Does a Patient- and Family-Centered Hospital Communications Program Reduce Medical Errors?

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“A wise family doctor once told me something that has stuck with me through the years. It went something like this: ‘Hospitals are not set up for patients. They are set up for doctors.’ As I struggled through years of care with my children, I saw firsthand how true this statement really was. We have to make it easier for families to be a true part of their children’s care. When patients and families are true members of the medical team, care is more informed, more targeted, and more safe for everyone.”

-Sharon Cray, a mother of two children with cystic fibrosis and partner in our study

We extend our sincerest thanks to the patient and family members of the Patient and Family Centered I-PASS Study Group, who partnered with us every step along the way, from development and implementation to analysis and dissemination, and without whom, this study would not have been possible.
# Table of Contents

Abbreviations ........................................................................................................... iv

Abstract ................................................................................................................... v

I. Background ......................................................................................................... 7

II. Participation of Patients and other Stakeholders ............................................. 10

III. Methods ........................................................................................................... 22

IV. Primary and Secondary Results ..................................................................... 38

V. Results from Subpopulation Analysis of Family-Reported Errors Using Pre-Intervention Data Only from the First 4 Study Sites ................................................................. 48

VI. Discussion ....................................................................................................... 52

VII. Conclusions .................................................................................................. 60

VIII. References .................................................................................................. 61

IX. Acknowledgements ....................................................................................... 68

X. Related Publications ..................................................................................... 68
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
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<tbody>
<tr>
<td>AAP</td>
<td>American Academy of Pediatrics</td>
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<td>ACGME</td>
<td>Accreditation Council for Graduate Medical Education</td>
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<td>AE</td>
<td>Adverse event</td>
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<td>CC</td>
<td>Coordinating Council</td>
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<td>CCC</td>
<td>Complex chronic conditions</td>
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<td>EEC</td>
<td>Education Executive Committee</td>
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<td>FAC</td>
<td>Family Advisory Council</td>
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<td>FCR</td>
<td>Family centered rounds</td>
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<td>FSI</td>
<td>Family safety interview</td>
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<td>GEE</td>
<td>General estimating equations</td>
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<td>HL</td>
<td>Health literacy</td>
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<td>IHI</td>
<td>Institute for Healthcare Improvement</td>
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<td>IOM</td>
<td>Institute of Medicine</td>
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<td>NAC</td>
<td>Nursing Advisory Council</td>
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<td>NPSF</td>
<td>National Patient Safety Foundation</td>
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<td>NVS</td>
<td>Newest Vital Sign</td>
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<td>PAS</td>
<td>Pediatric Academic Societies</td>
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<td>PHM</td>
<td>Pediatric Hospital Medicine</td>
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<td>NAM</td>
<td>National Academy of Medicine</td>
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<td>Pediatric Hospital Medicine</td>
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<td>QI</td>
<td>Quality improvement</td>
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<td>RA</td>
<td>Research assistant</td>
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<td>SOC</td>
<td>Scientific Oversight Committee</td>
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<td>SPN</td>
<td>Society of Pediatric Nurses</td>
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Abstract

**Background:** Interventions to improve handoff communications between healthcare providers are associated with improved patient safety. The association between safety and interventions to improve communication between healthcare providers and patients and families is poorly understood, particularly in pediatrics.

**Objectives:** To determine if medical errors and adverse events (AEs) (primary outcomes), family experience, family and nurse engagement, and communication processes between healthcare providers and pediatric patients and families improve following implementation of a structured communication intervention (Patient and Family Centered I-PASS).

**Methods:** We conducted a prospective multi-center study of a patient and family-centered communication intervention, “Patient and Family Centered I-PASS,” implemented in a staggered fashion at 7 North American pediatric hospitals from December 2014-January 2017. The intervention included a health literacy-informed, structured communication framework for family-centered rounds (multidisciplinary bedside rounds that include families and integrate their perspectives into clinical decision-making); written rounds summaries for families; a staff training and learning program; and strategies to support teamwork and implementation. The primary outcome had two principal components: medical errors (i.e., failures in care processes) and AEs (i.e., harms to patients due to medical care). Rates of errors and AEs were measured using an established systematic surveillance methodology including family safety reporting. Family experience was measured through pre-discharge surveys. Communication processes (e.g., family engagement, rounds duration, teaching on rounds) were assessed by means of direct observation. We used Poisson regression and generalized estimating equations clustered by site to compare pre- vs. post-implementation data. To inform the development of a reliable safety surveillance methodology incorporating patient/family input, we also conducted a subpopulation analysis of the first 4 study sites in the pre-intervention cohort to compare rates of errors/AEs: (1) gathered systematically with vs. without family-reporting; (2) reported by families vs. providers; and (3) reported by families vs. hospital incident reports.

**Results:**

Sample Characteristics: Of a total 3106 patient admissions, mean patient-age was 7.1 years; 50.5% were female; 50.4% were non-white; and 8.0% had ≥ 2 complex chronic conditions (CCC). For parents, mean age was 36.2 years; 80.8% were female; 53.1% were non-white; most attended college; and roughly half reported annual household incomes <$50k.

Study Findings: Harmful errors (preventable AEs) decreased 37.9% (20.7 vs. 12.9 per 1000 patient-days, p=0.01) and overall AEs decreased 45.6% (34.0 vs. 18.5, p=0.002) following
intervention implementation. The rate of overall medical errors did not change. Top-box (choosing the top-most response on a scale; e.g., “excellent”) ratings for 6 out of 25 components of family-reported experience improved; none worsened. Percent of rounds observations with top-box rated family engagement (55.6% vs. 66.7%, p=0.04) and nurse engagement (20.4% vs. 35.5%, p=0.03) scores on rounds improved. Percent of families expressing concerns at start of rounds (18.3% vs. 42.0%, p=0.02) and reading back plans (11.8% vs. 32.4%, p=0.04) increased. Observed teaching on rounds (73.4% of rounding encounters vs. 72.4%, p=0.78) and rounds duration (8.5 vs. 10.2 minutes per patient, p=0.13), as well as shared understanding between parent, nurse, and physicians, remained unchanged.

Subpopulation Analysis: Error rates in our pre-intervention only subpopulation analysis of the first 4 study sites were higher with family-reporting than without (45.9 vs. 39.7, p<0.001), as were rates of AEs (28.7 vs. 26.1, p=0.003). Family-reported incident rates (errors, AEs) were similar to those of providers (p>0.05 for both) and 5.0 times (p=0.009; errors) and 2.9 times (p=0.02; AEs) higher than those from hospital incident reports. More educated parents and parents of CCC had higher rates of family-reported errors.

Conclusions: Implementation of a structured family-centered communication intervention was associated with improvements in patient safety, family experience, and multiple aspects of hospital communication processes, without negatively impacting teaching or rounds duration. Moreover, families provided unique information about hospital safety. Including families in hospital safety and communication has the potential to improve hospital safety and quality of care.
I. Background

In 1999, the Institute of Medicine estimated that between 44,000 and 98,000 patients are killed each year in the U.S. due to medical error. Subsequent studies, including by our group, have found that medical errors remain widespread and that rates of harm due to care are not decreasing. In 2010, the U.S. Office of the Inspector General estimated that 180,000 patients die annually due to medical care. In a controversial 2016 analysis, Makary and Daniel extrapolated data from epidemiologic studies to conclude that 251,000 deaths may occur each year in the U.S. due to medical errors, a figure that would make medical errors the 3rd leading cause of death. Regardless of the precise numbers of deaths, there is no doubt that harms due to medical care are extremely common in pediatric and adult inpatient settings.

Miscommunication is consistently identified as a primary root cause of medical errors (failures in the delivery of medical care) and adverse events (AEs, harms due to medical care). According to Joint Commission data, communication errors are a leading cause of “sentinel events” — serious AEs and harms due to medical care — in hospitals. Communication errors include both handoff (e.g., change-of-shift) failures between clinicians and miscommunications between clinicians and patients.

Miscommunications between physicians, nurses, and families occur with high frequency, and are a major source of medical errors. Several developments in the health care system have exacerbated communication problems: (1) rising acuity of hospitalized patients; (2) need for increasingly complex teams of clinicians to care for sicker patients; and (3) introduction of resident work hour reductions in response to studies demonstrating the hazards of excessive work hours, which have increased the frequency of handoffs. While harm due to medical errors remains common, a number of interventions have been successfully demonstrated to reduce rates of errors and/or preventable AEs. Both written and verbal sign-out processes are prone to errors, and amenable to intervention. Adoption of standardized tools and practices can reduce the risk of miscommunications. Structured communications and checklists have been shown to improve patient safety and reduce medical errors, and verbal mnemonics have been strongly advocated for by
TeamSTEPPS and others, including patient advocacy groups, both to structure verbal handoffs and to decrease omissions of key information.

We previously found that implementation of a standardized resident-physician handoff communication program organized around the verbal mnemonic “I-PASS” (I: Illness Severity; P: Patient Summary; A: Action List; S: Situation Awareness/Contingency Planning; S: Synthesis by Receiver) was associated with a marked reduction in harmful errors (i.e., preventable AEs).

Notably, while such efforts to redesign handoffs, structure communications, institute verbal mnemonics, and improve written information exchange have been promising, they have typically not included patients and families or members of the inter-professional team. Additionally, handoffs are only one example of communication in hospitals. Rounds are another key point at which communication occurs.

Rounds are the time every morning when hospital staff (usually doctors, sometimes nurses) review patients’ interval events and come up with the day’s plan. Plans are often made without direct patient or family input. Patients and families may be directly excluded from rounds (e.g., when rounds occur in a conference room), or indirectly excluded from rounds (e.g., when rounds occur in the patient room in the presence of the family, but in a manner that does not truly engage the patient or family).

