Protocol Title

Family Activation and Communication about Errors and Safety (FACES) Study

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1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Family Activation and Communication about Errors and Safety (FACES) Study
Study Description:	Miscommunications are a leading cause of serious medical errors in hospitals, contributing to more than 60% of sentinel events, the most serious adverse events (AEs) reported to the Joint Commission. Efforts to improve patient safety in hospitals have centered on improving communication between providers. While provider-focused communication interventions have led to reductions in patient harm, patients and families have been notably absent from most interventions to improve patient safety. This proposal seeks to develop and investigate the effectiveness of a family safety engagement intervention aimed at reducing harm in hospitalized children, especially children with medically complex conditions. Families have the potential to serve as partners in safety surveillance and prevention, particularly in pediatrics. Research about the role of patients and families in safety efforts is limited, particularly regarding the effectiveness of intervention strategies to engage patients and families as partners in safety, and the effect of such interventions on patient safety and family experience.
Objectives:	1. Explore, using qualitative methods, parent, provider, and hospital leader perceptions of barriers to and facilitators of family engagement in hospital safety reporting in order to inform development of FACES 2. Develop and evaluate FACES using multiple methodologies: - Develop a feasible and acceptable version of FACES, informed by qualitative methods, communication science, and organizational behavior - Pilot FACES with a small group of parents to evaluate rates of reporting and experience (using quantitative survey data) in order to develop a final version of FACES
Endpoints:	A final FACES intervention to further test in an R01
Study Population:	English- and Spanish-speaking parents of hospitalized children with medical complexity (CMC)
Phase or Stage:	N/A
Description of Sites/Facilities Enrolling Participants:	This study will be conducted at a quaternary academic center with a dedicated, multi-unit, non-geographic complex care service.
Description of Study Intervention:	The FACES intervention will consist of (1) a family safety reporting tool for routine operational use, adapted from reporting tools used in research,

	supplemented with (2) family activation strategies and education about safety, and (3) provider training about family engagement in safety
Study Duration:	4 years
Participant Duration:	Duration of inpatient hospitalization

2 INTRODUCTION

2.1 STUDY RATIONALE

The "Family Activation and Communication about Errors and Safety (FACES)" intervention aim to engage families of children with medical complexity (CMC) in real-time hospital safety reporting. FACES will be informed by qualitative methods, communication science, and organizational behavior principles. FACES will operationalize family safety reporting in a pediatric hospital setting among CMC, which has not been done previously. It will uniquely draw on patient and family activation principles, which are not widely applied to or studied in hospital safety.

2.2 BACKGROUND

Recent studies suggest that as many as 250,000 US patients may die annually from medical errors.[1] There is growing interest in the role that patients and families play in identifying medical errors and adverse events (AEs, or harms due to medical care).[2–6] Patients and families can serve as "vigilant partners"[7] in safety, given their intimate knowledge of patients' histories, motivation for a good outcome, availability, and proximity.[8] This may be particularly true in pediatrics and for families of children with medical complexity (CMC), an AHRQ priority population. CMC are children with complex chronic conditions (CCCs, an ICD-9–based marker of medical complexity)[9] affecting multiple organ systems and severe functional limitations who require multiple medications and medical equipment to optimize health.[10] Hospitalized CMC are particularly prone to errors due to increased length of stay, number of medications, and providers' cognitive load.[11–15]

Several studies suggest that patients and families identify medical errors and AEs otherwise undocumented in the medical record.[3,5,6,16] Most hospitals, however, do not actively solicit patient or family reports about errors and AEs. Instead, most voluntary hospital incident-reporting systems, which capture a small percentage of safety incidents,[17–19] include only providers. However, providers recognize and report fewer than 1 in 7 errors and harms that are detected on systematic surveillance.[20]

Patients and families appear interested in engaging in safety efforts[21–23] and providers appear to support their involvement.[21,22,24,25] However, interpersonal, cultural, and other barriers interfere with patient activation and involvement in reporting.[26] These include failure to recognize a safety event or its severity, patient characteristics (e.g., medical complexity), parent characteristics (e.g., education, health literacy), cues to action (e.g., providers effectively activating families about safety), and perceived reporting benefits vs. barriers (**Figure 2,** adapted from the Health Belief Model[27]).

