

**Title:**

Novel IT to Create Patient-Integrated Quality Improvement

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## Structured Abstract

### Purpose:

Despite national efforts to make care safer, error rates remain high. Patients and family members are a potential source of patient safety data.

### Scope:

To identify safety events observed by hospitalized patients and their family members. To assess the association between event reporting and patient characteristics.

### Methods:

We developed the Family Input to Quality and Safety (FIQS) [tool](#), a mobile-responsive website. We piloted it June 2017-April 2018 on the medical-surgical unit of a children's hospital. Participants: Family members of admitted patients, and patients  $\geq 13$  years. We texted daily during hospitalization to elicit safety reports. We reviewed reports weekly in the quality huddle. Number of reports and participant characteristics were assessed using chi-squared testing and multivariate Poisson regression.

### Results:

During pilot testing, we enrolled 235 participants (44% of 537 reviewed for eligibility). Participants made 89 safety reports over 10 months, most regarding medications and communication. Report submission varied by patient age, gender, race/ethnicity, and prior utilization.

### Conclusion:

We demonstrated feasibility and participant and staff engagement with real-time patient and family member safety reports. Additional work remains to understand differences in patient reporting and how to best incorporate these data into hospital safety improvement efforts.

### Key Words:

Patient-centered, safety, quality improvement

## Purpose (Objectives of the study)

1. Determine feasibility and acceptability of the patient data collection and clinician dashboard tool.
2. Assess whether reporting patient- and family member- observed processes of care to clinicians leads to changes in the observed processes over time.
3. To assess participant experience with using the tool, with a specific focus on the role of being an observer and reporter of safety events, as well as assessing the pros and cons of making safety reports anonymous.

## Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

More than a decade after the seminal IOM report, “To Err is Human”, failure rates in patient safety remain stubbornly high in hospitals, with estimates of up to 400,000 premature deaths due to preventable harm annually, serious harm estimated to be 10-20 fold more common than lethal harm, and adverse events occurring in one-third of hospital admissions.<sup>1-4</sup> Prior efforts to improve hospital quality have had relatively limited impact, in part due to limited access to timely quality improvement data.<sup>5-9</sup>

Patient and family or caregiver ratings are associated with patient safety indicators such as mortality, readmissions, and infection rates,<sup>10-12</sup> indicating that consumers may observe care that is related to these outcomes. Yet patients and their family members remain virtually unheard in most hospital quality improvement efforts.<sup>13,14</sup> One of the substantial barriers to gathering patient or family member observations is the lack of enabling technologies. Hence, the goal of this series of projects was to develop and test technology to facilitate collection of these observations and sharing them with hospital teams for the purpose of safety improvements.

**Setting:** The medical-surgical unit of a quaternary care children’s hospital in Northern California. Admitting teams were hospitalists and surgical specialists.

**Participants:** Family members of admitted patients and patients  $\geq 13$  years. Patients were admitted to the medical-surgical unit on any of the teams. **Exclusions:** Non-English speakers, children in the foster care system, children without a parent or legal guardian present to consent to participate.

## Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)

**Aims 1 and 2.** We developed the Family Input to Quality and Safety (FIQS) tool, a mobile-responsive website (linked [here](#) or see **Appendix** for screenshots), based on prior literature and in collaboration with the Family Advisory Council and the Hospitalist faculty. We piloted the tool June 2017-April 2018 on the medical-surgical unit of a quaternary care children’s hospital. Categories for the tool included: Medication events (e.g., timing, dose); Communication (e.g., poor patient-provider communication, team miscommunication); Equipment (e.g., equipment was broken); Unexpected event (e.g., IV blocked; test done incorrectly). **Participants:** Family members of admitted patients, and patients  $\geq 13$  years. Participants were texted daily during hospitalization to elicit safety reports. Reports were reviewed weekly during a multi-disciplinary on-unit quality huddle.

**Aims 1 and 2 Analysis:** We tested associations between number of reports and participant characteristics using chi-squared testing and multivariate Poisson regression (Aim 1). We tracked changes over time in the number of reports using SPC charts (Aim 2).

**Aim 3.** We conducted semi-structured interviews with a randomly selected sample of study participants, using stratified sampling to select 10 participants who submitted a report and 10 participants who did not submit a report.