Family centered rounds (FCRs) is a model for rounds in which rounds occur in the presence of the family. In FCRs, physicians, nurses, and other hospital staff visit with family members and patients each morning to review updates and formulate plans. FCRs have been proposed to serve a critical role in inter-professional and patient/family communication. They are further associated with improvements in teamwork and engagement and satisfaction of families and providers. At their core an enhanced form of handoff, FCRs have been advocated for by the Institute of Medicine (IOM), the American Academy of Pediatrics (AAP), the Accreditation Council for Graduate Medical Education (ACGME), and the Society of Pediatric Nurses (SPN), and the communication techniques they espouse have been endorsed by patient and family advocacy groups. However, there is relatively little research on the relationship between FCRs and safety, or the role of particular FCR processes on safety or patient and family experience. Moreover, FCRs as commonly practiced are highly variable.
and often occur in a manner that does not fully incorporate families or inter-professional team members.

For instance, communication during FCRs often occurs in unidirectional fashion: staff may tell patients and families the plan but don’t always truly listen or partner with them to co-produce it. Staff often use medical jargon and do not always effectively ask families for their input or questions. Staff may not effectively ensure that the family understands the plan. FCRs may occur with the family present, but not truly involved.

In sum, medical errors are a leading cause of patient death and harm, and communication failures are in turn a leading cause of sentinel events, the most serious types of harmful errors. Interventions to improve poor handoffs of patient care between healthcare providers have been shown to improve patient safety. We previously found that implementing a standardized resident-physician handoff communication program organized around the I-PASS mnemonic was associated with a marked reduction in medical errors and AEs. Improvements in handoffs and communications have been identified as a priority in nationwide efforts to improve patient safety. Similarly, improved communications, focusing specifically on the importance of redesigning healthcare communications in a manner that better integrates patient and family voices, and standardizes the structure of family-clinician communications, are important. However, relatively little research has addressed the effect on patient safety of interventions to improve communications between providers and families.

In a single-center pilot study (the Nighttime Communication Study), we found that communication quality, shared understanding, and family experience improved after implementing a bundle of nighttime structured family-centered communication. Similarly, two recent single-center studies have suggested that such provider-patient communication interventions in hospitals might lead to improved patient safety.

To more definitively address this possibility, building on our prior work, we conducted a prospective, multi-center intervention study to determine whether implementation of a structured communication program between healthcare providers and patients and families that focused on improving FCRs and the entire 24-hour cycle of communication, not just nighttime communication – Patient and Family Centered I-PASS – was associated with:
(a) reductions in rates of medical errors and adverse events, determined both by an established, systematic daily hospital surveillance methodology and family reports;
(b) improvements in family experience;
(c) improvements in family and nurse engagement on family centered rounds (FCRs);
(d) improvements in communication processes between healthcare providers and patients and families during FCRs; and
(e) improvements in shared understanding between parents and caregivers.

We hypothesized that the implementation of Patient and Family Centered I-PASS would lead to:
(1) reductions in serious medical errors and adverse events (primary outcome),
(2) improvements in hospital experience (secondary outcome),
(3) improvements in communication (secondary outcome), and
(4) improvements in shared understanding (secondary outcome).

II. Participation of Patients and other Stakeholders

Patient and Family Centered I-PASS engaged a variety of stakeholders, including nursing and physician leaders, family advisors, and health literacy experts. We partnered with stakeholders throughout the entirety of the study, from study design and data instrument development to intervention implementation and dissemination. The Patient and Family Centered I-PASS 15-member Family Advisory Council (FAC), 14-member Nursing Advisory Council (NAC), and 6-member Health Literacy Subcommittee (HL Subcommittee) were integrated into all aspects of the program (Figure 1).
Figure 1. Patient and Family Centered I-PASS Organizational Chart. This figure represents the organization of the study. The study group includes nearly 100 individuals from varying institutions and backgrounds. In yellow are the central oversight committees (the I-PASS Executive Council which oversees all I-PASS projects and the Coordinating Council which oversees the study) as well as the key advisory councils (Health Literacy, Advisory Board, Family Advisory Council, Nursing Advisory Council). In dark blue are the two main study oversight arms: The Scientific Oversight Committee which oversees study science and data collection and the Education Executive Committee which oversees intervention development and the various intervention subcommittees. Light blue represents the main working groups of the study (e.g., the written communication subcommittee and rounds subcommittee). In gray are the participating hospitals (dark gray=study sites; light gray=pilot sites). Notably, family stakeholders, nursing stakeholders, physician stakeholders, and health literacy experts participated in both their dedicated committees as well as in the various other leadership, study science, and intervention subcommittees.
Engagement of Stakeholders

Engagement of stakeholders commenced with the inception of the Nighttime Communication Study, a single-center family-centered initiative that served to pilot Patient and Family Centered I-PASS, but which focused on solely nighttime communication, not daytime communication or FCRs. Stakeholder input by means of observation and feedback contributed toward informing refinements and prompting research questions that would ultimately lead to what is Patient and Family Centered I-PASS. We identified stakeholders for the Patient and Family Centered I-PASS program from the Nighttime Communication Study, as well as via introductions facilitated by study sites and partner institutions. Following identification, we hosted a kickoff meeting in Boston, Massachusetts to provide invited stakeholders with information on the general aims of the study and expected commitment of time. Health literacy experts were subsequently identified through the Institute of Medicine and National Academy of Medicine’s Roundtables on Health Literacy.

We have since constructed an infrastructure to facilitate the integration of stakeholders at the central level and ensure each group had a voice in all study decisions. Stakeholders ultimately contributed toward informing and guiding the establishment and refinement of all process and outcome measures and data collection instruments, as well as toward all analyses and dissemination efforts. In sum, stakeholders from all levels of care were intimately intertwined with the conception, design, and execution of the Patient and Family Centered I-PASS study and interwoven throughout all facets of the project.

Family Stakeholders

We formed a FAC that engaged patient and family advocates from across all study sites. The FAC was chaired by Dale Micalizzi and Helen Haskell, national patient advocates who lead patient safety improvement and engagement organizations. The FAC included parents with backgrounds in patient engagement and patient safety, many of whom had a wealth of healthcare experience with their own children. The FAC met monthly and reported back to the
larger group during quarterly study group calls. The parents also worked with family advisory councils at their own children’s hospitals to assist in implementation efforts. Beyond their role in the FAC, families were involved in all subcommittees, including the Coordinating Council (CC), Scientific Oversight Committee (SOC), the Education Executive Committee (EEC), and the Team Communication Subcommittee. The CC oversaw and coordinated all aspects of the Patient and Family Centered I-PASS Study and met on a weekly basis. The Patient and Family Centered I-PASS SOC assembled weekly to biweekly and was responsible for study design, research tool and protocol development, and data management and analysis. The EEC, which met weekly, designed and oversaw all aspects of the intervention, training, and coordinated the operation of educational subcommittees (including the Rounds Subcommittee, Simulation and Educational Strategies Support Team, Campaign Subcommittee, Dissemination Core, and Written Communication Tool Subcommittee). The Team Communication Subcommittee, which provided insight on inter-professional hospital communication processes, also met every other week as the intervention was being developed and refined. We compensated family advisors for their involvement through payment of honoraria.

*Nurse Stakeholders*

We formed an NAC that engaged nursing advocates and stakeholders from across all study sites. The NAC was chaired by Dr. Jennifer Baird and Ms. Jayne Rogers, both experts in inter-professional care and nurse engagement. The group met monthly over the course of the study and was similarly involved throughout all aspects of it, including development and implementation of the intervention, interpretation of findings, and formulation of future plans for dissemination. Like families, nurses were involved in our CC, SOC, EEC, and a variety of subcommittees, including the Simulation and Educational Strategies Support Team, the QI and Implementation, the Team Communication, the Rounds, the Campaign, and the Written Communication Tool Subcommittees. The CC, SOC, and EEC convened weekly to biweekly throughout the study, as described above (See Families), while the various Patient and Family Centered I-PASS Subcommittees met on a bi-weekly basis during the active intervention.
development and refinement phases of the study. We compensated nurse advisors for their involvement through payment of honoraria.

**Health Literacy Experts**

The HL Subcommittee was chaired by Drs. Benard Dreyer and Shonna Yin, leading experts in health literacy-informed communication strategies. This 6-member working group, included an interpreter, a health policy and systems design innovation expert, and clinicians and researchers with expertise in cultural competency and health literacy. The group convened every other week at the study’s onset and ad hoc as it progressed. Members worked closely with family stakeholders, including on a specific curriculum to define best practice for FCRs with low English proficiency patients. Health literacy experts provided invaluable insight on the design of our training program and materials, as well as on written materials used by providers and researchers throughout the course of the intervention, including parent- and researcher-specific assessment tools for evaluating its various components. Moreover, the HL Subcommittee was consulted to provide expertise on focused questions that arose. For instance, health literacy experts helped train residents on how best to perform synthesis with families on FCRs and partnered with us in dissemination efforts, outlined below.

**Physician and Other Stakeholders**

We additionally partnered with physician stakeholders and advocacy organizations. Physician stakeholders included frontline physicians and physician leaders (n=70). Physician leaders included physician administrators in various senior hospital leadership roles (e.g., chief medical officer, chief of graduate medical education, chief quality officer, residency program director) across North America, the bulk of whom were affiliated with a Patient and Family Centered I-PASS study site or attached to the I-PASS Study Group via the original Resident Handoff Study. We additionally engaged other physician stakeholders, such as leaders of national associations and advocacy organizations, including representatives of the Pediatric Research in Inpatient Settings (PRIS) network, Institute for Healthcare Improvement (IHI), and
the National Institute for Children's Health Quality (NICHQ). We ultimately convened an advisory board comprised of physician stakeholders as described above.