Additionally, parents are often unaware of how to report hospital safety concerns. In a 69-hospital field test of the Child Hospital Consumer Assessment of Healthcare Providers and Systems (Child HCAHPS) survey,[28] parents' lowest-rated measure of hospital experience was whether the hospital took steps to prevent mistakes and told parents how to report concerns, with an average "top-box" score of only 55%.[29]

Efforts to incorporate patients and families in hospital safety are increasing.[30–32] However, family engagement in safety reporting has not yet been operationalized in hospital settings. In a recent report, AHRQ described a recent 2-hospital pilot of a voluntary phone and online reporting system for patients and caregivers, the Health Care

Safety Hotline.[33] This pilot found that a centralized system for reporting safety events was feasible, with patients and their families providing useful, often otherwise undetected information. However, the system suffered from low reporting rates (only 37 safety reports from 91,325 admissions, or 0.04% of admissions).[34] These numbers are dramatically lower than those documented in other studies, which find medical errors in 25–50% of hospital admissions.[35,36] The report suggests several strategies to enhance reporting rates, such as incorporating safety screening questions into patient experience surveys.[33]

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 Known Potential Risks

The main risk for this study is the potential loss of confidentiality. Because this study intends to track reporting of medical errors, participation does pose possible, though highly unlikely, confidentiality and legal risks. Reports of adverse events in relation to the intervention will be forwarded to the principal investigator and then, as standard practice dictates, to the IRB. In addition, if we discover any serious errors in evolution that pose a risk to the patient, of which the clinical team is not already aware, we will address these directly with the clinical team, including the attending physician. In such cases, we will follow hospital guidelines for error reporting. In these rare instances, there is some risk to the confidentiality of study participants. However, any such issues will be preferentially addressed directly with the immediate care team, with involvement of supervisors and more senior personnel only where necessary in order to ensure patient safety.

2.3.2 Known Potential Benefits

The proposed research project may not pose direct benefits to participants. However, information gathered during the study may help activate families to engage in safety reporting. Hospital staff and parents may learn useful strategies for family activation and optimizing involvement of families in hospital safety efforts. The societal benefits from information gained through the proposed project are potentially large. Provider, parent, and hospital system barriers to and facilitators of family engagement in safety reporting may be better understood. More may be learned about the frequency and types of errors experienced by hospitalized pediatric patients. If successful, the project could produce a feasible and operational family safety reporting mechanism with the potential to inform structural integration of family voices into hospital error surveillance more widely. Ultimately, the project could inform efforts to prevent medical error and harm. Given what is already known about the frequency of medical errors and harm in hospitals, the potential benefits of this research outweigh its possible risks.

2.3.3 Assessment of Potential Risks and Benefits

Given the precautions that will be taken to protect study data and maintain participant confidentiality, the risk of a confidentiality breach is unlikely. If evidence of a serious medical error in evolution of which the team is not already aware becomes known, this information will be communicated to the attending physician of the medical team, who will then take action at his/her discretion. Prior research has demonstrated that even in direct observation, it is rare to find harmful errors in evolution that pose a clinical risk to the patient and of which the clinical team is not already aware. The research assistant will be trained such that, in cases where they feel there is an emergent need to intervene, they will immediately contact responsible clinical staff. In cases that are less time-emergent, they will contact the study Principal Investigator and discuss the case

before deciding how best to proceed. However, regardless of these safeguards, participants will always be participant to hospital protocols regarding error reports, and there is a slight risk that, in the event of legal action, a court could compel us to release the information. Of note, AHRQ has a Certificate of Confidentiality that provides additional privacy benefits.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
Develop a family safety reporting intervention.	*Creation of a feasible and acceptable family safety reporting intervention.*	*Developing an operational intervention for family safety reporting that is feasible and acceptable to both families and staff will help hospitals identify otherwise unrecognized and patient/family prioritized areas of safety and quality improvement.*
Secondary		