Topics covered in the semi-structured interview:

- Overall experience of using the reporting tool
- Timing of text message
- Topics included in the reporting tool
- Whether participants would be amenable to being provided the option to make their safety reports non-anonymous, so that hospital staff could follow up with additional questions.
- The experience of having a tool for safety reporting, reporting safety events, and on the issue of anonymity in reporting

We also conducted semi-structured interviews with hospital staff and quality leadership, sampling key informants from those who had attended the multi-disciplinary rounds to review the comments.

Topics covered in these interviews included:

- Acceptability of collecting and reviewing patient and family-member reported safety events
- Topics covered in the tool
- Timing and format of comment review
- Preference for anonymity of comments vs. non-anonymity of comments

### **Aim 3 Analysis:**

We used thematic analysis to analyze the interview transcripts. This includes a content analysis, coding for themes that we anticipated would arise in the transcripts, and an analysis for themes that arise in the transcripts that we were not anticipating.

### **Limitations:**

Aims 1 and 2: We did not include monolingual Spanish speakers, which excluded 10% of our potential population, for whom safety events may differ from English speakers. Future work will support translation and testing the tool for this population.

## [Results \(Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications\)](#)

### **Aims 1 and 2.**

Usability testing: During usability testing, done prior to enrollment for the main study, participants giving feedback on the tool requested the inclusion of a positive section, to provide feedback. In response, we added a positive category “What Went Well”.

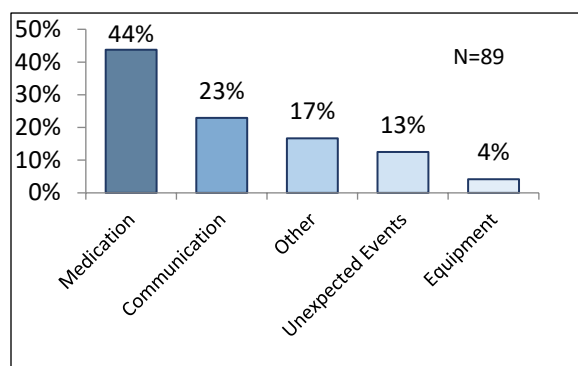
During pilot testing, we enrolled 235 participants (44% of 537 reviewed for eligibility). Participants made 89 safety reports over 10 months, with substantial proportions regarding medications and communication (**Figure 1**). Almost all participants left narrative comments,

providing rich data on safety events (see **Table 2** for representative comments). These results demonstrate almost six times higher engagement, likely due to the ease of use and the daily reminder, than a recent study using a website without mobile phone linkage (32 events over 20 months).<sup>15</sup> The number of reports submitted varied by patient age, gender, race/ethnicity, and prior utilization (**Table 1**).

In addition, participants submitted 30 positive comments under the “What Went Well” category. These positive comments were well-received by staff when reviewing all comments in the weekly huddle. The comments served to balance the safety reports with positive feedback. While many of the positive comments were more generally thank you and appreciation notes, some were actionable and provided a different perspective from some of the negative comments in a category (see **Table 2**).

In the SPC charts, the number of reports did not show special cause variation over time (**Figure 2**), likely due to a limited number of reports within any given sub-category and some weeks without any reports.