Frontline physicians at each of the study sites were engaged in the design and implementation of the study in a site-specific and central way. Information from frontline physicians on the current state of FCRs aided the evolution of the intervention and curriculum components. Formal quality improvement observations conducted by frontline physicians while the study was underway served to guide subsequent refinements.

Physician leaders of all tiers were integrated into the central direction of the study and contributed toward informing and refining the study's design, implementation, and dissemination. Many physician leaders were furthermore additionally engaged at the site-level and with working groups that supported the advancement of the program. By way of an illustration, Dr. Benard Dreyer, president of the American Academy of Pediatrics at the time, provided leadership on the Patient and Family Centered I-PASS Coordinating Council and served as chair of the Patient and Family Centered I-PASS HL Subcommittee. He thus ensured principles of health literacy were interwoven throughout our research strategy and implementation of the program across study sites.

Summary of Stakeholder Engagement

To sum, stakeholder engagement occurred at all levels and throughout each phase of our study. Families, nurses, and health literacy experts aided in the development of our intervention, curriculum, written communication materials, and assessment tools. Additionally, each group of stakeholders provided insight on and revisions to our various curricular materials, such as the “Rounds Report” and Patient and Family Centered Rounds Brochure, and participated in quality improvement (QI) observations. We intend to continue to actively include family and nurse stakeholders, as well as health literacy experts, in our future efforts, as outlined in the subsequent subsections of this chapter.
Scholarship

Our group has striven to and will continue to strive to actively include families, nurses, and health literacy experts in all scholarship from the Patient and Family Centered I-PASS Study, including national presentations (see Table A1 in Dataforms Appendix). In addition, we have submitted proposals to present at the 2018 Pediatric Academic Societies (PAS), Pediatric Hospital Medicine (PHM), and Institute for Healthcare Improvement (IHI) annual meetings, all of which are currently under review and include families, nurses, and health literacy experts as speakers.

Impact of Engagement

Relevance of the Research Question

Comments from families and nurses support the relevance and significance of the research question, and reinforced the importance of engaging families and nurses as true partners in the care team (Table 1).

Study Design, Processes, and Outcomes

Partnering with families, nurses, and health literacy experts enabled us to develop a more patient-centric study. As described above, each stakeholder group was represented in our SOC and CC and thus had a voice in the design of the study, as well as an influence on its various processes and outcomes. For instance, family members and health literacy experts were asked to provide input on our consent forms, to help us better define terms essential to our intervention, such as “rounds” and “safety,” using language that families would understand. Additionally, we asked the FAC for guidance on how to administer surveys to family members, and when we observed suboptimal levels of nurse engagement (see below), we sought the advice of NAC members about how to alter rounds processes to promote the role of nurses on FCRs.

Study Rigor and Quality

The involvement of health literacy experts and family and nurse stakeholders has greatly benefited the rigor and quality of our study. Notably, our primary outcome, patient safety, was
directly measured using a two-step methodology that included family safety reporting. The family safety reporting methodology relied heavily on input from family partners on how to best administer family safety interviews (FSIs) and phrase questions regarding sensitive matters in a manner that would gather the best possible data. For instance, when piloting the FSI dataform with family members, one parent suggested alternate wording to what we had initially proposed to help increase the yield of family safety reports. She suggested we add the following question to our dataform, which we consequently added: “Did anything else happen or almost happen that upset you or could have harmed your child during this hospital stay?”

In addition, parent and nurse stakeholders joined SOC meetings focused on interpreting results of our ongoing analyses. On several occasions, there were outcomes that deviated from our own expectations. However, by involving these stakeholders, clinical nurses and parents with years of experience caring for hospitalized children, we were able to view the unexpected occurrences from their own unique perspectives, helping us develop a richer understanding of why the particular phenomena might be occurring.

We additionally sought out input from family members and health literacy experts on the administration of the Newest Vital Sign (NVS) dataform, a tool to assess parent subject health literacy. During data collection, research assistants (RAs) expressed concerns that the NVS was awkward to administer to parents, requesting tips to improve its administration to parent participants. Consequently, we sought input from the HL Subcommittee about how best to administer the NVS to families (see below).

Participant Recruitment

On admission to the study unit, family members were approached by unit staff and briefed on the Patient and Family Centered I-PASS Intervention, namely through a Patient and Family Centered I-PASS Study Information Sheet and Family Centered Rounds Brochure. We asked the FAC and HL Subcommittee for guidance on both documents. Family members and health literacy experts helped refine the language of the study information sheet, as well as the framing of the intervention and various aspects of the study (such as the parent’s role on FCRs as described in the brochure) in a manner that was easy for parents to understand. The
brochure specifically made it clear to parents that our intervention was of direct relevance to their child. Furthermore, through input from both FAC and NAC members, the brochure was able to reinforce to parents the important role they played on rounds and in communications with all members of the care team. We believe that the involvement of families and nurses in these efforts ultimately helped to drive family participation in our intervention.

**Transparency of the Research Process**

Partnering with family and nurse stakeholders, as well as health literacy experts, encouraged us to consider their unique points of view and expertise throughout all phases of the study. Moreover, each stakeholder group was so intimately involved in the study that Patient and Family Centered I-PASS was truly co-produced by parents, nurses, physicians, educators, and researchers. Our relationship with stakeholders fostered a sense of transparency throughout the research process and helped ensure that we actively addressed issues that arose with the study and intervention in real-time. For instance, we struggled with engaging nurses on FCRs, encouraging families to perform synthesis on FCRs (e.g., “teach back” the plan), and ensuring intervention buy-in at certain implementation sites. Our course of action was to always reach out to our family members, nurses, and health literacy experts, to inform them of concerns and request their expert guidance on how to address them.

**Adoption of Research Evidence into Practice**

The questions we asked and sought to answer were relevant to families and nurses, as these stakeholder groups are essential, but often overlooked members of the hospital care team. We found that having family and nurse advisors participate in all study subcommittees ensured their voices were heard throughout each stage of the project. The FAC and NAC each fostered feelings of unity on the project and promoted a forum in which members of each council could share ideas, questions, concerns, and feedback on any aspect of the study. By empowering family and nurse advisors to provide honest feedback, and by promoting exchange of experience across various study sites with diverse geography, patient-mix, and institutional culture, we were able to learn from diverse and unique perspectives. Their input directly
influenced the research questions we asked and approaches we decided on. Our findings are higher impact and should be easier to implement because they are the result of a study that was grounded in the input of these essential members of the care team.

Working with stakeholder partners to widely disseminate our intervention and curriculum to national audiences is well underway. In 2017, we introduced Patient and Family Centered I-PASS to national audiences by means of plenary presentations and workshop sessions at the Pediatric Academic Societies (PAS) and Pediatric Hospital Medicine (PHM) annual conferences, as well as the Institute for Healthcare Improvement (IHI) National Forum on Quality Improvement in Health Care. We presented at the Beryl Institute Patient Experience and Patient and Family-Centered Care annual conferences in March of 2018 and are invited to speak at the 2018 PAS conference in May, the IHI-National Patient Safety Foundation (NPSF) in May 2018, and the PHM yearly meeting in July 2018. We are in the process of publishing our Dissemination Toolkit to MedEdPORTAL (see Implementation of Study Results), a peer-reviewed curricular repository published by the Association of American Medical Colleges. We are also working to publish our curricula in high profile academic journals and disseminate our results to patients and families through partner organizations (e.g., through Consumers Advancing Patient Safety and the Justin’s Hope blog) and in the lay press. We are partnering with families, nurses, and health literacy experts in each of these efforts.

Moreover, we are proposing to conduct a dissemination and implementation study of the Patient and Family Centered I-PASS program in community and academic pediatric hospitals across North America. We have received letters of support and widespread interest in disseminating Patient and Family Centered I-PASS by 36 sites across the US. We have convened a multidisciplinary Advisory Board consisting of national experts in safety, quality, patient advocacy, health literacy, and patient experience, many of whom are new partners enthusiastic to disseminate Patient and Family Centered I-PASS. The board includes senior leadership of key physician, nursing, patient, and family advocacy organizations, including IHI, NPSF, American Academy of Pediatrics, Children’s Hospital Association, Hospital Research Education Trust, PRIS, the Beryl Institute, the Patients’ View Institute, Consumers Advancing Patient Safety, Mothers Against Medical Error, the Leapfrog Group, Connecticut Center for Patient Safety, American
Our collaboration with these organizations will serve to facilitate our ongoing partnerships with and dissemination to stakeholders from all levels of care.

**Future**

Family, nurse, and health literacy expert stakeholders will remain involved in all future efforts, including ancillary and sub analyses, manuscripts, scholarly presentations, and grants.

**How Engagement of Stakeholders Changed the Research**

This study was a highly meaningful educational experience for all of us. Our collaboration with family members, nurses, and health literacy experts enriched the experience of every member of our study group, and allowed providers specifically to better understand the needs and concerns of the study’s populations (notable examples included in Table 2). We learned how valuable it is to meaningfully engage families, nurses, and health literacy experts as true partners in research and care, and we have every intention of continuing such a partnership as we adapt and spread the Patient and Family Centered I-PASS intervention.
Figure 2. Patient and Family Centered I-PASS Study Timeline.
III. Methods

Study Overview: Patient and Family Centered I-PASS is a bundle of communication interventions to improve the quality of information exchange between physicians, nurses, and families, and to better integrate families into all aspects of daily decision making in hospitals. This project tested the hypothesis that rates of medical errors/AEs (primary outcomes), hospital experience, communication, and shared understanding would improve following implementation of Patient and Family Centered I-PASS, as compared to current practice.

