AHRQ Grant Final Progress Report

Title of Project: Engaging Families in Bedside Rounds to Promote Pediatric Patient Safety

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1. Structured Abstract

Purpose: To leverage family engagement during family-centered rounds (FCR) to improve safety for hospitalized children.

Scope: This project develops, implements, and evaluates an intervention to foster family engagement during FCR.

Methods: Systems engineering methods were used to develop and implement the FCR Checklist (intervention). To evaluate impact, survey data and 673 FCR videos were collected from 298 families. Coders assessed videos for performance of eight checklist elements and family engagement. Parent perceptions of safety climate were assessed with the Children's Hospital Safety Climate Questionnaire. Random effects and linear regression models were used.

Results: The intervention significantly increased the number of checklist elements performed (β=1.2, $p<0.001$). Intervention rounds were significantly more likely to include asking the family (OR=2.43, $p=0.05$) or healthcare team (OR=4.28, $p=0.002$) for questions and reading back orders (OR=12.43, $p<0.001$). Compared to usual care, intervention families did not engage more or report better safety climate. Performance of specific checklist elements was significantly associated with changes in family engagement and improved perceptions of safety. For example, reading back orders was associated with greater family engagement in decision making. Asking the family for questions was associated with more positive views of the safety of handoffs and transitions.

Conclusion: FCR Checklist implementation significantly increased performance of key FCR elements. Performance of checklist elements was associated with changes in family engagement and improved perceptions of safety. The intervention has the potential to impact family engagement and safety for pediatric inpatients.

Key Words: healthcare system redesign; patient-centered care; family-centered rounds; checklist; communication; patient safety

2. Purpose

The overarching goal of this research is to enhance family engagement during family-centered rounds (FCR, also known as bedside rounds) to improve the safety of care provided to hospitalized children. The following specific aims support this goal:

1. To assess the effect of family engagement during FCR on safety for hospitalized children

2. To implement and evaluate an intervention addressing common barriers and facilitators of family engagement during FCR

3. To assess the impact of post-intervention family engagement on the safety of care for hospitalized children

This research was designed to be tightly aligned with the priorities of AHRQ's Patient Safety portfolio, addressing two important topics therein—"the role consumers can play and how they can contribute to making care safer" and "addressing the impact of human performance and working conditions on patient safety." Furthermore, children are a priority population and are especially vulnerable to medical error, making this project well suited for AHRQ's Patient Safety portfolio. The findings are directly responsive to AHRQ's budget priorities by identifying, implementing, evaluating, and disseminating effective practices to enhance patient safety and by

assessing ways to make system-level changes to improve patient safety. Overall, our findings suggest that the FCR Checklist intervention developed in this work results in higher-quality FCRs that better engage the families of pediatric patients and enhance their sense of safety during hospitalizations.

3. Scope
3.A. Background and Context
Children are highly vulnerable to medical errors, in part due to their inability to participate in the communication tasks necessary for medical decision making or to recognize and report adverse events.[1] The need for patient or family engagement in the care process as a mechanism for improving the quality and safety of care is widely accepted by experts from clinical medicine as well as by agencies charged with ensuring the health of the population.[1-5] FCRs, defined as "interdisciplinary work rounds at the bedside in which the patient and family share in the control of the management plans…," are suggested as the standard for inpatient pediatric care.[6] Despite theoretical promise, no prior evaluations assessed the effect of FCR on engagement or safety for hospitalized children nor addressed the barriers and facilitators of engaging families during FCR.

Although the premise that family or patient engagement in care can improve safety has been endorsed by many leaders in the field,[3, 4, 7-9] questions about the evidence base for this strategy have been raised. A growing body of literature suggests patients are willing to participate in this way,[10, 11] but they may exhibit limited self-efficacy around preventing errors and are often reluctant to undertake recommended steps to reduce errors.[10-12] In addition, healthcare team (HCT) members' acceptance of family engagement during FCR has met with some skepticism, including concerns such as decreased efficiency of rounds,[13] breach of confidentiality for patients,[13] confusion/anxiety for families,[14] and decreased comfort among team members.[14-16]

This project addresses critical gaps by evaluating the impact of an intervention to foster family engagement during FCR. Because any intervention is ultimately ineffective if solutions are not developed within the context of the work system, accepted systems engineering methods were used to develop and implement this project's intervention to fit the clinical context. Ultimately, this work directly addresses the question of whether family engagement in FCR can be leveraged to improve safety. By intervening to foster family engagement, this work aims to inform interventions and policies that improve pediatric patient safety and support family engagement in children's healthcare.