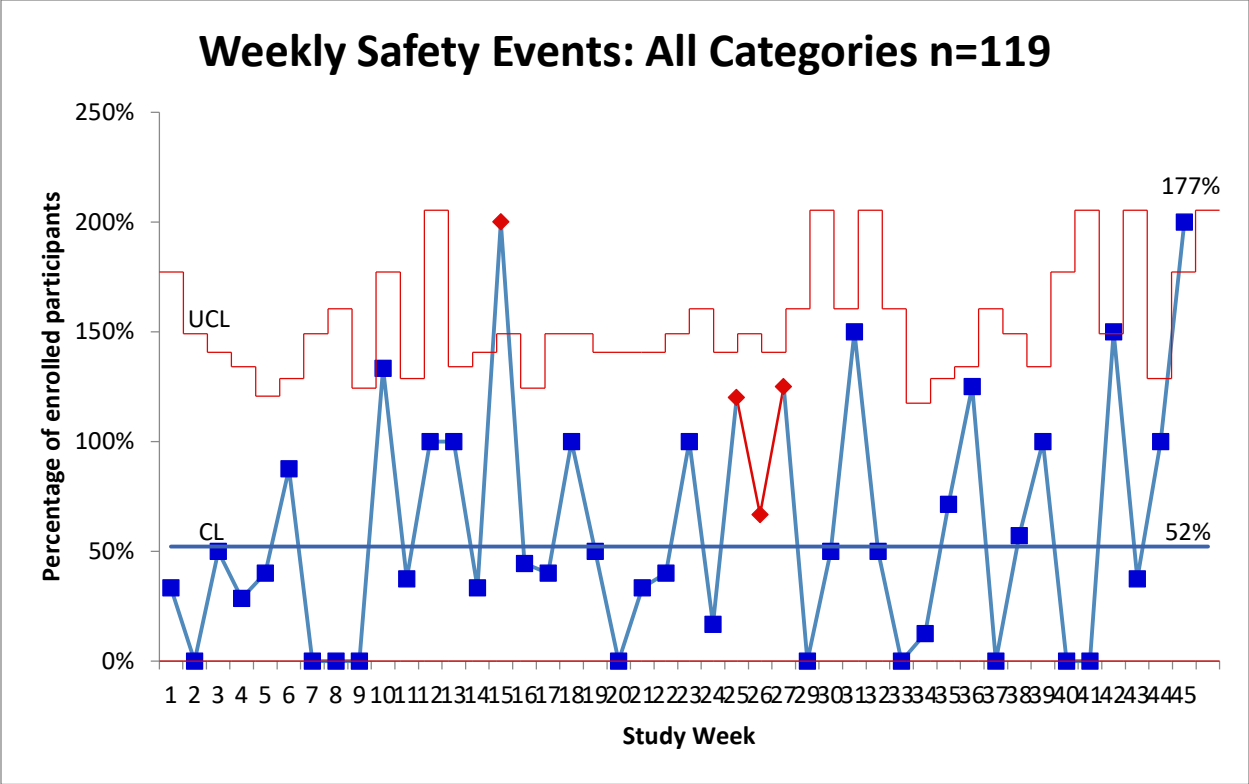
**Figure 1. Categories of Reports Made at the Point of Care by Hospitalized Patients and Family Members**



<b>Table 1. FIQS reporting by Patient Demographics (N=235 participants)</b>			
<b>Patient Demographics</b>	<b>Made a Report (n=59)*</b>	<b>Did Not Make a Report (n=176)</b>	<b>p-value</b>
Age (y), Mean (95% CI)	11.2 (9.8-12.5)	8.8 (7.9-9.7)	0.004
Female, n (%)	73 (58)	80 (45)	0.04
Race/Ethnicity, n (%)			
White	61 (48)	61 (35)	0.013
Hispanic	21 (17)	62 (35)	
African American	12 (9)	13 (7)	
Asian	26 (20)	25 (14)	
Other/Declined	7 (6)	15 (9)	
Hospitalizations in 2017, Mean (95% CI)	2.3 (1.7-3.0)	1.0 (0.8-1.3)	<0.001
Chronic Condition Status			
No chronic condition	5 (4)	17 (11)	0.13
Chronic, non-complex	18 (16)	29 (18)	
Complex chronic	91 (80)	115 (71)	