Study Design and Time Period: We conducted an intervention study on pediatric inpatient units at one Canadian and six U.S. teaching hospitals from 12/17/2014-1/3/2017. Each site was assigned to one of 3 staggered waves. We implemented the intervention over a 9-month period of iterative refinement and assessed processes and outcomes of care for 3 months both before and after the intervention (Figure 2). The pre-intervention period occurred between 12/17/2014-12/30/2015; post-intervention between 12/15/2015-1/3/2017. We selected these time periods to ensure that time of year and resident training levels were consistent between pre- and post-intervention. This allowed us to control for confounding due to level of resident-physician experience and seasonality. Resident-physicians and nurses included were those present on the study units, which, particularly for residents, typically varied between pre- and post-intervention periods. The Boston Children’s Hospital IRB approved the study. IRBs at participating institutions additionally approved the study through reliance agreements with Boston Children’s Hospital or through approval of the individual site’s IRB.

Study Team: Our study team included nearly 100 collaborating health services researchers, hospitalists, medical educators, parents, nurses, and health literacy experts across North America (Figure 3). We included parent, nurse, and health literacy expert stakeholders in every aspect of the study, from intervention development and refinement to study instrument creation (See Chapter II).
Figure 3. The Patient and Family Centered I-PASS Study Group comprised of health services researchers, hospitalists, medical educators, parents, nurses, health literacy experts, and stakeholders of all levels of care across the United States and Canada. Stars represent study sites and pins depict the affiliated institutions of study group members, with pin size directly corresponding to the number of study group members at the given site.
Participants: All patients, nurses, medical students, and resident-physicians on the study units were eligible to participate as subjects in the study. Parents/guardians or caregivers of children under 18 years of age who spoke a study language (English, Arabic, Chinese, Russian, and Spanish) were likewise eligible to participate. All sites had rotating medical students and residents. We determined study languages according to the most commonly spoken languages across the seven study sites. We obtained waivers of consent from Institutional Review Boards at participating institutions to review patient charts. We obtained verbal consent from parents and medical students and written informed consent from resident-physicians and nurses to conduct interviews and surveys. We offered participants small incentives (e.g., snacks) to participate.

Interventions and Comparators or Controls: FCRs served as the primary venue for improving communication with families of patients through a series of structural changes to enhance the two-way transfer of information about the patient between family members and providers. We developed the Patient and Family Centered I-PASS intervention iteratively, through a consensus-building process informed by our prior study, literature review, and partnership with collaborating parent stakeholders, nurse stakeholders, physician stakeholders and health literacy experts. The intervention included: (1) a structured high-reliability communication framework for patients and families on FCRs that was organized around the I-PASS mnemonic and bolstered by principles of family engagement, health literacy (such as use of plain language by providers, e.g., “fever” instead of “febrile”), bidirectional communication, and inter-professional and nurse engagement; (2) a “Rounds Report” (i.e., written daily summary of FCRs) provided for families in I-PASS format and completed in real-time on a whiteboard or on paper (see Figure A2 in Appendix); (3) a learning and training program for families and professional team members with interactive learner-specific workshops reinforced by simulation and role play exercises and computer-based video modules; and (4) strategies to support teamwork and
implementation of the intervention, including mid-shift nurse-physician huddles to confer on patient care issues and family concerns, structured observations of rounds with feedback to improve team performance, and a sustainability campaign (Figure 4).
### (1) Structured Verbal Communication During Family-Centered Rounds

- Structured communication framework based on I-PASS mnemonic
  - I - Illness Severity (parent reports if child is “better, worse, or same”)
  - P - Patient Summary (presenter presents brief summary of patient presentation, overnight events, plan)
  - A - Action Items (“to-dos” for the day)
  - S - Situation Awareness & Contingency Planning (what family and staff should look out for and what might happen)
  - S - Synthesis by Receiver (family reads back key points of plan for day, prompted by presenter)
- Emphasized:
  - Family engagement (e.g., family speaks first, shares their questions and concerns first on FCRs)
  - Health literacy (using plain language, e.g., “fever,” not febrile)
  - Bidirectional communication (“synthesis by receiver”)
  - Inter-professional and nurse engagement (nurses speaking early on rounds, nurse-physician huddles)

### (2) Structured Written Communication During Family-Centered Rounds

- Rounds Report (Figure A2 in Data forms Appendix)
  - Daily written summary of rounds for family organized in I-PASS format
  - Completed in real-time on whiteboard (5 sites) or paper (2 sites)

### (3) Training and Learning

- Interactive learner-specific workshops for faculty (1-hour), residents (2-3 hour), and nurses (15-minute) reinforced by:
  - Simulation and role play exercises
  - Computer-based video modules
- Family and patient orientation and family-centered rounds brochure

### (4) Strategies to Support Teamwork and Implementation

- Mid-shift afternoon and overnight nurse-physician huddles to address patient care issues and family concerns
- Structured weekly observations, assessment, and feedback by trained observers (physician faculty and nurses) to improve team performance on rounds
- Sustainability campaign (development of a logo, posters, and other materials to promote the program and provide visual reminders to the team about it)

Figure 4. The Patient and Family Centered I-PASS Intervention.
For sites that already had FCRs, I-PASS was introduced as a high-reliability framework that was complementary to but built upon existing rounding models. Certain elements of I-PASS were clear improvements to existing FCRs because they were nonexistent (e.g., Illness severity, synthesis by receiver) or inconsistently included on FCRs (e.g., situational awareness) pre-intervention. Certain elements (patient summary and action items) aligned nicely with existing FCR practices, but were reframed to emphasize health literacy principles and problem-based assessments. Moreover, all sites already used I-PASS for resident-resident handoffs, which also helped facilitate buy-in.

**Study Outcomes:** Primary outcomes were rates of medical errors and AEs. Secondary outcomes included hospital experience, communication processes, and shared understanding, as described below. Additionally, we compared rates of errors/AEs: (1) gathered systematically with vs. without family-reporting; (2) reported by families vs. providers; and (3) reported by families vs. hospital incident reports.

**Study Setting:** We collected data at seven North American inpatient pediatric medical (i.e., non-intensive care) units, ranging in size from 189 to 540 beds. Study sites, which included free standing children’s hospitals (n=3), pediatric hospitals within a larger system (n=3), and a pediatric unit within an adult system (n=1), determined their medical units to select for inclusion in the program. Study units varied in average daily patient census, ranging from 10 to 30 patients, and clinical services represented, which included general pediatrics (n=7), specialty care (n=3), and complex care (i.e., children with medical complexity including multiple health concerns/needs, multi-service/specialty involvement, multiple medications, medical technology-dependence, or frequent emergency department/hospital visits; n=1). Five of the study sites practiced FCRs prior to the intervention, though practices and levels of experience differed.
Data Collection and Sources:

Medical Errors and Adverse Events

We assessed rates of medical errors (failures in care processes\textsuperscript{11}) and AEs (harms to patients due to medical care\textsuperscript{12}, e.g., a reaction to penicillin in a patient with a known allergy) per 1000 patient-days using an established systematic safety surveillance methodology that included family safety reporting (Figure 5).\textsuperscript{34,43,53–56}

Notably, overall errors are the sum of harmful errors (also known as preventable AEs) and non-harmful errors (Figure 6). Overall AEs are the sum of preventable AEs (also known as harmful errors) and non-preventable AEs.
Patient and Family Centered I-PASS: Integrating Family Safety Surveillance in Research

**Figure 5. Patient and Family Centered I-PASS Safety Surveillance Methodology.** Neither patients nor families are included in the established two-step systematic surveillance methodology typically considered highest yield for detecting medical errors and AEs. In Patient and Family Centered I-PASS, we integrated family involvement in our error detection methodology via Family Safety Interviews. Adapted from “Families as Partners in Hospital Error and Adverse Event Surveillance,” by Khan et al., 2017, JAMA Pediatrics, 171(4), 372-381.
Figure 6. Participant Flow by Type.
Every weekday, across all sites, research clinicians collected potential medical errors and AEs by reviewing hospital incident reports, post-shift provider (e.g., resident-physician and nurse) surveys, and medical records of all study unit patients. To incorporate input from families into the error surveillance process, we additionally collected potential medical errors and AEs using Family Safety Interviews (FSIs) of parents/guardians or caregivers of eligible hospitalized patients before discharge (and every 7 days for longer-stay patients) (See Family Safety Interviews), and ultimately merged family-reported safety data with safety data collected from other sources. Trained physician-reviewer pairs blinded to pre- vs. post-intervention status independently categorized all research clinician- and FSI-collected events as exclusions, non-harmful errors, or AEs. Physician-reviewer pairs further categorized AEs as preventable or non-preventable. AEs that were clearly caused by a failure in a care process were deemed preventable, while all other cases were deemed non-preventable. Discordant categorizations by physician-reviewers were reconciled through consensus.

**Family Safety Interviews**

We collected family reported safety data by administering FSIs to families. We developed the FSI using a modified Delphi method with input from experts in survey methodology, patient safety, and health literacy, as well as family advisors. The FSI was piloted and iteratively refined through cognitive interviews with family members at Boston Children’s Hospital.

To educate families on information to report, the FSI provided descriptions, definitions, and examples of safety events related to miscommunications, delays in care, and complications of care, among other incident classifications. Using closed- and open-ended questions, families were asked to indicate whether their child’s illness worsened or almost worsened because: (1) of medical care (i.e., AE); (2) something was not done that should have been (i.e., preventable AE due to error of omission); or (3) something was done that should not have been (i.e., preventable AE due to error of commission). Parents were also asked to
indicate whether a mistake occurred that did not result in harm to their child (i.e., non-harmful error) and if anything else happened or almost happened that was upsetting or could have harmed their child (See Engagement).

The FSI was administered to parents of eligible patients every 7 days while hospitalized and prior to their child’s discharge (see Figure A8 in Data forms Appendix). Interviews typically lasted between 3-5 minutes (when no safety concerns) and 10-15 minutes (when safety concerns). Research clinicians (nurses or physicians) then classified family concerns as safety, non-safety-related quality (e.g., unpleasant interaction with provider), other (e.g., difficult IV placement), or exclusions (e.g., off-unit safety concerns).