3.B. Setting and Participants
The study was conducted at a 61-bed, academic children's hospital in the Midwest where FCRs are conducted daily with the family and the patient's HCT members. Overall, 298 families of children hospitalized on one of the four inpatient services (two general pediatric hospitalist, one pulmonology, and one hematology/oncology service) from October 2010-May 2011 (pre-intervention) and October 2012-May 2013 (post-intervention) participated in our evaluation of the FCR Checklist (the study's intervention), having their FCRs video-recorded and completing surveys.

The study included both women and minorities. No racial/ethnic minorities were specifically excluded. Over 80% of parents were female, and 50% of children were female. About 10% of children or parents self-identified as a minority. Because our study received a waiver of written informed consent for the HCT members, no enrollment data existed for nurses or physicians.

In addition, 37 children, parents, and HCT members participated in stimulated recall interviews to develop the intervention. Also, 172 medical students were surveyed about their views of FCR and barriers and facilitators to their learning during FCR. Detailed characteristics of the participants for all our work are found in our papers or in the results section of this document. The University of Wisconsin-Madison Health Sciences Institutional Review Board approved this research.

4. Methods

4.A. Development and Implementation of the FCR Checklist Intervention (Aim 2)

4.A.1 Design and Sample

To inform the development and implementation of the study's FCR Checklist intervention, we used accepted human factors engineering principles, such as ensuring stakeholder engagement and employing stimulated recall techniques, commonly used in industry.[17] To obtain stakeholder engagement, a Family-Centered Rounds Steering Committee composed of 10 leadership level stakeholders met every 4 months throughout the project period. In addition, an Intervention Implementation Team composed of parents, physicians, and nurses from our children's hospital met six times during the intervention's development and implementation.

Stimulated recall interviews were used to identify key elements for the FCR Checklist. These interviews were conducted with 22 HCT members and 15 parents and children from four inpatient services. Participants were drawn from a larger study, in which English-speaking patients and/or families admitted to one of four inpatient services (n=2 hospitalist, 1 pulmonary, and 1 hematology/oncology) and their HCT members were enrolled and their FCR were video recorded. A purposive sampling technique[18, 19] was employed to select interviewees that represented the various groups of stakeholders of rounds, including parents, children, attending physicians, resident physicians, medical students, and nurses. For child interviews, we restricted selection to those age 8 to 17 years in an attempt to focus on children of a sufficient age to understand the process and provide feedback.

Once possible strategies to improve family engagement in FCR were identified from these interviews, stakeholders were engaged in prioritizing these possible strategies, choosing which strategies to implement and then creating the final FCR Checklist product. Stakeholder engagement occurred through meetings and surveys. In addition, to ensure consideration of the issues that learners face during FCR, researchers also surveyed 172 third-year medical students about their views of FCR and barriers and facilitators to their training during FCR.

4.A.2 Data

Participants' FCR video recordings were selected for use in the interview process if (1) we recorded the full session at sufficient audio and video quality to support the stimulated recall analysis, (2) the family was willing to complete the stimulated recall interview, and (3) all persons appearing in the video had given consent to have the video used for this purpose. All interviews were conducted by trained researchers, who used the same semi-structured interview guide. The process consisted of two steps: (1) review of the video by the family or the HCT member and (2) discussion of work system barriers and facilitators of family engagement evident in the video. During each interview, the interviewee was asked to watch his/her own rounding video and to pause when noticing something that made it easy (facilitator) or hard (barrier) to engage the family. Every time the interviewee paused the video to describe what was noticed, the interviewer then asked follow-up, open-ended questions to solicit specific information that focused on strategies for enhancing family engagement during FCR. If the interviewee had not stopped the video by the halfway point, the interviewer would pause the video and review the instructions. After the interviewee had viewed and commented on the entire rounding video, an opportunity was offered to reflect on other factors that influence family engagement during rounds. All interviews were audio recorded.