\*Some participants made more than one report

<b>Table 2. Categories and Sub-categories and Representative Quotes</b>	
<b>Event Category</b>	<b>Quotes</b>
<b>Medication</b>	
Medication given by the incorrect dose	"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. Doctor blamed pharmacy but did change the order. This is our 25th infusion here -- doctors and nurses should be able to read past orders. I should not have to or be expected to correct doctors."
I did not understand why a medication was given	No one told me or my husband that they were implementing another blood pressure medication for our son. In the middle of the night, the nurse told me that they gave our son the new medication. I had no idea what they were talking about. I didn't have time to look in to the medication in order to understand how it works/side effects it may cause and it was already in my sons system. This left me feeling very unsafe.
	Meds are being changed without my knowledge
Medication miscommunication between team members	Medication was put on hold but nurse came to give it and I had to tell her it was on hold conflicting chart notes that had to be checked
	Upon discharge the pharmacist gave instructions other than what the doctors instructions were. When I questioned this the pharmacist had to call and confirm with the doctor what the correct orders were...
	ER was notified, as well as the Med/Surg Doctor when we transitioned to the 4th floor, about my child's home medications. No orders were written resulting in a delay of 4 hours... I ended up using my own med supplies.
<b>Communication</b>	
I heard different plans about my child's treatment from different staff members	...I suggested with the social worker to call a family meeting so everyone can be on the same page. Which we did have yesterday afternoon but it still feels when there is a change no one communicates it to "new" in coming staff or staff that were not at the meeting... ...I should be able to ask questions and plan for my daughters care without unnecessary actions between the doctors and departments creating issues... ...I have spoken to other parents here with children admitted and this unfortunately is a trend ... It is horrible that patients care suffer due to having "to many cooks in the kitchen." ...I do have hope for change since this study for better care is in place. Thank you for giving me the opportunity to express my experience... (one parent for all comments in this cell)
	People keep offering my daughter juice when she is npo.
	We were told by different sources that my daughter could eat nuts. And then that she couldn't.
	IV fluids discontinued but nurse not informed
What Went Well companion comments	It is awesome to see that members of the care team are on the same sheet of paper. There appears to be no confusion as a parent. ...Excellent communication...everyone has the same game plan. I also would like to acknowledge that my son is also included in the conversations that take place. As the parent i feel confident in the care my son is receiving. (same parent as above)



**Aim 3.** We are analyzing transcripts from our interviews with patients. Our preliminary results from initial analyses found that while participants preferred default anonymous reporting, there was a general comfort with allowing participants to opt for individual report to be identified. One participant recommended that if a participant chose to identify themselves in a report that it would be important to provide follow-up even if their problem could not be addressed immediately. Overall, the participant response to the tool was positive in the interviews, with all participants endorsing continuing using the tool to collect data.

**Discussion:**

We demonstrated feasibility and participant engagement with real-time patient and family member technology-enabled safety reports. Variations in reporting by patient characteristics may reflect differences in the rate of patient safety events, differences in recognition of events, differences in capacity to use the reporting tool, or differences in comfort with reporting. Additional work remains to better understand these different populations and to incorporate these data into hospital safety improvement efforts.

Specific next steps include the following: translate the tool into Spanish in order to collect data from monolingual Spanish speakers; allow participants to submit a report and opt to make it non-anonymous if they are open to being approached by a staff member for follow-up; test the tool in other contexts; develop best practices regarding how to incorporate patient and family-member safety reports into hospital safety efforts.

**Conclusions:** Patient Safety reporting from hospitalized patients and their family members is feasible and well accepted. It may provide a promising new strategy to reveal gaps in inpatient quality and safety.

List of Publications and Products (Bibliography of Outputs) from the study. Follow the AHRQ Citation Style Format at <https://www.ahrq.gov/funding/grant-mgmt/refstyle.html>.