Provider Event Reporting Surveys

We collected potential safety events from providers by modifying a reporting instrument used in previous studies34,43(see Figure A3 in Data forms Appendix). Survey respondents were asked to describe errors/AEs and procedures, medications, fluids, or other therapies that were: unnecessary or questionably beneficial, delayed, involved in an error/AE, or ordered erroneously but intercepted before reaching the patient (near-misses).57 Providers were additionally requested to report resident-physician or nurse sign-out omissions or inaccuracies that led to problems with patient care. Every weekday morning during both the pre- and post-intervention periods, research clinicians at all sites administered the survey (on paper or verbally) to post-shift overnight resident-physicians. Surveys were also posted on the study units to allow voluntary, anonymous error-reporting from unit staff not enrolled in the study.

Family Experience Surveys

We measured family experience before and after implementation of the Patient and Family Centered I-PASS intervention using a survey administered to two randomly selected parents per week per site, prior to their child’s discharge (see Figure A4 in Dataforms Appendix). The survey was developed, cognitively tested, and piloted at Boston Children’s Hospital, and then translated into Arabic, Chinese, Russian, and Spanish. The <15-minute
survey, which had a Flesch-Kincaid reading grade level of 5.9, was verbally administered by RAs at each site and asked families to rate their experience, using predominantly 5-point Likert scales: during and after FCRs, with written communications, with resident-physicians and nurses, and during the overall hospitalization.

**Structured Observation of Rounds**

To measure hospital communication processes, RAs conducted 1-hour weekly in-person observations of FCRs at each site, concurrently completing a real-time structured direct observation assessment tool for each patient and audio-recording rounds. RAs assessed and recorded a median of 3 (IQR 2, 5) patients during each observation session. RAs conducted real-time assessments using a structured observation assessment tool developed by our study team to rate various aspects of quality of communication during rounds processes, as well as engagement of parents and nurses, using Likert scales (see Figure A5 in Data forms Appendix). They also kept track of rounds duration. In addition, research clinicians at each site who were blinded to pre- vs. post-intervention status conducted post-hoc analyses of a subset of FCR audio recordings (2 patients per week per site) using a structured assessment tool that measured rounding team adherence to evidence-based communication processes (e.g., plain language was used effectively).

**Shared Understanding**

We measured shared understanding between parents, residents, and nurses before and after implementation of the intervention. A research assistant at each site verbally administered the survey, which was cognitively tested, piloted, and translated as described above (see Figure A6 and A7 in Data forms Appendix). The survey asked parents, as well as physicians and nurses, to report their understanding of key elements of the medical plan. Percent concordance was assessed through a comparison of responses and mean concordance ratings were compared pre- vs. post-intervention.

**Demographic Data**
We obtained patient characteristics from hospital administrative data and collected provider and parent demographic information through surveys.

Subpopulation Analysis of Family-Reported Errors

Because we were interested in the role of family safety reporting, we also sub-analyzed data from the first 4 study sites (using pre-intervention data only; selected because they participated in the study first chronologically) to further evaluate the utility of family safety reporting. In this subanalysis, we sought to compare rates of errors and AEs: (1) gathered systematically with vs. without family-reporting; (2) reported by families vs. providers; and (3) reported by families vs. hospital incident reports.

Analytical and statistical approaches: To compare error and AE rates (events per 1000 patient-days) pre- vs. post-intervention, we used Poisson regression estimated via generalized estimating equations (GEE) to account for clustering of patients within site. For experience and rounds observation data, we compared percent top-box ratings (choosing the top-most response on a scale; e.g., “excellent” or 5 out of 5) pre vs. post using a GEE chi-squared test for binary outcomes, clustered by site. For shared understanding, we used t-tests to compare mean concordance ratings before and after implementation.

We analyzed all collected variables that could be potential confounders, including patient, parent, nurse, and physician characteristics, in the pre- vs. post-intervention cohorts to ensure none of these variables differed significantly and required adjustment in analyses. To account for missing data, we used multiple imputation appropriate for missing data in clustered studies (calculating p-values for variables with more than 5% missing data using multiple imputations; 300 imputations used). Distributions of possible confounders were comparable in the pre and post periods. For simplicity, we present unadjusted results, accounting for clustering by site (see Results).

For our two primary outcomes (overall errors and overall AEs), we applied a Bonferroni correction and considered p<0.025 significant. For our three secondary analyses (family experience, communication processes, and shared understanding), we considered p<0.05
statistically significant. We used REDCap\textsuperscript{62} to collect and manage study data and SAS 9.4 (SAS Institute) to conduct analyses.

**Changes to the original study protocol:** We made slight modifications to the original protocol, as outlined below (Table 3 and Study Protocol Appendix). Regarding our statistical analyses, we analyzed our data as per our analysis plan except for a few minor modifications. For errors and AEs, rather than using existing adult family safety reporting instruments, we adapted existing adult and pediatric family safety reporting instruments in order to develop a more robust inpatient pediatric family safety reporting methodology. We did so in conjunction with parent partners and health literacy experts and created a final methodology that was based on piloting and cognitive interviewing our instrument. We recently published this methodology and our findings in JAMA Pediatrics.

In addition, there was no way to cluster error and AE rates by resident as originally planned, because we were only able to attribute a fraction of all captured errors and adverse events to a particular resident or other provider. Rather, we were examining system-wide rates of incidents. Therefore, it was not possible to cluster by resident. However, for any future analyses, where we examine only the subset of errors attributable to residents, we will cluster by resident.

To evaluate communication processes on FCRs, although our original plan was to do 25 FCR observations pre-intervention and 25 FCR observations post-intervention, we ended up doing considerably more direct observations (a total of 653 across 7 sites). However, due to pragmatic limitations, we only analyzed audio recordings for a subset of these FCR observations (n=164).

Moreover, we had originally planned to measure process and content changes in communication via direct observation and development of a validated Verbal Handoff Score (VHS) to assess FCRs (i.e., a global numerical rating of FCRs). Although developing a VHS for FCRs is within the scope of our future work, for the time being, we felt it more salient to compare the individual elements we thought best represented the key components of our...
intervention (e.g., statement of illness severity at start of rounds, synthesis by receiver, use of plain languages) (see Figure 9). Developing a global VHS score for FCRs is a future direction.
IV. Primary and Secondary Results

Participant Flow

A total of 2148 parents (83.6% of those confirmed as eligible; generally, one parent per patient was enrolled), 435 nurses (97.3%), 203 medical students (99.5%), and 586 residents (95.6%) consented to participate in the study. No patients were lost to follow-up and missingness (which ranged from 2.0%-9.7%, except for patient race and annual household income) was similar in pre- and post-intervention cohorts. In total, we collected 2034 FSIs (95.9% of patients approached) and 1224 family experience surveys (97.8% response rate), and we conducted 654 direct observations of FCRs. Participant flow is depicted below by participant type (Figure 7) and intervention cohort (Table 4).
Figure 7. Family Experience Before and After Implementation of Patient and Family Centered I-PASS.

*P<0.05
†Top-box = Top-most response on a scale (e.g., "excellent").
Response options for scales = (“Not at all,” “Slightly,” “Somewhat,” “Very,” “Extremely”) except when marked by § (“Never,” “Rarely,” “Sometimes,” “Usually,” “Always”) or ¶ (“Poor,” “Fair,” “Good,” “Very good,” “Excellent”).
Table 4. Patient Admissions per Hospital by Intervention Cohort

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Pre-Intervention, n</th>
<th>Post-Intervention, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>318</td>
<td>297</td>
</tr>
<tr>
<td>2</td>
<td>189</td>
<td>204</td>
</tr>
<tr>
<td>3</td>
<td>197</td>
<td>192</td>
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<td>4</td>
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<tr>
<td>5</td>
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<td>230</td>
</tr>
<tr>
<td>6</td>
<td>194</td>
<td>235</td>
</tr>
<tr>
<td>7</td>
<td>208</td>
<td>152</td>
</tr>
</tbody>
</table>

Sample Characteristics

We reviewed a total of 3106 patient admissions (1574 pre-intervention, 1532 post-intervention) for medical errors and AEs, representing 13,171 patient-days (6326 pre-intervention, 6845 post-intervention). Across both cohorts, mean patient-age was 7.1 years; 50.5% were female; 50.4% were non-white; and 8.0% had ≥ 2 complex chronic conditions (CCC). Patient characteristics were similar in the pre- and post-intervention cohorts (Table 5).

A total of 2148 parents (83.6% of those approached), 435 nurses (97.3%), 203 medical students (99.5%), and 586 residents (95.6%) consented to participate in the study. In total, we conducted 654 direct observations of FCRs processes and collected 1224 family experience surveys (97.8% response rate) and 2034 FSIs (95.9%). Across both cohorts, mean age was 36.2 years for parents, 34.8 years for nurses, and 28.4 years for physicians; 80.8% of parents, 90.5% of nurses, and 68.2% of residents were female; and 53.1% of parents, 90.5% of nurses, and 68.2% of residents were non-white. Most parents attended college and roughly half of families reported annual household incomes less than $50,000.
Medical Errors and Adverse Events (primary outcome)

Kappa statistics of the physician reviewer categorization of all suspected events as exclusions, non-harmful errors, or AEs (pre-consensus agreement=68.9%; \( \kappa=0.53, 95\% \text{ CI } [0.48-0.58] \)) and subsequent categorization of AEs as preventable or non-preventable (pre-consensus agreement=83.5%; \( \kappa=0.64, 95\% \text{ CI } [0.54-0.74] \)) indicated reliability. Examples of validated medical errors and adverse events are provided in Table 6.