To evaluate the potential impact of identified FCR improvement strategies, a survey was conducted with 134 FCR stakeholders (28 families, 31 nurses, 55 attending and resident physicians, and 20 medical students). To understand the potential feasibility of implementing specific strategies, a second survey was conducted with 82 FCR stakeholders (14 families, 13 nurses, 43 attending and resident physicians, and 12 medical students). Details about the surveys are published elsewhere.[20-22]

To understand medical student experiences with FCR, researchers surveyed 172 of 189 third-year students during pediatric clerkship rotations. Students reported frequencies of FCR concerns (14 items) and teaching experiences (17 items), with five response options (1 = never, 2 = rarely, 3 = occasionally, 4 = usually, 5 = always, dichotomized with "frequent" being usually or occasionally). Students also reported pre-clerkship and post-clerkship attitudes about FCR with four items on a 7-point scale (1 = strongly disagree, 7 = strongly agree).

4.A.3 Analytic Approach

Qualitative content analysis of interview transcripts was performed in an iterative process. Two research assistants reviewed the audio recordings and identified all instances related to strategies for improving family engagement during FCR. These assistants, under the supervision of a researcher, reviewed the coding process together, held consensus meetings, and cross-checked interviews for coding consensus. A researcher transcribed all strategy-related instances, which were then reviewed by two additional researchers. To ensure that all strategies remained conceptually similar within categories, the constant comparative method[23, 24] was applied to the coding process. A strategy-related instance could be coded under more than one strategy or category. Interviews and analysis occurred concurrently in an iterative process, informing each other. Thus, recruitment continued until we reached theoretical saturation.[25, 26] Analysis of the survey data regarding impact and feasibility of strategies identified from the interviews as well as medical student surveys included descriptive statistics and adjusted means or proportions. To explain medical student self-efficacy with FCR, researchers constructed measurement models via exploratory and confirmatory factor analyses. Composite indicator structural equation models evaluated what experiences influenced self-efficacy during FCR.

4.A.4 Limitations

Data are from a single academic children's hospital, which may limit generalizability. However, we found many similar barriers to engaging families during rounds as those published elsewhere.[14, 27] Because interview participation was voluntary, our interviewees were likely more engaged participants in general. Specifically, the viewpoints of engaged families and HCT members may not represent the viewpoints of those who are less engaged or supportive of FCR. We also did not enroll non-English-speaking patients and families, which is a potential direction for future research.

4.B. The Impact of the FCR Checklist Intervention on Family Engagement and Safety and How Safety Is Affected by Family Engagement (Aims 1 and 3)

4.B.1 Design and Sample

In a pre-post controlled design, two services were randomized to use the FCR Checklist developed for this study (details of this development are found in Section 5.A), and two other services delivered usual care. From 2010-2013, 673 FCR videos and survey data were collected from 298 families. From these videos, trained coders evaluated performance of eight FCR Checklist elements. Family engagement was assessed from the videos using standard coding schemes.[28-30] Parent perceptions of safety climate were assessed with the Children's Hospital Safety Climate Questionnaire,[31, 32] whereas parent's safety behaviors (medication safety and hand hygiene) were assessed by self-report. Random effects models were used to examine the intervention's impact.

To understand how family engagement in FCR influenced safety, regression analyses related survey data on parents' safety behaviors and scores on the Children's Hospital Safety Questionnaire to family engagement, as measured from the videos. In addition, videos were also used to understand whether and how FCR offer families the opportunity to participate in error recovery related to children's medications. This latter study described family-initiated dialogue about medications and HCT responses to this dialogue during FCR to understand the potential for FCR to foster safe medication use.

4.B.2 Data

Prior to the family's first FCR, 298 parents completed surveys of demographics, reason for admission, comorbidities, and prior hospitalizations. Child characteristics included child age, gender, and health status (single item, 5-point Likert). Parent characteristics included age, gender, race/ethnicity, and education (8th grade or less; 9th-12th grade but not high school graduate; high school graduate or equivalent; some college; bachelor's degree; graduate or professional degree). Hospitalization characteristics included the reason for hospitalization and length of stay, based on admit and discharge dates. A researcher video recorded each FCR during the child's stay (n=673 videos).