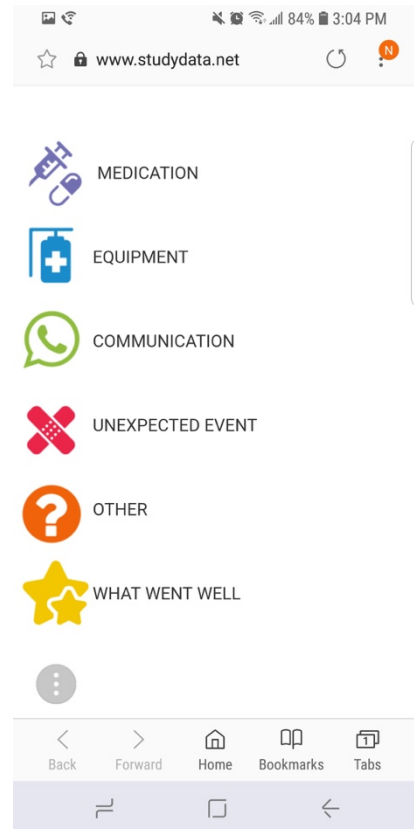
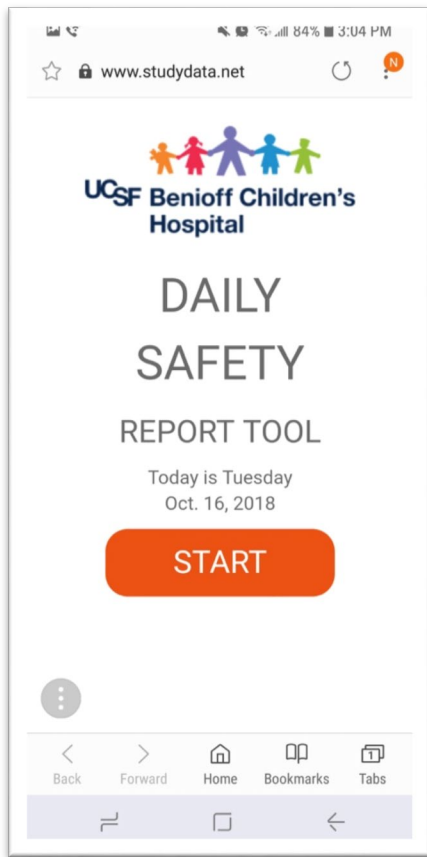
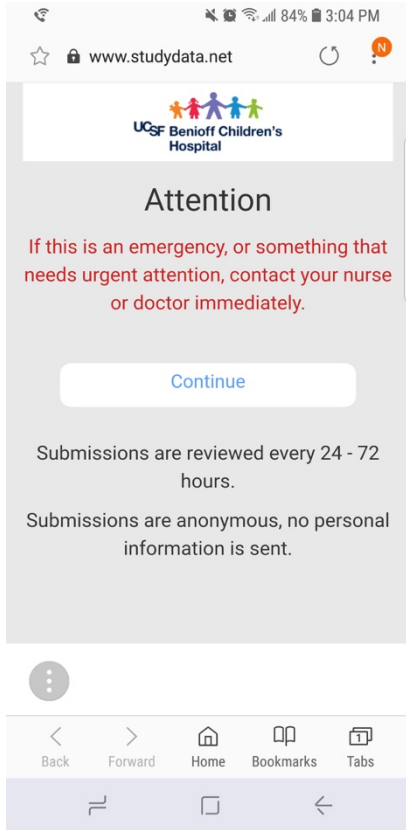
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2. **Bardach NS**, Fiore D, Sharma A, Sarkar U, Rosenbluth G. *From the Closest Observers of Care: Point of Care Inpatient Safety Reporting from Families and