 13.5)	.20
12–18	94 (40.0)	7.9 (5.6 to 10.2)	.29
Gender			
Female	109 (46.4)	8.8 (6.5 to 11.0)	Ref.
Male	126 (53.6)	7.3 (4.7 to 9.8)	.40
Race/ethnicity			
White	91 (38.7)	10.1 (6.9 to 13.2)	Ref.
Latinx	72 (30.6)	3.9 (1.9 to 5.9)	.002
African-American	17 (7.2)	13.2 (5.7 to 20.6)	.41
Asian	34 (14.5)	10.3 (5.3 to 15.4)	.93
Other/Declined	21 (8.9)	9.0 (2.3 to 15.6)	.78
Insurance			
Commercial	113 (48.1)	12.8 (9.6 to 16.0)	Ref.
Medicaid	94 (40.0)	3.7 (2.0 to 5.5)	<.001
Other/Unknown	28 (11.9)	6.8 (2.8 to 10.9)	.06
Prior hospitalizations[a]			
0	132 (59.7)	7.1 (4.9 to 9.2)	Ref.
1	32 (14.5)	4.9 (1.0 to 8.9)	.40
2	30 (13.6)	9.0 (3.9 to 14.0)	.48
3 or more	27 (12.2)	12.8 (7.4 to 18.1)	.03
Chronic condition status			
No chronic condition	21 (8.9)	4.8 (−1.8 to 11.4)	Ref.
Chronic, non-complex	36 (15.3)	9.4 (3.6 to 15.3)	.38
Complex chronic	158 (67.2)	7.9 (6.0 to 9.7)	.49

[a] Prior hospitalizations and chronic condition status are not available for 20 (9%) of patients, due to declining to consent for medical record review. Prior hospitalization is defined as the number of prior hospitalizations in 2017 prior to patient study enrollment.

[b] *p* Value for testing of the association between the patient characteristic and the number of safety reports/100 patient-days. Postestimation testing to assess for overall statistical significance across categories (testparm command in STATA) resulted in the following *p* values: Age group $p = .27$; Gender $p = .40$; Race/Ethnicity $p = .01$; Insurance $p < .001$; Chronic condition status $p = .66$; Hospitalizations in 2017 prior to study enrollment $p = .08$.

In multivariable analyses, we included race/ethnicity, insurance type, caregiver education, employment, activation level, decision-making preference, and the number of hospitalizations in 2017 prior to study enrollment. When only including socioeconomic-status

TABLE 2 Participant survey responses and rate of safety reporting bivariate analyses

Characteristics	*N* (%)	# Reports/100 patient-days	*p* Value
Relationship ($N = 248$)			
Mother	167 (69.9)	7.7 (5.7 to 9.7)	.87
Father	47 (19.7)	8.1 (3.7 to 12.5)	Ref.
Other	7 (2.9)	4.9 (−1.9 to 11.6)	.50
Self (adolescent)	18 (7.5)	11.1 (5.8 to 16.4)	.40
Caregiver education ($n = 221$)			
Graduate degree	40 (18.1)	20.0 (12.2 to 27.8)	.001
Four-year college degree	46 (20.8)	6.1 (2.6 to 9.5)	Ref.
Some college	86 (38.9)	6.9 (4.5 to 9.3)	.71
High school or less	49 (22.2)	2.4 (0.04 to 4.7)	.10
Caregiver employment ($n = 221$)			
Employed full time	124 (56.1)	10.1 (7.2 to 13.1)	Ref.
Employed part time	34 (15.4)	5.7 (2.2 to 9.3)	.11
Not in the labor force	33 (14.9)	9.5 (4.1 to 14.9)	.85
Unemployed	30 (13.6)	2.6 (0.3 to 4.8)	.004
Caregiver prefers to rely on doctor knowledge ($n = 221$)[a]			
Strongly disagree	48 (21.7)	16.7 (11.3 to 22.1)	Ref.
Moderately disagree	18 (8.1)	7.8 (1.0 to 14.7)	.11
Slightly disagree	21 (9.5)	14.5 (4.5 to 24.6)	.72
Slightly agree	29 (13.1)	9.0 (2.3 to 15.6)	.13
Moderately agree	50 (22.6)	4.5 (1.5 to 7.4)	<.001
Strongly agree	55 (24.9)	1.9 (0.4 to 3.4)	<.001
Cell phone use ($n = 248$)[b]			
Strongly disagree	9 (3.6)	6.5 (−0.9 to 13.9)	Ref.
Disagree	5 (2.0)	0 (−0.01 to 0.01)	.98
Agree	69 (27.8)	5.7 (2.6 to 8.8)	.83
Strongly agree	153 (61.7)	8.7 (6.4 to 11.0)	.62
Missing	12 (4.8)	Omitted	NA
Caregiver or patient activation ($n = 248$)[c]			
Level 1	6 (2.4)	12.9 (0.3 to 25.5)	Ref.
Level 2	13 (5.2)	4.5 (−1.8 to 10.8)	.23