4.B.3 Measures

4.B.3.a FCR Checklist Element Performance

Pairs of trained coders evaluated FCR videos for performance of checklist elements, except for the element "Assess family preference for rounds," which was not evaluated because this often occurred before rounds and therefore was not always captured on video. Coders received 23 hours of training over 6 weeks, using a training manual and pilot videos, and then met monthly over 8 months to resolve areas of disagreement. Coders were blinded to control/intervention status, but they may have been able to distinguish between control and intervention after coding multiple videos. For stays longer than 7 days, seven videos were coded (admit day, day after admission, day before discharge, discharge day, and the 3 days marking ¼, ½, and ¾ of the duration of the stay).

4.B.3.b Family Engagement in Rounds

Family engagement was assessed from FCR videos using two reliable, validated coding schemes. Using the Roter Interaction Analysis System (RIAS), videos were assessed for the family's engagement in relationship building, information giving, and information gathering.[28, 33] To evaluate family engagement in decision making (proposing a plan, raising risks or benefits of a possible plan, or disagreeing with a proposed plan), coders applied a validated coding scheme developed by one of the collaborators.[29, 30] Talk was coded only for periods in which the HCT was present. Child and parent talk was summed to reflect family engagement. As with checklist element performance, seven representative videos were coded for stays longer than 7 days. To represent family engagement over the hospital stay, the counts of utterances or events for each communication task for each day of FCR were averaged.

Family engagement was assessed by a team of 20 trained, blinded coders, each of whom received a minimum of 20 hours of training, using a training manual and pilot videos. Subsequently, coders met at least monthly over 9 months to review areas of disagreement. Intercoder reliability was assessed by double-coding a random sample of FCR videos (93 videos [13%] for RIAS and 84 videos [12%] for engagement in decision making). Reliabilities were near perfect for relationship building, information giving, and information gathering (intraclass correlation coefficient>0.8) and were substantial for engagement in decision making (kappa>0.6).[34, 35]

4.B.3.c Pediatric Patient Safety

The Children's Hospital Safety Climate Questionnaire was used to assess parent perspectives of safety during the stay.[32] To develop and validate this measure, the research team began from the AHRQ Patient Safety Culture Survey,[36] adapting it to reflect domains that were visible to hospitalized patients or parents. Parents (n=172) were surveyed about perceptions of hospital safety climate (14 items representing four domains— overall perceptions of safety, openness of staff and parent communication, and handoffs and transitions). Domain scores were created by averaging item responses, which were on a 5-point Likert scale (1=strongly disagree, 5=strongly agree), with negatively worded items reverse scored. Confirmatory factor analysis indices suggested good model fit for safety climate domains. Additional details of this scale's development and validation are found in our publication and toolkit (available at https://www.hipxchange.org/CHSCQ).[31, 32]

In addition, we surveyed parents about behaviors related to hand hygiene and medication awareness, using items drawn from the literature[37, 38] as well as relevant Press Ganey items that were of interest to our Steering Committee of hospital leaders. Given the highly skewed distributions of these items and ceiling effects (e.g., over 90% of parents reported that HCT members always cleaned their hands) in our population, our study was underpowered to demonstrate impact of the intervention on these measures. Thus, we did not attempt to determine the impact of the intervention upon these outcomes.

To assess family-initiated dialogue about medications during FCR, trained coders sorted all family-initiated medication dialogue into mutually exclusive categories, reflecting place of administration, therapeutic class, topic, and corresponding HCT responses. HCT responses were coded to reflect intent, actions taken by the HCT, and appropriateness of any changes made to medication orders. Additional details of the development and implementation of this coding scheme are found in our publication.[39] Videos from the first 150 families enrolled (n=372) were used in this investigation.

4.B.4 Analytic Approach

All analyses of intervention impact were performed by originally assigned group. Descriptive analyses were performed, including proportions or means and standard deviations. Random effects linear or logistic regression models were used to assess the impact of the intervention on the number of FCR Checklist elements performed, the performance of each checklist element, family engagement, and parent perceptions of safety, as well as the associations of performance of the FCR Checklist elements (predictor) with family engagement. These models included a random intercept to account for the association in the repeated measures across the stay for a given patient. The association of checklist element performance with parent perceptions of the hospital's safety climate was assessed with linear regression. All models were adjusted for child age and health status, parent education, and length of stay. Results are presented as odds ratios (OR) or regression coefficients with 95% confidence intervals (CI). Significance was assessed at $p<0.05$.