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Increasing family safety reporting in hospitals.	*Rates of family safety reporting pre versus post intervention.*	*Currently, families informally share safety and quality concerns frequently with their providers which leads to variable and often local improvement. However, formal mechanisms for families to proactively share are limited, which limited the ability of hospitals to hear from families in a systematic matter, address concerns globally, and improve safety and quality. We seek to understand whether creation of a feasible and acceptable family safety reporting intervention increases formal reporting from families in a systematically captured matter that the hospital can use for improvement.*
Tertiary/Exploratory		

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Increasing family safety reporting in hospitals by families who might not otherwise report.	*Rates of family safety reporting pre versus post intervention among families with lower educational attainment.*	*Families who have lower educational attainment have 2-5 lower odds of sharing safety concerns. Given our intervention is informed by health literacy, qualitative methods, and communication science, we hypothesize that families with lower educational attainment may be more likely to report than otherwise after intervention implementation.*

4 STUDY DESIGN

4.1 OVERALL DESIGN

Prospective cohort pre-post intervention study

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

A parent-nurse-physician-hospital leader team will coproduce the FACES intervention. FACES involves (1) an English/Spanish mobile (email/text/QR) family-safety-reporting tool ("Comment Card," CC) with regular reminders, (2) staff/family education, and (3) a process for reviewing/sharing comments regularly with unit/hospital leaders. Pre- and post-intervention, we will survey families pre-discharge about safety concerns. Post-intervention only, families will also be prompted to complete the FACES CC, which includes examples of events with definitions. FACES is informed by qualitative interviews, health literacy, communication science, and organizational behavior.

4.3 JUSTIFICATION FOR INTERVENTION

Miscommunications are a leading cause of serious medical errors in hospitals, contributing to more than 60% of sentinel events, the most serious adverse events (AEs) reported to the Joint Commission. Efforts to improve patient safety in hospitals have centered on improving communication between providers. While provider-focused communication interventions have led to reductions in patient harm, patients and families have been notably absent from most interventions to improve patient safety. This study seeks to develop and investigate the effectiveness of a family safety reporting intervention aimed at reducing harm in hospitalized children, especially children with medically complex conditions. Families have the potential to serve as partners in safety surveillance and prevention, particularly in pediatrics. Research about the role of patients and families in safety efforts is limited, particularly regarding the effectiveness of intervention strategies to engage patients and families as partners in safety, and the effect of such interventions on patient safety and family experience.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed study surveys and been discharged from inpatient care.

5 STUDY POPULATION

We will recruit parents (i.e., primary caregivers), physicians, nurses, and hospital leaders of CMC hospitalized on the complex care service of the study center. CMC will be defined as children under the age of 18 and with greater than or equal to 3 complex chronic conditions, along with neurologic impairment or technology dependence. We will use purposeful sampling criteria to include parents from varied racial/ethnic, cultural, and socioeconomic backgrounds. As we found differences in family reporting by education in prior research,[37] we will ensure half our parent participants have ≤high school education. This sampling will help us develop a culturally relevant intervention informed by diverse perspectives. We will include hospital leaders in medical/nursing, safety/ quality, patient advocacy, and legal roles; resident and attending physicians; and bedside and charge nurses.

5.1 INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Admitted on a study-affiliated unit
2. English- and/or Spanish-speaking

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. In Department of Children and Families (DCF) custody
2. International patient
3. Boarding for psychiatric placement
4. Will be discharged from hospital directly to a residential care facility

5.3 Inclusion of Vulnerable Participants

N/A

5.4 Inclusion of Pregnant Women, fetuses or neonates

N/A

5.5 Lifestyle Considerations

N/A

5.6 Screen Failures

Screen failures are defined as participants who consent to participate in this study but do not subsequently receive the study intervention or participate in the study. Individuals who do not meet the criteria for participation in this trial (screen failure) because of meeting one or more exclusion criteria that are likely to change over time may be rescreened.