From the pre-intervention period to the post-intervention period, we found that implementation of Patient and Family Centered I-PASS was associated with a 45.6% reduction in the rate of overall AEs (per 1000 patient-days), from 34.0 (95% CI, 26.4-43.7) to 18.5 (13.3-25.6) \( p=0.002 \). The intervention was also associated with a 37.7% decrease in preventable AEs (also known as harmful errors) from 20.7 (15.3-28.1) to 12.9 (8.9-18.6) \( p=0.01 \). Non-preventable AEs also decreased from 12.6 (8.9-17.9) to 5.2 (3.1-8.8) \( p=0.003 \).

The overall medical-error rate (i.e., the sum of harmful errors and non-harmful errors) did not change between the pre- and post-intervention periods (41.2 [31.2-54.5] vs 35.8 [26.9-47.7], \( p=0.21 \)) (Table 7). This result was likely driven by the fact that non-harmful errors (20.0 [13.2-30.2] pre- vs. 22.0 [15.1-32.1] post, \( p=0.50 \)) did not change pre- vs post-intervention, as harmful errors (also known as preventable AEs, rates given above) significantly decreased post-intervention. Notably, given the utility of family safety reporting, all of these numbers include family safety reports.
Table 6. Examples of Validated Medical Errors and Adverse Events.

<table>
<thead>
<tr>
<th>Non-harmful errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 yo admitted for leg pain, historical information in care plan inaccurately listed patient as having sickle cell anemia.</td>
</tr>
<tr>
<td>14 yo with severe cerebral palsy, blood cultures not obtained as directed when patient spiked a fever.</td>
</tr>
<tr>
<td>11 yo with cystic fibrosis exacerbation, dose of antibiotics missed (8-hour delay).</td>
</tr>
<tr>
<td>1 wk old infant with jaundice accidentally received an extra dose of vitamin D following a miscommunication on transfer between two units.</td>
</tr>
<tr>
<td>3 yo with neurological abnormalities and gastrostomy dependence whose flow sheet had been set for the incorrect age (5-12 year) causing risk for improper documentation.</td>
</tr>
<tr>
<td>2 mo with congenital heart disease who was, contrary to the plan, given a 50cc bolus feed instead of planned very gradual 5 ml/hr advance.</td>
</tr>
<tr>
<td>6 yo with metabolic disorder on a special metabolic formula received 6 bottles of incorrect metabolic formula missing a key ingredient before the error was recognized.</td>
</tr>
<tr>
<td>9 yo with lymphadenitis experienced delay in vancomycin administration due to pump failure.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preventable adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 mo with suspected mitochondrial disorder experienced a delay in therapy to address vomiting, low albumin, and elevated PTT due to lost blood samples</td>
</tr>
<tr>
<td>3 mo with congenital heart disease had nasopharyngeal airway inadvertently inserted into esophagus, and experienced desaturations</td>
</tr>
<tr>
<td>4 yo admitted with history of drop attacks and seizures (also with a history of vertigo consistently before events), fell and hit head after had a seizure while being transferred from wheelchair to chair</td>
</tr>
<tr>
<td>17 yo with inflammatory bowel disease flare who had a 2-day delay in pain treatment service consultation, after which patient ultimately required a narcotic drip for pain control.</td>
</tr>
<tr>
<td>3 mo on parenteral nutrition for failure to thrive who experienced hypoglycemia requiring glucose injection due to delayed recognition of TPN pump malfunction.</td>
</tr>
<tr>
<td>2 mo admitted for fever and upper respiratory symptoms who contracted norovirus while in the hospital.</td>
</tr>
<tr>
<td>2 mo with feeding intolerance and failure to thrive on NG feeds experienced failure to gain weight because incorrect volume of feeds were being given.</td>
</tr>
<tr>
<td>16 yo with chromosomal abnormality, seizure disorder who developed skin breakdown from oxygen tubing.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-preventable adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>10mo with urosepsis, delay in drawing follow-up labs and correcting electrolyte disturbances due to difficult stick.</td>
</tr>
<tr>
<td>12yo on chemotherapy with elevated glucose due to steroids.</td>
</tr>
<tr>
<td>16yo with anal abscess and immunodeficiency, who developed anaphylaxis on immunotherapy (no history of prior reaction).</td>
</tr>
<tr>
<td>8yo with Chiari malformation who developed C. difficile colitis following surgical procedure.</td>
</tr>
<tr>
<td>6yo with bone marrow disorder had IV infiltrate while out on pass with family.</td>
</tr>
<tr>
<td>3 yo with complicated pneumonia requiring chest tubes who developed chest tube clog with leak.</td>
</tr>
<tr>
<td>13 yo s/p endoscopic sinus surgery who developed post-operative emesis with narcotics for which ondansetron was required.</td>
</tr>
<tr>
<td>12 yo with pneumonia developed respiratory depression and oversedation from narcotic administration, requiring narcan administration.</td>
</tr>
</tbody>
</table>
Top-box ratings for 6 of 25 components of family-reported experience improved significantly between the pre- and post-intervention periods. Specifically, there were improvements in the percentage of parents reporting top-box (selecting the topmost Likert scale option, e.g., “excellent”) scores for understanding of what was said on rounds (53.9% pre-intervention vs. 62.8% post-intervention, p=0.03), receipt of written updates (15.6% vs. 33.7%, p<0.001), and understanding of written updates (46.5% vs. 57.9%, p=0.04) (Figure 8). Several elements of family experience linked to communications with nurses also improved significantly following implementation of the intervention, such as shared understanding of the care plan (55.3% vs. 65.4%, p=0.02), and whether nurses addressed concerns (61.2% vs. 70.2%, p=0.02) and made family members feel a part of the healthcare team (63.2% vs. 70.7%, p=0.04). No
elements of family experience worsened significantly between pre- and post-intervention cohorts.
Changes in rounds process data before and after implementation based on: (A) real-time structured direct observations of rounds and (B) post-hoc analyses of audiorecordings of a subset of rounds observations. After implementation of our intervention, frequency of family-centered rounds, nurse and family engagement on rounds, and provision of written summaries to families significantly increased, as did families expressing concerns at the start of rounds and synthesizing (i.e., reading back) key action items and contingency plans. Families reporting illness severity improved but not significantly. Effective use of plain language by providers on rounds was unchanged.

* P<0.05
† Top-box = 5, “Nurse present and paying attention to rounds. Answers questions, asks questions, and speaks up to fill in missing details and correct misinformation without prompting.”
‡ Top-box = 5, “Family completely engaged in rounds. Answered questions, asked questions, and spoke up to fill in missing details and correct misinformation without prompting.”
§ Top-box = 3, “Yes, completely.”
¶ Top-box = 4 “To a great extent.”
Structured Observation of Rounds (secondary outcome)

Real-time structured direct observations of rounds indicated that FCRs (as opposed to rounding in a non-FCR-manner) occurred more frequently post-intervention (72.2% of 305 patients observed on rounds vs. 82.8% of 347 patients observed on rounds, p=0.02), as did the provision of written summaries to families (17.8% vs. 53.6%, p<0.001). We additionally found that family engagement (55.6% vs. 66.7%, p=0.04) and nurse engagement (20.4% vs. 35.5%, p=0.03) on FCRs improved significantly following implementation of the intervention (Figure 9A). Frequency of teaching on rounds (73.4% vs. 72.4%, p=0.78) and average rounds duration (8.5 vs. 10.2 minutes per patient, p=0.13) did not significantly change between the pre- and post-intervention periods.

Post-hoc analyses of FCR audio recordings indicated that frequency of adherence to key communication behaviors improved post-intervention, with increased levels of parents expressing concerns at the start of rounds (18.2% vs. 37.7%, p=0.03) and completing synthesis (4.7% vs. 26.5%, p=0.02) on rounds (Figure 9B). Family reporting of child’s illness severity (e.g., better or worse) on rounds trended upwards but did not increase significantly (28.8% vs. 43.5%, p=0.08). Effective use of plain language on rounds did not change significantly (28.8% vs. 34.7%, p=0.36).
Figure 9. Sources of Medical Errors and Adverse Events. Incidents validated through two-step methodology. Adapted from “Families as Partners in Hospital Error and Adverse Event Surveillance,” by Khan et al., 2017, JAMA Pediatrics, 171(4), 372-381.
Shared Understanding (secondary outcome)

Initial analyses indicate that mean concordance ratings for shared understanding between parent, nurse, and physician did not significantly change from the pre-intervention to post-intervention period. Mean shared understanding (on a scale of 1=5, with 1=not at all agree, 5=completely agree) between parents and nurses about the overall medical plan for hospitalization went from 3.45 (SD 1.20) pre-intervention to 3.37 (1.29) post-intervention (p=0.60). Mean shared understanding between parents and physicians about the overall medical plan for hospitalization went from 3.28 (1.27) pre-intervention to 3.51 (1.24) post-intervention (p=0.14). Mean shared understanding between nurses and physicians about the overall medical plan for hospitalization went from 3.52 (1.21) pre-intervention to 3.70 (1.20) post-intervention (p=0.23).

V. Results from Subpopulation Analysis of Family-Reported Errors Using Pre-Intervention Data Only from the First 4 Study Sites

Sample Characteristics

In the subpopulation analysis of the first 4 study sites (using pre-intervention data only), a total of 746 parents (95.4% of those approached), 146 nurses (98.6%), and 207 resident-physicians (95.4%) consented to participate, and 717 family members completed 763 FSIs, while 77 residents completed 284 post-shift provider event reporting surveys. The data from all residents rotating through these first 4 sites in the pre-intervention period were included. Of the family members that provided consent, median (interquartile range) age was 32.5 (26-40) years; 380 (53.0%) were non-white; roughly half had attended college (53.0%); and the majority were female (78.9%) and English-speaking (84.1%) (Supplementary Table 1).