This study was powered to detect small to moderate effect sizes ($0.2-0.3\sigma$) in family engagement, based on prior work.[29, 30] There were no prior data on which to base power calculations for the domains of the Children's Hospital Safety Climate Questionnaire. However, based on data collected before the intervention's delivery, our sample size provided 80% power to detect a 10% change in safety climate domain means.

In examining how family engagement in FCR influences pediatric patient safety, descriptive analyses, such as means and proportions, were undertaken. Linear regression analyses were used to understand how family engagement affected pediatric patient safety. Generalized estimating equations with the log link and robust standard errors were used to compare parent, child, and hospitalization characteristics for families who initiated medication dialogue to those of all families who attended FCR.

4.B.5 Limitations

First, as a single institution study, the findings may not generalize to children's hospitals broadly. Our study population has relatively few minority families and is better educated than the general population. Thus, we may under-represent the impact of the FCR Checklist for these families who may be especially likely to benefit, given they are often more concerned about the safety of healthcare.[40] In addition, our trial did not include non-English-speaking families, who may face unique challenges in participating in FCR. The FCR Checklist, however, does incorporate many of the recommendations for successful FCR with non-English-speaking Latino families.[41] Our measures of family engagement are counts of key family-centered care communication tasks but may not reflect the quality of communication as viewed by the families. Also, due to IRB requirements, we have limited data on those parents who refused to learn about the study or did not consent. Given that absent or sleeping parents constituted our most common reason for nonparticipation, our sample

might over-represent parents who were more concerned or children who were sicker than the general population of admissions. Last, because of survey length limitations, we did not collect data on concepts such as general beliefs about communication in healthcare encounters, the safety of healthcare, or prior experiences with medical error, all of which could influence outcomes.

5. Results
5.A. Development and Implementation of the FCR Checklist Intervention (Aim 2)
We used established systems engineering approaches to develop and successfully implement the intervention in this study—the FCR Checklist. The following describes results that informed the checklist's development and implementation.

From our qualitative analysis of the 37 stimulated recall interviews, 338 instances related to strategies for improving family engagement in FCR were identified and sorted into 21 categories. Using the Systems Engineering Initiative for Patient Safety (SEIPS) model, these categories were organized into two themes: the work system and process of FCR. Of the 21 categories, 12 were mentioned by both families (parents and/or children) and HCT members, and nine were solely mentioned by the HCT. Strategies for improving family engagement in FCR were found in all five elements of the FCR work system: people (size and composition of HCT), tasks (roles of HCT members), organization (timing, scheduling, and training of HCT), environment (location of FCR and positioning of HCT members), and tools and technologies (use of computers on FCR). In the interest of space, illustrative quotes from the interviews are not presented here but are published elsewhere.[42]

People. Both parents and HCT members referred to HCT composition as contributing to family engagement during FCR. Two seemingly contradictory strategies were proposed. Some interviewees suggested that a smaller HCT with members familiar to the family would be more engaging. Other interviewees stressed the need to involve different relevant disciplines (e.g., social worker, nutritionist, etc.) during FCR rounds.

Tasks. Both attending and resident physicians alike emphasized the importance of defining the role of each HCT member before rounding. Interviewees also suggested that these roles should be explained to families, ideally at admission.

Organization. Organizational strategies that can enhance family engagement during FCR included timing and scheduling as well as training. Some attending physicians, nurses, and parents suggested the need to consistently schedule rounds and to inform families and nurses of the schedule so that all parties could plan ahead. Some resident physicians and medical students recommended training of medical students on how to give a family-centered presentation using methods such as role modeling and practicing with the senior resident physician or in small groups.

Environment. Environment-related strategies addressed both the location of rounds and the position of the HCT in the patient room. Some interviewees suggested conducting rounds in patient rooms. Others suggested conducting rounds first in another location (e.g., hallway) with or without the family and then going to the bedside to round with the family. When conducting rounds in the patient room, some interviewees suggested that some HCT members (e.g., attending and senior resident physicians) could sit down with the family, with the rest of the HCT standing close to the family in a semi-circle.