5.7 Strategies for Recruitment and Retention

We will recruit parents and staff (including physicians, nurses, medical students, nursing students, other support staff) of patients hospitalized in pediatric units as well as hospital leaders. Eligible parents will be domestic/non-international primary caregivers of children who are hospitalized during the study period. English- and Spanish-speaking parents will be eligible. All physicians, nurses, students, and support staff employed on the study units will be eligible to participate. We will also recruit hospital leaders in medical, nursing, safety, quality, patient advocacy, and legal roles. We will include parents from varied racial/ethnic and socioeconomic backgrounds to ensure diverse perspectives. Since we found differences in parent error-reporting by education in prior studies,[37] we will purposefully sample parent participants to ensure that half have lower levels of education (e.g., high school or less). We will also include parents from varied racial/ethnic and socioeconomic backgrounds to ensure diverse perspectives. Patient medical records will be reviewed for screening purposes (only the minimum amount of information required to confirm eligibility or lack thereof will be reviewed) and screen-positive families will be approached by study staff on the hospital unit. If families are not present on the unit (we are told by providers that families are often not present for a majority of the hospitalization), we will call, email, and/or teleconference (e.g., via Zoom) the screen-positive families to recruit, consent, and administer surveys (if the family consents), or to determine an interested family's preferred time of future contact. Once approached, study staff will actively collect email addresses and mailing addresses (or verify previously entered emails and mailing addresses from the medical record) for consenting, interview scheduling, survey administration, and renumeration delivery purposes. For eligible providers and staff, study staff will make the first contact by email or in-person to gauge interest in participation and consent participants. Interviewees may be asked to participate as key informants in more than one cycle of qualitative interviews. We may use hospital interpreters or Spanish-speaking staff to recruit, consent, and conduct interviews with eligible Spanish-speaking families; the staff will be trained in our qualitative interview guide. Participants will be made aware that they are free to discontinue participation in the study at any time and that the investigators reserve the right to discontinue the protocol at any time. We will meet and/or email with each potential participant, acquaint him or her with the study procedures, and obtain informed consent (through method other than written consent, i.e., verbal, email, or survey completion-based consent) for study enrollment.

5.7.1 Costs

N/A

5.7.2 Compensation

Parent and staff participants will rceive a $25 gift card after completing a one-one-one qualitative interview. Parents will receive small snacks or gift cards (e.g., $5) for completing surveys. Staff participants will receive either a small snack/meal (e.g., pizza lunch) or receive a $5 gift card for completing surveys. Tokens will be given in-person, distributed via email (e-gift card), or mailed if a parent participates but is unable to receive tokens in-person (e.g., participates via phone or Zoom and will not be visiting hospital prior to their child's discharge, or staff unable to deliver token in-person due to COVID-19 policies).

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTIONS(S) OR EXPERIMENTAL MANIPULATIONS(S) ADMINISTRATION

6.1.1 Study Intervention and Data Collection Description

In partnership with families, nurses, physicians, and hospital leaders, we will design a safety-reporting intervention for families of hospitalized CMC to share safety concerns, comments, and suggestions.

Pre- and post-intervention, we will survey families before they are discharged from the hospital about safety concerns. Our survey, which is based on prior research[2,37,38] will provide examples of mistakes and safety issues (e.g., medication problems, equipment problems, communication problems, diagnostic mistakes). It will ask families to share whether their illness got worse because of medical care or something wasn't done that should have been, a mistake that didn't cause harm occured, a "good catch" occurred, their concerns not heard, or anything else upsetting or potentially harmful occured. Parents will also complete questions about safety climate (from the Children's Hospital Safety Climate Questionnaire measure[39]) and whether the hospital told them how to report safety concerns (from the Child HCAHPS measure[28]). They will also be assessed for level of health literacy (via the Newest Vital Sign[40]), parent patient-activation (via P-PAM[41]), language proficiency (via US Census questions), and demographics (e.g., self-reported race and ethnicity, education).