Patients*. Submitted as an abstract to the Pediatric Academic Societies Meeting, Baltimore MD, 2019. Under review.
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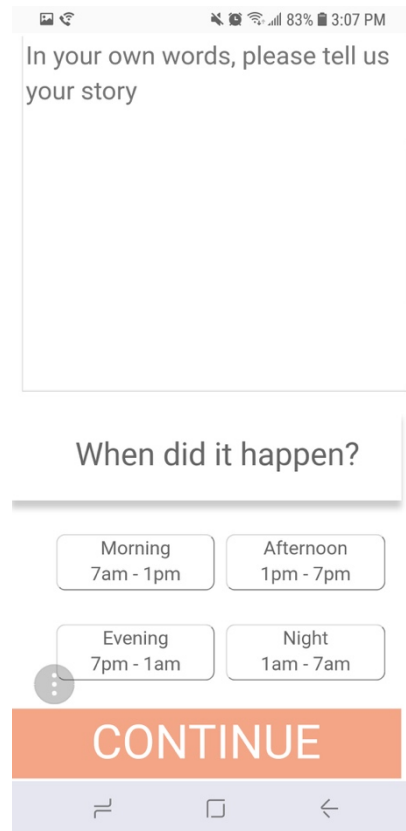
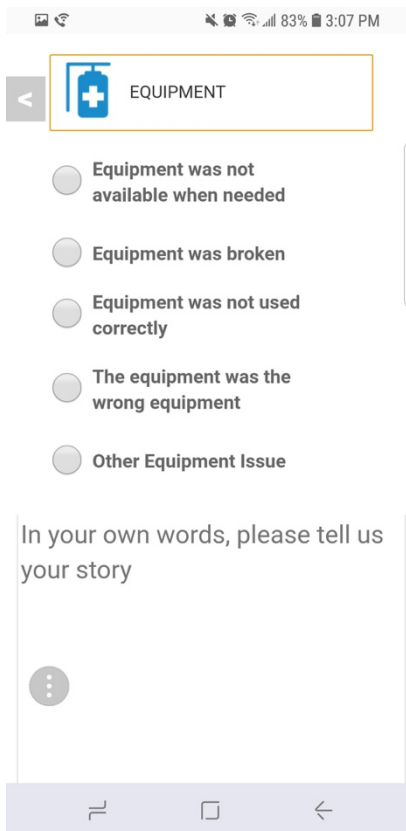
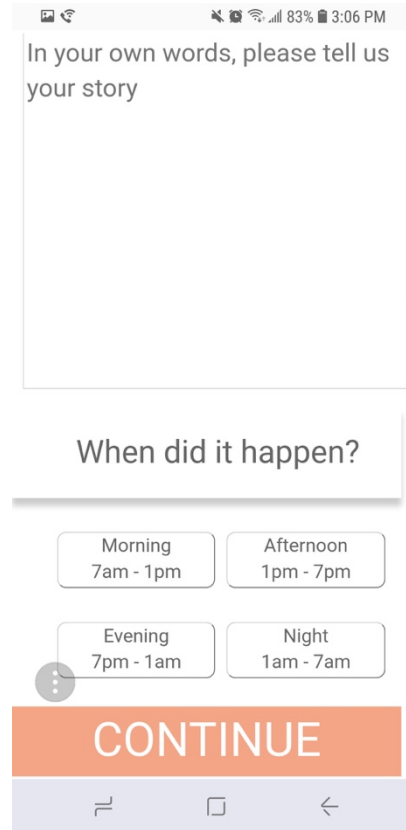
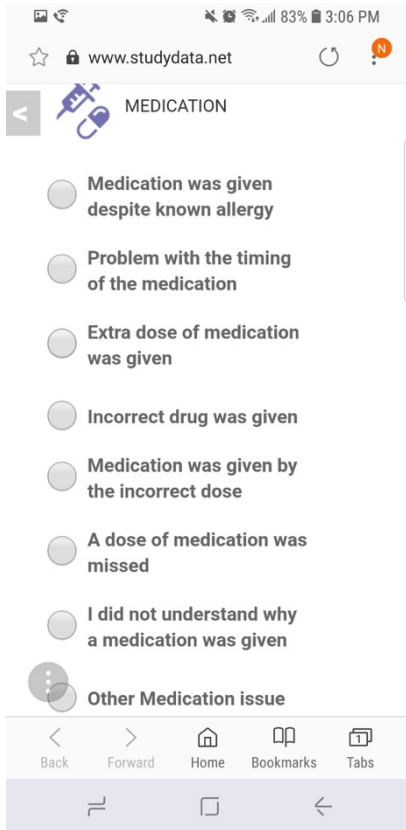