Tools and technologies. Many HCT members discussed the use of computers during rounds. Some interviewees thought that conversation with families could be negatively affected by the use of computer and therefore suggested not using them in patient rooms. Alternatively, other interviewees considered computers a tool to facilitate the interaction between the HCT and families, such as showing X-rays or lab values. Several

interviewees suggested that computers should not be positioned to block eye contact between HCT members and families; therefore, only HCT members not presenting should use the computers.

Other strategies for improving family engagement in FCR related to the process of FCR, categorized into three phases: before, during, and after FCR. Many interviewees suggested that both the HCT and families need preparation before FCR began. HCT members suggested that medical students should collect up-to-date patient information and review this with the senior resident physicians in order to reach a consensus before starting FCR. To prepare families for rounds, parents and HCT members suggested that the HCT should orient families to the rounding process, build relationships with families, and ask for their permission and preferences regarding participation in rounds.

A number of strategies for improving FCR was suggested to occur during the actual rounds, with a specific focus on the beginning of rounds. Parents, children, and HCT members stressed the need to introduce HCT members by role and inform families to whom to direct questions. It was also suggested that parents introduce themselves to the team. Some interviewees recommended that the HCT explain the rounding process to families at this time. Interviewees also recommended strategies related to the presentation and communication between the HCT and families during rounds. Many interviewees suggested restructuring and shortening the presentation by focusing on the assessment and plan. According to all interviewees, the HCT should present in a conversational manner and use an engaging communication style (e.g., making eye contact, using appropriate humor) and appropriate language (e.g., qualitative trend instead of numbers, plain language instead of medical jargon) to communicate with families. To ensure families' understanding, HCT members should encourage and address families' questions and concerns. In addition, families should be given the opportunity to provide information (e.g., patient history and overnight events) and to express their opinions about the plan. If teaching is required during rounds, the HCT should involve families and ask for permission to teach. Other strategies on rounds were suggested, such as giving nurses the opportunity to actively participate during rounds, pausing and confirming the physical exam findings, minimizing distractions and interruptions, attending and/or senior resident physicians leading and being role models for FCR, and understanding families' expectations of rounds and adapting rounds to families' needs. With regard to improvements that could be made after FCR, some HCT members talked about the importance of following up with families after rounds. Specifically, suggestions that nurses could stay with families immediately after rounds were made, while physicians could return to families later in the day.

A range of organizational and environmental barriers and facilitators was also identified. For instance, appropriately scheduling rounds ("the nurse at that time did give me the forewarning that rounds would be coming… and I was prepared for that") and role clarity of clinicians ("they [parents] really want to know what your role is on the team, that might help people figure out what the different roles are on the team") can facilitate the rounding process. In contrast, delayed rounds ("that is a huge source of frustration for patients and families") and absence of nurses during rounds ("sometimes they [nurses] are not there, and to me, this is definitely a drawback") are considered major barriers to family engagement. Environmental factors include interruptions and distractions ("when they [rounding team] come in, to maybe talk to the kid, could you please turn that [TV] down or off") and positioning to the HCT members so that clinicians are standing close to each other or sitting down with the parent and the child.

Throughout this work, we recognized that, although family engagement is recommended as a critical component of care, strategies to improve engagement may be in direct opposition to other goals of the HCT. Such was the case with strategies related to size of the HCT during FCR. Some of our participants suggested that having a smaller team may be more beneficial for family engagement on rounds. In some settings, it may be feasible to have a small team. However, in institutions that accommodate a large number of learners,

excluding students from the teaching opportunity of rounds may actually compromise educational experiences. Finding a balance between engaging families, teaching learners, and maintaining efficiency is paramount.

To address this issue, the researchers made use of survey data from 172 medical students.[43, 44] Despite concerns that student education might be negatively impacted by FCR, students reported frequently experiencing 12 of 17 clerkship teaching items during FCR. Furthermore, student attitudes about the benefits of FCR for families were significantly more positive at the end of their clerkships. For students, observing role models and practicing for mastery supported self-efficacy with family-centered communication during FCR (each P < 0.01). This data about how much students gained from simply observing as well as practicing FCR informed the decision not to create smaller teams by leaving some trainees out of FCR.