Post-intervention only, families will also be prompted to complete the FACES comment card, which will include examples of events with definitions. Parents will be told to report concerns both via comment card and survey.

Surveys, comment cards, and intervention materials will be professionally translated into Spanish and reviewed by a bilingual team member. Spanish responses will be translated professionally post-hoc (for surveys) and by hospital interpreter services within 24 business-hours (for comment cards).

6.1.2 Administration

For our study's QI intervention, which will be iteratively refined using Plan-Study-Do-Acts aligned with QI principles, we are designing and implementing a mobile reporting safety application based on piloting with parents and continuous feedback from our intervention development working group. The intervention will involve a family brochure, a family safety comment card (via paper, email, SMS, or QR code), and staff education. The family safety comment card will be available on paper and electronically (the latter is housed in REDCap), both of which we will pilot and iteratively refine based on stakeholder feedback. Our REDCap link will make use of Twilio, a SMS-based communication platform to facilitate patient-facing communication. The SMS link will be used to provide a secure REDCap link via text. No safety reports will be transmitted to Twilio as it is merely serving as a tool for our institution's REDCap platform to effectively text a secure REDCap link to enrolled participants. The REDCap link to the family safety comment card will be available via email, SMS, or QR code. Before we email or text the families the comment card, we will ask their permission to do so. A secure REDCap link to the comment card will be sent to them periodically during their admission via email or SMS. We will pilot the various components of the intervention, which is QI itself, with parents and staff and iteratively refine it accordingly in accordance with QI principles. In order to recruit families for the study, the research assistant will approach them after admission and provide them the info sheet and family brochure with enclosed safety comment card. The research assistant or investigator will obtain permission from the family to email or text them a secure REDCap link to the safety comment card periodically during admission. If they do not wish to receive email and text links to the comment card, they can still voluntarily complete the safety comment card via paper or QR code. The research assistant will also approach the family prior to or after discharge to administer the family survey.

6.2 FIDELITY

6.2.1 Interventionist Training and Tracking

Study staff will be trained by the PI and other study staff regarding intervention implementation and will be observed until they are capable of independently implementing the intervention.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

N/A

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

N/A

6.5 CONCOMITANT THERAPY

N/A

6.5.1 Rescue Therapy

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

N/A

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue a participant from the study for the following reasons:

- Significant study intervention non-compliance, unless varying compliance is an aspect of the study objectives
- Lost-to-follow up; unable to contact participant (see **Section 7.3, Lost to Follow-Up**)
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation
- Screen failure
- Participant has completed the study follow-up period

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if he or she fails to complete the study (e.g., surveys) and is unable to be contacted by the study site staff. The research assistant will attempt to contact the participant in person or by phone (if not present at bedside) to administer the missed study activities and ascertain if the participant wishes to and/or should continue in the study.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 SCREENING PROCEDURES

8.1.1 Screening activities performed prior to obtaining informed consent

Minimal risk activities that may be performed before the participant has signed a consent include the following:

- Email, written, in person or telephone communications with prospective participants
- Review of existing medical records

8.1.2 Screening activities performed after a consent for screening has been signed

N/A

8.2 STUDY EVALUATIONS & PROCEDURES

8.2.1 Biospecimen Evaluations

N/A

8.2.2 Samples for Genetic/Genomic Analysis

N/A

8.3 SAFETY ASSESSMENTS

Our study focuses on patient safety in hospitals overall. We do not expect our intervention itself to be associated with any safety events. Thus, while we will obtain family-reported safety events, these events relate to their hospitalization, not the intervention or study procedures themselves.