(Continued)

TABLE 2 (Continued)

Characteristics	*N* (%)	# Reports/100 patient-days	*p* Value
Level 3	48 (19.4)	20.7 (12.4 to 29.0)	.38
Level 4	180 (72.6)	6.5 (4.9 to 8.2)	.19
Missing	1 (0.4)	Omitted	NA

Note: Adolescents did not reply to questions except cell phone use and patient activation levels.

Postestimation testing to assess for overall statistical significance across categories (testparm command in STATA) resulted in the following *p* values: Relationship $p = .51$; Education $p < .001$; Employment $p = .02$; Decision-making preference $p < .001$; Cell phone use $p = .55$; Activation < .001.

[a] "I prefer to rely on my doctor's knowledge and not try to find out about my condition on my own."

[b] "I use my cell phone to text people almost every day."

[c] Patient activation levels: Level 1: May not yet believe that the caregiver/patient role is important; Level 2: Lacks confidence and knowledge to take action; Level 3: Beginning to take action. Level 4: Working on maintaining behaviors over time.

variables (insurance, education, and employment) and the number of hospitalizations prior to study enrollment, Latinx patients continued to have statistically significantly lower rates of reporting compared to White patients (5.5 reports/100 patient-days vs. 12.0, $p = .03$). Once including activation and preference in decision making, reporting rates differences for Latinx versus White patients narrowed and were not statistically significantly different (6.7 vs. 12.0, $p = .14$). Insurance type, preference to rely on doctor knowledge, and number of prior hospitalizations were associated with statistically significantly different reporting (Table 3).

Sensitivity analyses including "What went well" reports showed a rate of 11.4 reports/100 patient-days. Results were similar, though in the fully adjusted model ethnicity was statistically significantly different (8.7 for Latinx patients vs. 17.0 for White patients, $p = .04$).

Review of safety events in the weekly huddle led to changes in communication about timely delivery of medications during the study and plans for team communication improvements at study end. Some staff expressed a preference for patient identification to allow potential report follow-up.

DISCUSSION

In this study of patient and caregiver reports of safety events in the pediatric inpatient setting using a mobile-responsive website and daily text messages, we found a higher overall safety reporting rate than prior studies,[17,44] with lower reporting rates in Latinx patients and those with Medicaid insurance. Patients who had been hospitalized previously had higher reporting rates, and insurance status and caregiver preference in decision-making remained independent predictors in adjusted models.

In a prior study, almost half of patient and family safety complaints were confirmed in physician review, but only 2.5% also appeared in IRs.[15] We have similar findings in this study, with 55% of reports confirmed as safety reports and 40% potential IRs, with only 1.1% in the institution's IR system.

The most common categories of reports were "What went well" and medication and communication; equipment safety reports were rare. The predominance of medication and communication content is similar to content emphasis in prior studies of parent observations of care.[45–47] The high proportion of "What went well" reports supports prior evidence that patients and family members engage not only in negative feedback but also in identifying positive aspects of care.[48]

Our technology-based approach is distinctive from prior efforts to collect patient and caregiver safety reports.[14–17,26,44,47] We found increased engagement compared to prior efforts, with almost six times higher engagement than in a 2018 study using a website without mobile phone linkage,[44] likely due to our straightforward interface and daily text reminder. The daily text also addressed potential recall bias or forgetfulness inherent in prior efforts collecting data at or after discharge,[26,47] and allowed for timely availability of data, in contrast to lagged patient data from the standard inpatient experience surveys (e.g., HCAHPS and Press Ganey). In addition, patient and caregiver narrative text provided information not collected in those standard inpatient experience surveys. Grob et al.[27] demonstrated in a study of outpatient quality narratives that this type of feedback is more actionable than quantitative data.[27]

The mobile phone interface with de-identified reporting addressed the limitations of collecting reports in-person or non-anonymously.[13–16] In-person reports may be hindered by social desirability bias (desire to be perceived as a good patient) or by a fear of care team retribution for a negative report.[22] Nonanonymous reports may lead to a focus on service recovery and "putting out fires", as Lui et al.[49] described in recent qualitative work, distracting from sustainable system-level improvements with potentially higher long-term benefits. Using the anonymous collection of reports addresses the potential patient and caregiver reluctance to report as well as supports a focus on system improvements. However, in future iterations, participants could opt to share their report nonanonymously, to allow for additional information gathering for root cause analyses or for service recovery. This would allow teams both to focus on system solutions and to undertake follow-up as appropriate.