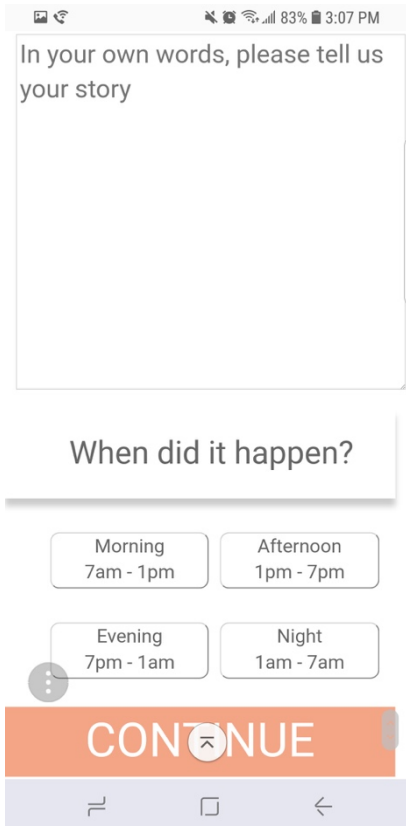
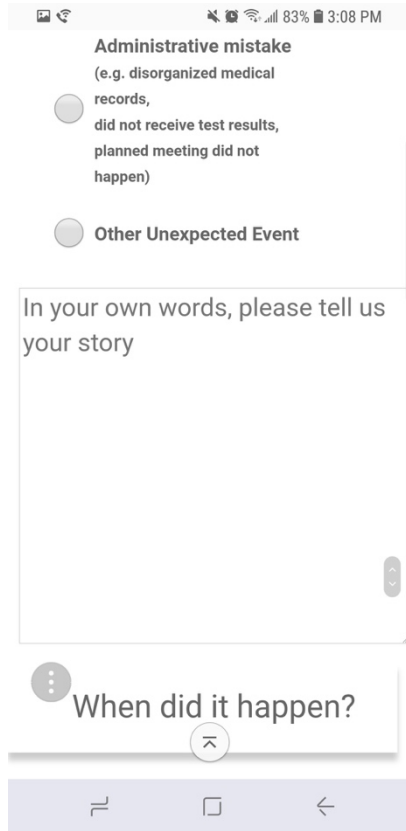
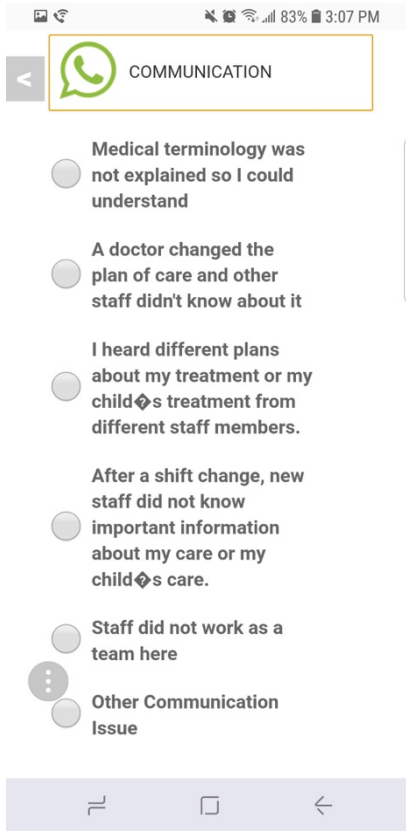
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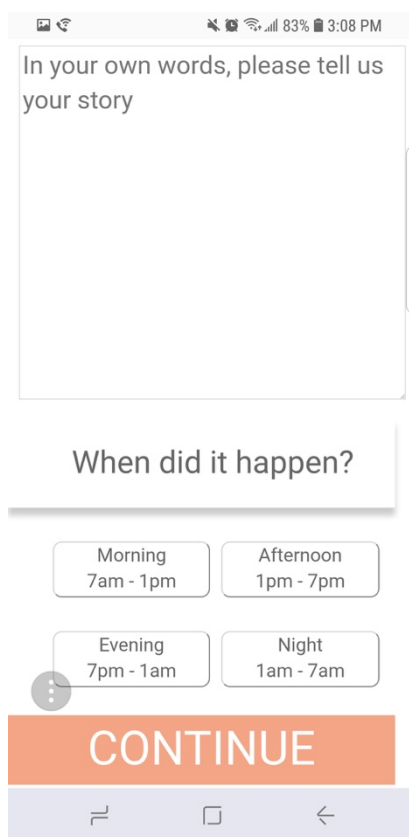
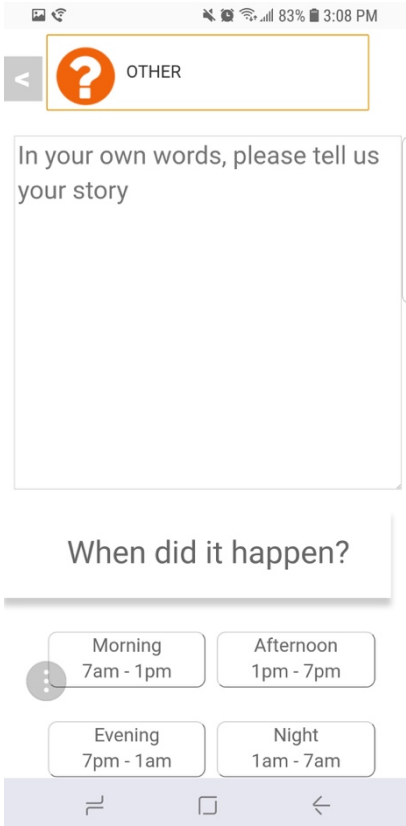
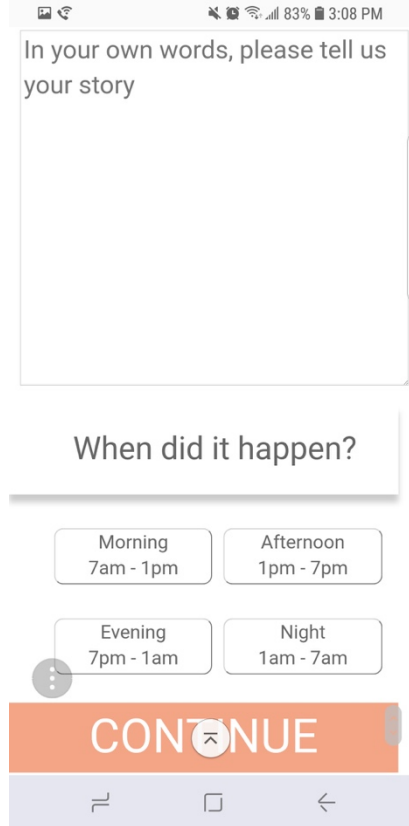
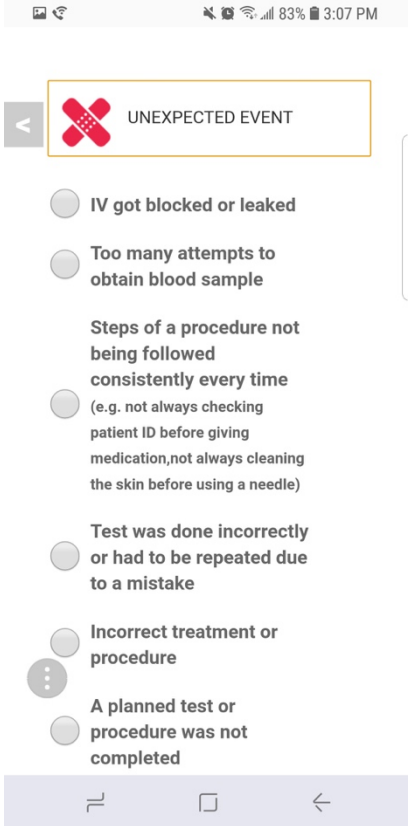
**Appendix.** Screen Shots of the Family Input for Quality and Safety (FIQS) mobile responsive website