8.4 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.4.1 Definition of Adverse Event

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

8.4.2 Definition of Serious Adverse Events (SAE)

An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

8.4.3 Classification of an Adverse Event

8.4.3.1 Severity of Event

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".]

8.4.3.2 Relationship to Study Intervention/Experimental Manipulation

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately trained clinician based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

Related – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study

procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.

Not Related – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

OR

Definitely Related – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study procedures administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study procedures should be clinically plausible. The event must be pharmacologically or phenomenologically definitive.

Probably Related – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the study procedures, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal.

Potentially Related – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of study procedures). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related", as appropriate.

Unlikely to be related – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study procedures administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study procedures) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).

Not Related – The AE is completely independent of study procedures administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.

Of note, the FACES intervention itself and study procedures, which involve surveys and interviews, are very low-risk and unlikely to lead to or be related to any adverse events.

8.4.3.3 Expectedness

A clinician with appropriate expertise in hospital medicine will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

8.4.4 Time Period and Frequency for Event Assessment and Follow-Up

Safety concerns obtained from the comment card will undergo real-time and biweekly review by a multidisciplinary team consisting of at least one each parent, nurse, physician, and research assistant. They will review patient charts for further information, brainstorm ensuing QI projects, and notify clinical staff if patient care is believed to be at risk. All safety concerns (from survey and comment card) will also undergo post-hoc review by 3 trained physicians with patient safety expertise after they first separate and consolidate comments into unique concerns. Next, they will review and classify concerns based on prior research.[2,37,38] They will assess each event's clinical category (e.g., diagnosis), safety category (e.g., nonpreventable adverse events, harmful errors, nonharmful errors, hazards, non-safety-related quality issues, or neither, NCC MERP[3] classification, and whether the concern was communication-related.

8.4.5 Adverse Event Reporting

Adverse events detected by the FACES study will be reported to the primary care team. Of note, events found as part of the primary outcome of the study are not related and/or caused by the intervention.

8.4.6 Serious Adverse Event Reporting

N/A

8.4.7 Events of Special Interest

N/A

8.4.8 Reporting of Pregnancy

N/A

8.5 UNANTICIPATED PROBLEMS

8.5.1 Definition of Unanticipated Problems (UP)

Any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied; and
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others (which many include research staff, family members or other individuals not directly participating in the research) at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or expected.

8.5.2 Unanticipated Problem Reporting

The investigator will report unanticipated problems (UPs) to the Boston Children's Hospital IRB.

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESIS

- Primary Endpoint: We hypothesize that rates of family safety reporting will increase post-intervention.
- Secondary Endpoint(s): We hypothesize that rates of family safety will increase post-intervention among families with lower educational attainment.

9.2 SAMPLE SIZE DETERMINATION

We will recruit a minimum of 77 parents of CMC to participate in this pilot and complete questionnaires about their experience using FACES. With a sample size of 77, we anticipate >80% power to detect an increase in reporting from 0.04% at baseline to 10% post-implementation, assuming a 2-sided α error of 0.05. This number of parents should be feasible to obtain, given the patient census and prior study participation rates in this unit (>80%).

For qualitative interviews, we will collect data until we reach thematic saturation, which we expect to reach at around 20 interviews. We anticipate this will involve interviewing 8 parents, 4 physicians, 4 nurses, and 4 hospital leaders (as themes may overlap among physicians, nurses, and hospital leaders). We chose these numbers to ensure diversity of opinions and multiple perspectives from all stakeholders in the family safety reporting process. However, we will adjust our sample size and interview more or fewer participants as needed.

9.3 POPULATIONS FOR ANALYSES

All participants (both staff and families/caregivers of CMC) who consented to enroll in the study and contributed data via surveys, comment card, or interviews.

9.4 STATISTICAL ANALYSES

9.4.1 General Approach

Our primary outcome is family-reported safety concerns, which we define as reporting a safety concern via pre-discharge survey (pre- and post-intervention) or FACES comment card (post-intervention). Safety concerns will be counted once if reported both via survey and comment card. Secondary outcomes include safety experience (Child HCAHPS measure) and safety climate scores.