Once possible strategies to improve family engagement in FCR were identified from the interviews, stakeholders were engaged in prioritizing these strategies, choosing which strategies to implement and then creating the final FCR Checklist product. A survey was conducted with 134 FCR stakeholders (28 families, 31 nurses, 55 attending and resident physicians, and 20 medical students) to evaluate their perceptions of the potential impact of identified FCR improvement strategies on family engagement. Details of the survey can be found elsewhere.[20] Intervention Implementation Team members reviewed this impact survey data and categorized strategies into three groups: (1) should be addressed by the intervention, (2) might be addressed by the intervention and (3) should not be addressed by the intervention. Intervention Implementation Team members then brainstormed ideas for the intervention by focusing on strategies in the group "should be addressed by the intervention." Researchers summarized proposed intervention ideas in three 'big picture' ideas: (1) scheduling rounds, (2) family preference system for rounds, and (3) best practices for rounds. To understand the potential feasibility of implementing specific strategies, a second survey was conducted with 82 FCR stakeholders (14 families, 13 nurses, 43 attending and resident physicians, and 12 medical students). Intervention Implementation Team members reviewed this feasibility survey data and made a group decision to design and implement an FCR Checklist of best practices for performing rounds and a family preference system asking families beforehand for their preferences for rounds.

Figure 1. Family-Centered Rounds Checklist

UW Health
American Family
Children's Hospital

Family-Centered Rounds Checklist

☐ Ensure **nurse** is present
☐ **Check family preference** for rounds
 • Participate with patient (in room/in hallway)
 • Participate without patient (in hallway)
 • Not participate
☐ **Ask** if the family **knows everyone** on team
 • If not, **introduce** unfamiliar team members and roles
☐ Discuss **assessment** & **plan for day** with family
☐ Review and update **goals for discharge** with family
☐ **Ask family** for questions
☐ **Ask team** for questions
☐ **Read back** orders

Complete all items
before moving on to the next patient

After this meeting, researchers conducted additional observations to understand how an FCR Checklist (the main element of the intervention) could fit in the current workflow. Literature on checklist design and implementation was reviewed and presented to Intervention Implementation Team members. The Intervention Implementation Team discussed and finalized details about the FCR Checklist, including:

• The content, such as tasks that should be done and the order of items on the FCR Checklist.
• The format, such as paper vs. laminated paper vs. electronic, dimensions, color and font size.
• Roles related to the FCR Checklist, such as who will complete each task on the checklist and who is the 'checklist holder'.
• The workflow associated with the FCR Checklist, such as where, when, and how checklist items would be done.

Ultimately, our work on developing an intervention to improve family engagement in FCR resulted in eight "best practices" for FCR, organized as the FCR Checklist. (Figure 1.) Checklist

elements are arranged in the order they typically occur during rounds, beginning with ensuring the child's nurse is present and ending with reading back orders. Our systems engineering methods also informed the FCR Checklist implementation. To optimize implementation, the FCR Checklist was bundled with a 1-hour interactive training, brief refresher training, tools to monitor implementation, and laminated FCR Checklists for use as prompts, constituting the FCR intervention (Toolkit available at http://www.hipxchange.org/familyrounds).

5.A.1 Conclusions and Implications

To develop the FCR Checklist intervention used in this study, we used recognized systems engineering methods to identify, prioritize, and implement strategies for enhancing family engagement on FCR from the perspectives of a diverse group of stakeholders. We also described how these strategies target fundamental elements in both the hospital work system and rounding process. We initially identified 21 categories of strategies corresponding to two themes related to the structure and process of FCR. Our research both confirms and builds upon practices previously described in the FCR literature.[14, 45, 46] In addition, our research identifies a variety of new work system related strategies, such as scheduling rounds, using computers effectively, and providing training of HCT members.

Systems engineering methods are crucial to developing and implementing interventions in complex work systems. Methods such as the stimulated recall methodology can provide opportunities for a range of participants, including parents and children, to become involved in improving healthcare processes. Stimulated recall or 'confrontation' methods have been typically used with single workers; we have extended the methodology to teamwork in which multiple individuals (e.g., physician, nurse, parent, trainees) communicate and collaborate to provide and/or support patient care. Furthermore, engaging various stakeholders in the rounding process is critical to ensure that their needs are adequately addressed,[20] as was done through our Steering Committee and our Intervention Implementation Team as well as through observational techniques and our surveys of medical students.