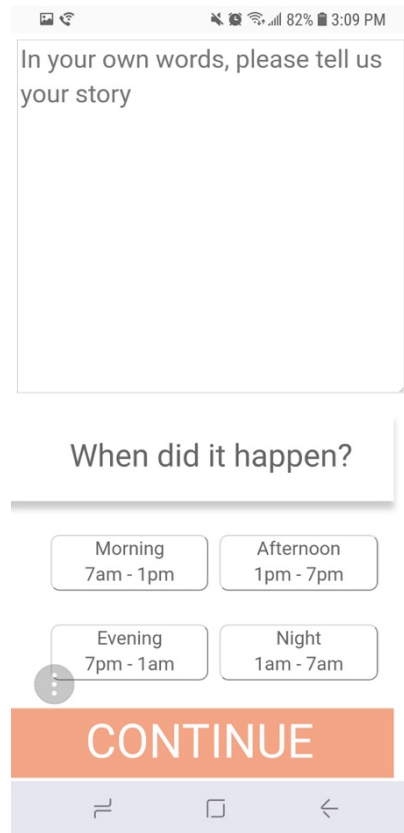
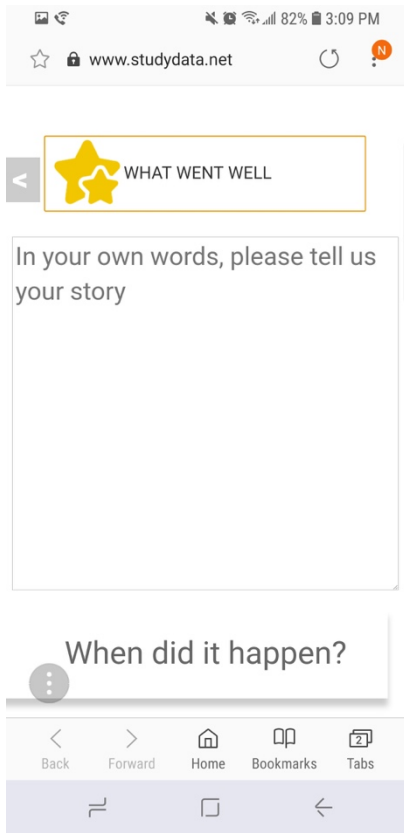






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