Patient/family characteristics and study outcomes will be descriptively summarized using means (SD) for continuous variables and proportions for categorical variables. Comparisons of characteristics according to pre- vs post-intervention group will use Chi-square tests for categorical variables. The Shapiro-Wilk test will test normality for continuous variables. T-tests will be used for normally distributed continuous variables and Wilcoxon Rank-Sum Tests for nonparametric continuous variables.

We will use generalized estimating equation (GEE) models to examine association between safety concerns and intervention-period, adjusting for patient/family characteristics that vary pre/post-intervention and within-patient clustering. We will also conducted subgroup analyses by education and cases (pre- and post-intervention) occurring during the COVID-19 pandemic (7/2020 onwards), hypothesizing that reporting may have changed with the pandemic. We will also examine top-box (top-most, e.g., 5 of 5 or excellent, Likert scale) safety climate scores pre- vs

post-intervention and proportion of parents reporting "yes definitely"/"yes somewhat" vs "no" to the Child HCAHPS "tell you how to report" question.[42] A two-sided p-value <.05 will considered statistically significant.

We will also examine hospital voluntary incident reporting to determine the percent of events reported via FACES comment card also captured in voluntary incident reporting.

We will use REDCap (Vanderbilt) for study management and SAS v.9.0 (Cary, NC) for analyses.

9.4.2 Analysis of the Primary Endpoints

Our primary outcome is family-reported safety concerns, which we define as reporting a safety concern via pre-discharge survey (pre- and post-intervention) or FACES comment card (post-intervention). Safety concerns will be counted once if reported both via survey and comment card. Secondary outcomes include safety experience (Child HCAHPS measure) and safety climate scores. These endpoints will be analyzed as described above

9.4.3 Analysis of the Secondary Endpoint(s)

Secondary outcomes include safety experience (Child HCAHPS measure) and safety climate scores and will be analyzed as described above.

9.4.4 Safety Analyses

N/A

9.4.5 Baseline Descriptive Statistics

Baseline descriptive statistics will be collected and analyzed during the pre-intervention study period.

9.4.6 Planned Interim Analyses

Interim analyses will include (1) a study of baseline (pre-intervention) and (2) a study of qualitative interviews results. The first will access rates of safety reporting and safety events in patients enrolled in the pre-intervention arm of the study. The second will access qualitative data from multiple study stakeholders including but not limited to: parents, physicians, nurses, and hospital leaders.

9.4.7 Sub-Group Analyses

We expect to analyze data by subgroups including those with lower education (less than college degree) and those that speak a language other than English (Spanish-speaking participants).

9.4.8 Tabulation of individual Participant Data

N/A

9.4.9 Exploratory Analyses

N/A

10 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1 INFORMED CONSENT PROCESS

10.1.1 Consent/Assent Procedures and Documentation

Families interested in participating will provide verbal consent for enrollment and this will be documented. Upon approaching families, study staff will verify that the email addresses and phone numbers already collected by the hospital in the medical record are accurate. If an email address or phone number is not listed in the medical record, study staff will ask families if they are willing to provide their email address and phone numbers. These email addresses and phone numbers will be used for interview scheduling, survey administration, consenting purposes (for the instances in which parents are not at bedside), and mobile reporting tool participation. If parents choose not to or are unable to provide an email address or phone number, the research team will respect such a situation and reiterate the other available ways the parent can still participate in the study should they choose to. Families will receive information about our study as part of their admission packet.

10.1.2 Consent for minors when they reach the age of majority

N/A

10.1.3 Considerations for Consent of AHRQ staff, or family members of study team members

N/A

10.1.4 Consent of Participants who are, or become, decisionally impaired

Adults unable to provide consent are excluded from enrolling in the protocol. However, it is possible that participants enrolled in the protocol may permanently lose the capacity to consent for themselves during the course of this study. In the event this occurs, the participants will be withdrawn from the study.