Family-Reported Safety Incidents

This subanalysis of FSIs from pre-intervention data only from the first 4 study sites revealed a total of 255 family-reported incidents. These incidents were reported by 185 parents (25.8%). Among these 255 incidents, 132 (51.8%) were classified as safety concerns, 102 (40.0%) as non-safety-related quality concerns, and 21 (8.2%) as other concerns. Of those
classified as safety concerns, 97 occurred on study units, while 35 occurred outside of study units and were consequently excluded from further analyses. Following two-step review, 50 of the family-reported safety concerns were confirmed as medical errors (17 non-harmful medical errors) and/or (22 preventable AEs) AEs (11 non-preventable AEs). Family reports included 13 otherwise unidentified medical errors and 8 otherwise unidentified AEs, including 7 preventable AEs. Medical errors and AEs uniquely reported by parents included delay in diagnosis and multiple needle sticks, inadequate suctioning, and side-effects from medication, accordingly.

These family-reported incidents subsequently underwent the same two-step validation as incidents detected by any source.

**Validated Errors and AEs**

Upon two-step validation of all errors and AEs collected by any source (family-reported or otherwise), we detected a total of 179 validated medical errors and 113 validated AEs overall (using pre-intervention data only from the first 4 study sites). Parents reported 21.8% (n=39) of these 179 validated medical errors (10.6% uniquely and 11.2% in combination with another source) and 29.2% (n=33) of these 113 validated AEs (7.1% uniquely and 22.1% in combination with another source) (Figure 10).

**Error/AE Rates Without vs. With Family-Reporting**

In this subanalysis of pre-intervention only data from the first 4 study sites, we found that errors (per 1000 patient-days) were 15.5% higher with family-reporting than without (45.9 vs. 39.7, p<0.001). AEs were 9.8% higher with family-reporting than without (28.7 vs. 26.1, p=0.003) (Figure 11).
Family-Reported vs. Provider-Reported Errors and AEs

In this subanalysis of pre-intervention only data from the first 4 study sites, we found that family-reported rates of medical errors and AE were equivalent to provider-reported rates. Families reported 10.0 medical errors and 8.5 AEs per 1000 patient-days, while providers similarly reported 12.8 (p=0.25) and 6.2 (p=0.20) errors and AEs, respectively (Figure 11).

Family-Reported vs. Hospital Incident Report Rates of Errors/AEs

Among sites with available hospital incident report data (3 of the 4 subanalysis sites), hospital incident reports comprised 5% (n=5), while family reports comprised 23% (n=25) of errors detected through all sources (n=111). Hospital incident reports comprised 10% (n=7), while family reports comprised 28% (n=20) of AEs detected through all sources (n=71).
Family-reported error rates (per 1000 patient-days) across these sites were 5.0-fold (8.7 vs. 1.7, p<0.001) higher than hospital incident report rates, and family-reported AE rates were 2.9-fold (6.9 vs. 2.4, p=0.02) higher than hospital incident report rates (Figure 11). Examples of errors and adverse events by reporting source are listed in Table 8.

| Table 8. Examples of Errors and Adverse Events by Reporting Source. |
|-------------------------|--------------------------|
| **Error**              | **Adverse Event**         |
| **Family-Reported Only** |                          |
| Toddler with Kawasaki disease whose diagnosis of pleural effusion and pulmonary edema and treatment with furosemide was delayed by >12 hours despite mother reporting to staff rapid breathing and an unusual sound coming from chest. | Infant with bronchiolitis requiring ICU admission for high flow nasal cannula, who on transfer back to unit was found by parent to be vomiting, choking, and having difficulty breathing due to how swaddler was wrapped around neck. Nursing staff did not suction as requested by the family. |
| **Clinician-Reported Only** |                          |
| Teenager with cystic fibrosis presenting with CF exacerbation who received a bolus of Dextrose 5% + 0.9% Sodium Chloride + KCl 20 mEq/L despite nurse raising concerns to overnight resident that creatinine levels were elevated. | School-aged child with history of Carnitine-acylcarnitine translocase deficiency deficiency presenting with pancreatitis whose pain medication was delayed due to an inappropriate rate of hydromorphone ordered for patient-controlled analgesia. |
| **Reported by Both Family and Clinician** |                          |
| Teenager with inflammatory bowel disease on ketamine drip for pain control who received 3-fold the appropriate rate of medication due to equipment failure. | Toddler admitted with fever and dehydration presenting with *Streptococcus*, adenovirus, and coronavirus infection who experienced a >10 hour delay in the ordering of maintenance IV fluids after family reported decrease oral intake and urination, resulting in symptomatic dehydration, including tachycardia and dry mucus membranes. |

*Adapted from “Families as Partners in Hospital Error and Adverse Event Surveillance,” by Khan et al., 2017, JAMA Pediatrics, 171(4), 372-381.*

**Predictors of Family-Reported Errors and AEs**

Bivariate predictors of family-reported errors included parent/caregiver proficiency in written and spoken English and higher parent education, as well as patient age and ≥1 CCC.
Multivariate predictors of family-reported errors included older parent age and higher parent education, along with younger patient age and ≥1 CCC.

Bivariate predictors of family-reported AEs include higher parent/caregiver education and greater family presence during hospitalization, as well as ≥1 CCC. Multivariate predictors of family-reported AEs included higher parent education and ≥1 CCC.

VI. Discussion

**Context for Study Results:** In a 7-center study, we found that implementation of a structured patient and family-centered communication intervention emphasizing family engagement and health literacy – “Patient and Family Centered I-PASS” – was associated with a 38% reduction in harmful errors and 46% decrease in overall AEs. The intervention included: (1) a structured high-reliability communication framework to better engage patients and families on FCRs, organized around the I-PASS mnemonic and bolstered by principles of health literacy, bidirectional communication, and inter-professional and nurse engagement; (2) a written daily summary of FCRs for families in I-PASS format (the “Rounds Report”); (3) a learning and training program for families and professional team members with interactive learner-specific workshops; and (4) strategies to support teamwork and implementation of the intervention (Figure 4).

Family engagement on rounds improved significantly following implementation of the intervention, as did multiple aspects of family experience with communication. Moreover, improvements in safety, experience, and quality of communication on rounds occurred without a significant increase in rounds duration, or a decrease in the amount of teaching that occurred on rounds. We additionally found that by integrating family safety reporting into the two-step (nurse review followed by 2-physician review, Figure 5) systematic safety surveillance typically used in research, medical errors and AEs that we would have previously missed were reported by families and included in our analyses. Furthermore, parents identified comparable rates of medical errors and AEs as healthcare providers and five times more errors and three times more AEs than the hospital incident reports used operationally in most hospitals. 57

This study addresses several limitations of our single-center pilot Nighttime Communication Study, in which we found improvements in parent and provider experience as
well as shared understanding following implementation of a bundle of family-centered, inter-professional nighttime communication interventions.\textsuperscript{49} We incorporated refinements to more effectively engage family members and nurses and better integrate the intervention into physician and nurse workflow. We focused on communication during the entire 24-hour cycle (particularly during morning rounds), not just nighttime communication. Moreover, we conducted a subpopulation analysis and found that family safety reporting increased overall error detection by 16\% and AE detection by 10\%, compared to what was typically considered the highest yield methodology in safety surveillance research, which typically excludes patients and families. Consequently, our study directly measured safety outcomes pre- and post-intervention using a novel expanded active surveillance methodology that incorporated input from families.\textsuperscript{63}

**Generalizability of the findings:** Prior studies have indicated that improved teamwork is associated with improved patient outcomes.\textsuperscript{64,65} However, there is relatively limited empirical evidence on the relationship between family-centric care and patient safety.\textsuperscript{50,51} A recent single-site adult ICU study showed that implementation of a multifaceted intervention emphasizing patient and caregiver engagement, communication, and information technology was associated with decreases in harmful errors and improvements in patient and provider experience.\textsuperscript{50} Our study expands on this work by indicating applicability beyond an adult critical-care setting and suggests the ability to generalize a family-centered communication program across multiple sites. Moreover, concepts of structured communication and adherence to health literacy principles that serve as the core of our intervention are likely to be applicable across settings. Our study provides evidence of generalizability to pediatric inpatient units in academic hospitals. Further study is warranted to confirm generalizability in other types of clinical units and non-pediatric hospitals.

In our subpopulation analysis of pre-intervention only data from the first 4 study sites, we found that family safety reporting was a valuable source of safety data. Although our study focused on pediatric patients, family and caregiver reporting may be broadly applicable for other patient populations where patients may be unable to fully advocate or speak for
themselves (e.g., ICU patients, geriatric patients, etc.). Additional research is required to confirm generalizability and feasibility in these and other settings.

**Implementation of study results:** Physician,66–68 nursing,69 and family70,71 advocacy organizations have called for improvements in the family-centeredness and quality of care. For instance, FCRs have been advocated by the IOM, the AAP, the ACGME, and the SPN.39,40 The communication techniques FCRs espouse have been endorsed by patient and family advocacy groups.32 However, there is relatively little research on FCRs and safety, or on FCR processes and safety and patient/family experience.41 Our intervention to improve family-centered communications and patient safety – “Patient and Family Centered I-PASS” – was directly responsive to these calls and fills these gaps in the literature. In this study, implementation of a bundle of communication interventions targeting FCRs and inter-professional hospital team communications across seven sites was successful in that it was associated with a 38% reduction in harmful errors and 46% decrease in overall adverse events. Additionally, family engagement on rounds improved significantly, as did multiple aspects of family experience with communication.

To facilitate future implementation of this successful program, we are finalizing a Patient and Family Centered I-PASS Mentored Implementation Toolkit that we will publish in MedEdPORTAL and hope to distribute, with additional support, through the Mentored Implementation methodology and PRIS network. The Toolkit will provide a summary of our findings and will describe the fundamental building blocks of a successful program. It will include details about our training, FCRs, and other communication processes, process measures, and details of how the program was implemented across sites using the Mentored Implementation methodology. Lessons learned in our study both from sites where adoption was optimal and sub-optimal will be included, as will principles that other programs should consider to maximize the probability of successful adoption of the program. We believe that actively disseminating results will lay the groundwork for ensuring that our program will be successfully adopted widely, and that implementation efforts will inform improvement efforts.
Additionally, our study group has an extensive track record of partnering with PRIS and SHM, with whom we hope to work to carry out future dissemination and implementation efforts.