Paradoxically, in contrast to the lower rates of safety reporting from Latinx patients in this study, Stockwell et al.[6] found higher adverse safety event rates in inpatient pediatric Latinx populations, when identified through medical record review as did Khan et al.[50] in inpatient non-English speakers (71.4% Spanish speakers). A potential explanation, highlighting the importance of specifically engaging Latinx patients and caregivers, is suggested by our finding that lower reporting rates in Latinx patients were explained by confounding due to variations in activation, patient preference in decision-making, and lower socioeconomic status (SES). To address the underlying reporting differences, future directions could include improving patient engagement efforts through language concordance and cultural specificity, and supporting health literacy, patient activation, and shared decision-making in minority and low SES populations.[51]

Similarly, we found that patients with Medicaid made almost three-fold fewer safety reports than those with commercial insurance, as did those who were unemployed compared to those with full-time employment (Table 3). This indicates potential social vulnerabilities, both operational and interpersonal, that likely contribute to decreased reporting.[52]

Without addressing these differences in reporting, the IR system will likely be the major source of data for Latinx patients and other groups that under-report. But relying on IRs may exacerbate disparities, given our finding that almost all physician-confirmed safety

TABLE 3 Associations between race/ethnicity and rate of safety reporting, multivariate analyses

	Baseline model (socioeconomic status + number of hospitalizations)[a]		Baseline + activation		Baseline + activation + decision preference	
Characteristics	Adjusted	*p* Value	Adjusted	*p* Value	Adjusted	*p* Value
Race/ethnicity						
White	12.0 (7.3–16.7)	Ref.	12.1 (7.4–16.8)	Ref.	12.0 (7.0–17.0)	Ref.
Latinx	5.5 (2.3–8.7)	.03	6.3 (2.4–10.2)	.09	6.7 (2.5–11.0)	.14
African-American	24.6 (1.3–48.0)	.17	31.3 (0.0–62.9)	.08	18.1 (0.0–39.0)	.50
Asian	5.6 (2.2–9.0)	.04	5.9 (2.4–9.5)	.05	9.0 (3.1–15.0)	.46
Other/declined	17.4 (1.3–33.6)	.45	17.9 (1.3–34.6)	.43	22.2 (0.4–44.0)	.25
Insurance						
Commercial	14.0 (9.2–18.8)	Ref.	15.4 (9.7–21.0)	Ref.	15.0 (9.5–20.5)	Ref.
Medicaid	4.9 (2.3–7.5)	.002	4.9 (2.3–7.4)	.001	5.5 (2.3–8.6)	.007
Other/unknown	1.4 (0.0–4.4)	.035	1.7 (0.0–5.2)	.05	2.3 (0.0–7.5)	.12
Caregiver education						
Graduate degree	15.7 (7.8–23.7)	.013	14.0 (7.0–21.1)	.04	13.8 (6.7–20.9)	.29
Four-year college degree	5.8 (2.4–9.1)	Ref.	6.0 (2.5–9.5)	Ref.	8.8 (3.3–14.2)	Ref.
Some college	10.3 (6.0–14.6)	.11	12.1 (6.6–17.7)	.06	11.6 (5.9–17.2)	.49
High school or less	5.7 (0.0–12.0)	.99	6.1 (0.0–12.8)	.98	7.8 (0.0–16.7)	.85
Caregiver employment						
Employed full time	11.2 (7.3–15.2)	Ref.	11.9 (7.7–16.2)	Ref.	11.8 (7.5–16.2)	Ref.
Employed part time	8.9 (3.2–14.5)	.52	8.6 (3.1–14.2)	.39	15.0 (3.8–26.2)	.57
Not in the labor force	9.4 (3.9–14.8)	.61	10.5 (4.2–16.8)	.72	9.6 (3.7–15.5)	.57
Unemployed	3.3 (0.2–6.4)	.02	3.4 (0.2–6.5)	.01	3.8 (0.0–7.7)	.05
Caregiver or patient activation						
Level 1 (low activation)			5.2 (0.0–11.2)	Ref.	8.9 (0.0–21.0)	Ref.
Level 2			7.1 (0.0–17.9)	.75	6.7 (0.0–17.5)	.80
Level 3			18.3 (8.4–28.2)	.06	23.9 (10.2–37.5)	.19
Level 4 (high activation)			8.6 (5.7–11.4)	.41	8.7 (5.7–11.8)	.99
Caregiver prefers to rely on doctor knowledge[b]						
Strongly disagree					20.7 (11.3–30.0)	Ref.
Moderately disagree					6.1 (0.2–12.0)	.03
Slightly disagree					25.7 (5.4–46.0)	.63
Slightly agree					9.9 (1.9–17.9)	.11
Moderately agree					4.9 (1.4–8.5)	.001
Strongly agree					4.4 (0.4–8.5)	.0041