10.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance of study staff to the protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

10.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor or funding agency, representatives of the Institutional Review Board (IRB), regulatory agencies or representatives from companies or organizations supplying the product, may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at Boston Children's Hospital (BCH). This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by BCH research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at BCH.

10.3.1 Measures Taken to Ensure Confidentiality of Data Shared per the AHRQ Data Sharing Policies

The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

10.3.2 Certificate of Confidentiality

To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human participants research funded wholly or in part by the federal government for AHRQ-funded research. Recipients of AHRQ funding for human participants research are required to protect identifiable research information from forced disclosure per the terms of the AHRQ Policy. As set forth in 45 CFR Part 75.303(a), recipients conducting AHRQ-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the protocol is managed in compliance with Federal statutes, and regulations.

10.4 FUTURE USE OF STORED SPECIMENS AND DATA

N/A

10.5 SAFETY OVERSIGHT

N/A

10.6 CLINICAL MONITORING

N/A

10.7 QUALITY ASSURANCE AND QUALITY CONTROL

Each clinical site will perform internal quality management of study conduct, data collection, documentation and completion. All sites will follow a common quality management plan.

Quality control (QC) procedures will be implemented as follows:

Informed consent – Study staff will review the documentation of the consenting process. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

10.8 DATA HANDLING AND RECORD KEEPING

10.8.1 Data Collection and Management Responsibilities

Data collection will be the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

Clinical data (including adverse events (AEs) reported as a primary outcome of the study) will be entered into a secure REDCap stored behind the firewall at BCH. The data system includes password protection. Clinical data will be entered directly from the source documents.

10.8.2 Study Records Retention

In accordance with AHRQ and federal policy, study documents should be retained for a minimum of 3 years after the conclusion of enrollment. Per BCH regulations, study records will be retained for a minimum of 7 years after conclusion of enrollment. No records will be destroyed without the written consent of the sponsor, if applicable.

10.9 PROTOCOL DEVIATIONS AND NON-COMPLIANCE

It is the responsibility of the investigator to use continuous vigilance to identify and report deviations and/or non-compliance to the BCH Institutional Review Board. All deviations must be addressed in study source documents, reported to the AHRQ Program Official and the BCH IRB. The investigator is responsible for knowing and adhering to the reviewing IRB requirements.

A protocol deviation is any changed, divergence, or departure from the IRB-approved research protocol.

- Major deviations: Deviations from the IRB approved protocol that have, or may have the potential to, negatively impact the rights, welfare or safety of the participant, or to substantially negatively impact the scientific integrity or validity of the study.
- Minor deviations: Deviations that do not have the potential to negatively impact the rights, safety or welfare of participants or others, or the scientific integrity or validity of the study.

10.10 HUMAN DATA SHARING, INCLUDING GENOMIC DATA SHARING, AND PUBLICATION

N/A

10.10.1 AHRQ Data Management and Sharing Policy

This study will comply with the AHRQ Data Management and Sharing Policy.

10.11 COLLABORATIVE AGREEMENTS

10.11.1Agreement Type

Per AHRQ guidelines, sites participating in this study will rely on a single IRB at the sponsor institution. All sites participating in research will have DUA and DTA with the sponsor institution.

10.12 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the AHRQ has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest. These conflicts of interest will be reported to the BCH IRB.

11 ABBREVIATIONS

AE	Adverse Event
AHRQ	Agency for Healthcare Research and Quality
CFR	Code of Federal Regulations
CMC	Children with Medical Complexity
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
DCC	Data Coordinating Center
DSMB	Data Safety Monitoring Board
DTA	Data Transfer Agreement
DUA	Data Use Agreement
FACES	Family Activation and Communication about Errors and Safety
IRB	Institutional Review Board
MOP	Manual of Procedures
MSDS	Material Safety Data Sheet

NCT	National Clinical Trial
NIH	National Institutes of Health
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

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