We will continue to disseminate our findings directly to patients and family through multiple avenues, including the lay press, social media, blogs, patient advocacy networks, family advisory councils of our parent partners and their networks, and national organizations (including the Beryl Institute and the Patient and Family Centered Care Conference). We will also continue to actively engage our parent partners in these dissemination efforts.

**Implementation of Prior I-PASS Resident Handoffs**

Our group is currently completing an I-PASS handoff dissemination and implementation project in 32 community and academic hospitals based on results from our prior I-PASS Resident Handoff Study.34

Preliminary analyses of the first 16 sites demonstrate significant increases in adoption of I-PASS processes to a level (70%) that exceeded what we achieved in the prior multi-center I-PASS Resident Handoff study, as well as a significant reduction in mean rate of staff-reported harms (15% vs. 4% of patients per month experiencing a major harm due to a handoff failure).72 These findings demonstrate our ability to disseminate and implement a rigorous communication improvement program with important patient safety implications in diverse settings, and collaborate successfully with PRIS and the SHM Mentored Implementation Program.

**Future Directions**

We hope to embark on a similar process in the present Patient and Family Centered I-PASS Study to likewise disseminate and implement our successful Patient and Family Centered I-PASS intervention across diverse pediatric centers. Based on the promising nature of the Patient and Family Centered I-PASS intervention, as well as our successful dissemination and implementation of our prior Resident Handoff Study using the SHM Mentored Implementation Program, broad dissemination of the Patient and Family Centered I-PASS intervention has the potential to directly improve patient safety and family experience across a wide range of clinical
settings. Moreover, improving uptake of sub-optimal elements of the intervention (e.g., nurse engagement and use of plain language) will enable us to better improve the quality of information exchange between physicians, nurses, and families and consequently further improve patient safety, as well as hospital experience and communication. Additionally, as concepts of inter-professional communication, teamwork, and adherence to health literacy principles are thought to be universal, our intervention may be adaptable to a wide range of hospital settings, such as adult, geriatric, and critical care settings.

Our initial approach to data collection in this study was intentionally rigorous in order to provide a sound evidence-base for the validity of our findings. However, we have had success in the past when transitioning from initial research to subsequent dissemination projects by using a systematic and rigorous, but far less labor-intensive methodology to capture safety events that is more widely reproducible and generalizable across hospitals. For instance, in the Mentored Implementation 32-hospital dissemination project of the original 10-center I-PASS Resident Handoffs Study, we used a far less labor-intensive surveillance methodology that demonstrated a >40% reduction in AEs\textsuperscript{73} (a rate comparable to the >30% reduction in AEs we detected using more intensive safety surveillance methods in the original 10-center study).\textsuperscript{34} The results of Patient and Family Centered I-PASS can similarly be generalized and reproduced as we disseminate it to additional sites using less labor-intensive but still rigorous safety measurement methods.

Many individuals were involved in the initial process of thoughtfully developing and refining our initial Patient and Family Centered I-PASS intervention. However, at each given site, implementing the intervention required the buy-in and support of a much smaller group of ~6-8 key individuals. This group generally included, for instance, the site lead, program director, parent champion, nurse champion, hospitalist director, and faculty champion. Thus, future dissemination of our intervention to a wide range of hospitals and settings should be feasible and practical, if each site is able to recruit such a group of ~6-8 key individuals.

**Subpopulation considerations:** Our subpopulation analysis of pre-intervention only data from the first 4 study sites suggested the importance of including family safety reporting in order to
accurately capture hospital safety. We found that errors and AE rates were significantly higher with family safety reporting than without. Families reported error incidents at rates similar to providers and ~5 times (medical errors) and ~3 times (AEs) higher than hospital incident reporting rates. More educated parents and parents of children with CCCs had higher rates of family-reported errors. Although family error reporting is promising, particularly for medically complex children, the best method for operationalizing family safety reporting in hospitals for quality improvement and research safety surveillance remains to be seen.

Study limitations: Our study has several limitations. First, the study design limits our ability to definitively establish a causal link between the intervention and error rates or other outcomes. Rigorous studies of quality and safety improvement interventions are often not amenable to classic randomized trial designs. Because we believed our intervention was highly unlikely to harm patients, our lack of equipoise precluded patient-level randomization or a cross-over design. We opted against a step-wedge design for pragmatic reasons, as a step-wedge design would have required us to collect data continuously at all 7 sites, rather than in a staggered fashion for 3 months pre- and 3 months post-intervention at each site (see Timeline in Figure 2). This magnitude of data collection was beyond our resource constraints. Additionally, there was logistical difficulty of randomizing the timing of introducing a complex intervention involving physicians, nurses, and families and ensuring that no simultaneous co-interventions were occurring that might confound results. While our pre-post intervention design is at risk of confounding due to secular trends, prior research strongly suggests that a change in AEs of the magnitude we observed is unlikely in such a short period due to secular trends alone. Additionally, given we observed simultaneous improvements in patient safety outcomes, family experience, and rounds communication processes as hypothesized, and because findings were derived from data gathered across seven sites (lowering the likelihood that changes were due to unmeasured site-specific confounders), we believe it is likely the improvements seen were related to the implementation of the intervention.

Second, we cannot be sure that our findings would be reproducible in other types of clinical units or non-pediatric hospitals. However, as above, concepts of structured
communication and adherence to health literacy principles that served as the core of our intervention are likely to be applicable to other settings. Furthermore, although unit selection in our study might limit generalizability, systemic interventions such as ours must consider and account for the nuances of an intervention setting, given that proper unit selection and preparation is an essential part of the intervention.

Third, medical error/AE classification is a complex and imperfect process that could have resulted in mistakes in classifying AEs and medical errors.\textsuperscript{34,43} However, the reliability (i.e., kappa) of our ratings was similar to or better than prior studies.\textsuperscript{34,43} Additionally, our understanding of the preventability of AEs is constantly changing and interpretation of errors and AEs is not always crystal clear. Moreover, it is unlikely that primary reviewer bias could explain the significant differences in rates of AEs observed given that final error and AE classifications were ultimately made by secondary reviewers blinded to pre- vs. post-cohort status only after post-intervention data collection was complete. Additionally, if our findings were primarily explained by primary reviewer bias, and our intervention was in reality ineffective, we would expect fewer “soft-call” non-harmful errors in the post-intervention period, as biased primary reviewers may be less likely to include events that they were uncertain about in the post-intervention period. Instead, we found no change in non-harmful errors in both periods. It is likely in fact that this lack of change in non-harmful errors pre- vs post-intervention explained why overall medical error rates were unchanged (since the subset of errors that were harmful significantly decreased post-intervention).

Finally, although our instruments for assessing safety have been validated in other patient populations and settings, those for measuring experience and communication were novel instruments that have not been validated outside of this study, but which generally should good reliability statistics, such as Cronbach’s alpha.

**Future research:** Our finding that non-preventable AEs decreased was unexpected. Physician-reviewers were instructed to classify AEs as preventable only when incidents were clearly caused by a failure in a care process. Therefore, it is possible that we may have been overly conservative in judging preventability of patient harm. However, it is generally accepted within
the patient safety field that our understanding of the preventability of AEs is constantly changing. Hospital-acquired central line infections, for instance, were once generally considered to be non-preventable because there is typically no observable error (e.g., break in sterile technique) that results in infection. We now know, however, that interventions can prevent nearly 80% of central line infections. In a similar way, it is conceivable that by improving inter-professional communications or better engaging families and nurses as essential members of the care team, for instance, our intervention prevented or avoided some AEs from occurring through mechanisms not yet apparent to us. Additional research is required to further explore this possibility.

Other areas of future study including examining the impact of this intervention on children with medical complexity, further evaluating and engaging adolescents in FCRs, and return on investment analyses of our program. In addition, further work is warranted to engage low English proficiency families in FCRs and examine the resulting impacts on safety and experience. Families can also be more involved in QI observations to improve and provide feedback to teams on FCR performance. Families can also participate in future efforts to collect data as this will further enhance stakeholder engagement and may make respondents more likely to share impressions openly with other families.

Regarding our subpopulation analysis of family-reported errors, further research is needed to determine the best method for operationalizing family safety-reporting in hospitals, and to assess its feasibility, success, and safety implications.
VII. Conclusions

In sum, we found that implementation of Patient and Family Centered I-PASS – a multifaceted, structured patient- and family-centered communication intervention designed to enhance patient and family engagement, inter-professional communication, and adherence to health literacy principles – was associated with a marked reduction in preventable and non-preventable AEs as well as improvements in family experience and hospital communication processes. These improvements occurred without a significant increase in the duration of rounds or a reduction in the amount of teaching occurring during rounds.

We additionally developed and studied a novel family safety reporting methodology that suggests families are useful partners in hospital safety reporting. We performed a subpopulation analysis of pre-intervention only data from the first 4 study sites. We found in this subanalysis that families reported events not otherwise detected or documented, and that integrating family safety reporting allowed us to better detect medical errors and AEs than if we were to use either the voluntary hospital incident reporting systems currently employed by most hospitals or the systematic safety surveillance used in research. We therefore integrated family safety reporting into all subsequent error and AE analyses.

Our study supports the inclusion of family-reporting in safety surveillance and provides important evidence that improved communication between healthcare providers and patients and families could be an important means to reducing failures in care processes and incidents of patient harm.
VIII. References


IX. Acknowledgements

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X. Related Publications