(Continued)

TABLE 3 (Continued)

	Baseline model (socioeconomic status + number of hospitalizations)[a]		Baseline + activation		Baseline + activation + decision preference	
Characteristics	Adjusted	*p* Value	Adjusted	*p* Value	Adjusted	*p* Value
Prior hospitalizations[c]						
0	9.1 (5.9–12.2)	Ref.	8.9 (5.9–12.0)	Ref.	10.4 (6.5–14.4)	Ref.
1	6.2 (1.2–11.3)	.41	6.7 (1.2–12.2)	.53	5.0 (0.8–9.2)	.13
2	11.4 (3.3–19.4)	.56	12.7 (3.6–21.7)	.37	16.5 (3.9–29.1)	.27
3+	16.6 (7.4–25.9)	.07	21.1 (8.1–34.0)	.02	22.6 (7.5–37.7)	.04

Note: *N* = 204 for all models due to missing data from surveys and missing data for prior hospitalizations from declining to consent to medical record review.

[a] Baseline model included race/ethnicity, insurance, caregiver education, and caregiver employment. We only included variables from adjusted model with $p < 0.20$ in overall significance testing (testparm command in STATA).

[b] "I prefer to rely on my doctor's knowledge and not try to find out about my condition on my own."

[c] Prior hospitalization is defined as the number of prior hospitalizations in 2017 prior to patient study enrollment.

observation reports from FIQS did not appear in the IR system. While medical records are an alternative source of safety events, Khan et al.[47] found that 43% of parent-reported events were not identified in the medical record. There is currently no definitive source of safety events and the parent or patient observations identify events not otherwise identified in existing systems. This suggests the importance of future research to engage and activate groups who under-report.

Finally, we found that prior hospitalization was associated with higher rates of safety reporting, implying that more "experienced" patients and caregivers make more safety observations. This may reflect greater knowledge about the patient's condition (e.g., correct medications) or familiarity with hospital procedures and systems (e.g., hand hygiene and team communication). Future research could assess these potential explanations and test interventions to improve observations and reports from patients or caregivers of those hospitalized for the first time.

This study has a few notable limitations. Participants were English speakers in an academic center; our findings may not be generalizable to nonacademic center populations and our findings regarding Latinx participants should be further explored using a Spanish-language tool. The approach relies on smartphone ownership. However, data from the Pew survey show that there is wide access to and ubiquitous use of smartphones (81% of US adults surveyed in 2019 own a smartphone) across race and ethnicity (79%–82% by race and ethnicity group) and SES (71%–95% by annual income category),[53] implying that mobile phone data collection may be a generally feasible approach. Finally, this approach requires technology infrastructure that is not standard. Additional work to make the tool scalable could make it broadly accessible.

CONCLUSION

This study demonstrates the feasibility of gathering patient and family member observations of safety in the inpatient setting, using text messaging and an anonymous mobile phone reporting interface. This approach addresses some limitations of prior efforts, including ease of use, timely availability of data, patient and family member concern for potential retribution, and a potential focus on service recovery rather than systems improvements. Expert review found that over half of the observations were relevant safety concerns and 40% were potential IRs, indicating that hospital leaders and quality improvement teams should consider eliciting patient and caregiver observations as a potentially important source of patient safety data. Differences by race, ethnicity, insurance status, socioeconomic variables, activation, and preference in shared decision-making indicate that variations in reporting may need to be addressed in order to not exacerbate existing disparities in patient safety.

ACKNOWLEDGMENTS

This study was funded by the Agency for Healthcare Research and Quality (R21 HS024553) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (R01 HD100393). Dr. Sharma was supported by AHRQ (K08HS028477-01). Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the NIH under Award Number KL2TR001870. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH.

CONFLICTS OF INTEREST

The authors have reported no conflicts of interest.

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How to cite this article: Bardach NS, Stotts JR, Fiore DM, et al. Family Input for Quality and Safety (FIQS): Using mobile technology for in-hospital reporting from families and patients. *J Hosp Med*. 2022;1-10. doi:10.1002/jhm.2777