5.B. The Impact of the FCR Checklist Intervention on Family Engagement and Safety and How Safety Is Affected by Family Engagement (Aims 1 and 3)

5.B.1 Findings

In general, we found that the FCR Checklist significantly increased the performance of key FCR elements and that performance of specific ones of these elements significantly impacted family engagement and improved patient safety. In addition, family engagement during FCR was associated with more frequent performance of recommended safety behaviors related to medication safety by parents. Family engagement during FCR was not related to improved parent perceptions of safety for hospitalized children. Last, FCR was found to offer a crucial venue for families to initiate dialogue about medications, resulting in changes to treatment plans and resolution of issues often related to adverse drug reactions or to medication schedules. Details of these analyses follow.

To assess the impact of the FCR Checklist (intervention), 874 potential participant admissions (402 pre-intervention; 472 post-intervention) were identified. Of 518 eligible admissions approached, 340 (66%) agreed to participate, with 164 families participating in the pre-intervention period and 176 in the post-intervention period. Our final sample was 298 families: 144 pre-intervention (19 families had incomplete data; one withdrew due to stress of a new diagnosis) and 154 post-intervention (21 families had incomplete data; one withdrew due to stress of a new diagnosis).

On average, children were young (5-6 years of age), and most were in good to excellent health. Parents were predominantly White, non-Hispanic, mothers with a wide range of educational attainment. Common reasons for hospitalization were breathing problems, gastrointestinal problems, and fever. Hospital stays were typically

fewer than 3 days, although about 20% of children stayed longer. Rounds were approximately 10-11 minutes in length. (Table 1)

From the hospital stays of the 298 children in the study, 673 FCR videos were evaluated. Usual-care services contributed 348 FCR videos (164 pre-intervention videos from 70 families; 184 post-intervention videos from 76 families); intervention services contributed 325 FCR videos (155 pre-intervention videos from 74 families; 170 post-intervention videos from 78 families).

Family engagement in relationship building during FCR ranged from a mean of 36-44 utterances across services. (Table 1) On average, families made 23-33 information giving utterances and about three information-gathering utterances per round. Families engaged in decision making on average three to four times during FCR. Overall, families reported strongly positive views of four hospital safety climate domains, with mean scores ranging from 3.9-4.6. (Table 1) In general, families related their own ability to communicate openly most highly, whereas the other three measures of safety climate received less-positive ratings. On average, about four to six of the eight FCR Checklist elements were performed during rounds. (Table 1) Three elements were performed frequently (nurse present, plan summarized, discharge goals discussed), and others were performed with less regularity.

Table 1. Descriptive Characteristics of the Participants and Study Outcomes for Usual Care and Intervention Services, Pre- and Post-Intervention[a]

Participant Characteristics	Usual Care Admissions		Intervention Admissions	
	Pre (n=70)	Post (n=76)	Pre (n=74)	Post (n=78)
Child				
Female child, % (n)	46 (32)	57.9 (44)	50 (37)	44 (34)
Child age, mean (sd), years	6.0 (5.7)	5.7 (5.3)	5.6 (5.6)	5.0 (5.2)
Child health status, % (n)				
Good to excellent	86 (60)	87 (66)	85 (63)	87 (68)
Parent				
Mother, % (n)	81 (57)	83 (63)	88 (65)	82 (64)
White, non-Hispanic, % (n)	84 (59)	89 (68)	84 (62)	91 (71)
Parent education, % (n)				
High school or less	21 (15)	8 (6)	15 (11)	26 (20)
Some college	31 (22)	38 (29)	39 (29)	27 (21)
Bachelor's degree or more	46 (32)	54 (41)	46 (34)	47 (37)
Parent age, mean (sd), years	35.0 (7.6)	35.4 (6.7)	34.6 (7.9)	33.9 (6.9)
Reason for hospitalization, % (n)				
Breathing problem	36 (25)	37 (28)	30(22)	28 (22)
Stomach or intestinal problem	20 (14)	20 (15)	20 (15)	22 (17)
Fever	10 (7)	16 (12)	27 (20)	15 (12)
Asthma	7 (5)	11 (8)	14 (10)	3 (2)
Seizure or headache	4 (3)	5 (4)	5 (4)	10 (8)
Cancer	0 (0)	0 (0)	12 (9)	22 (17)
Infection	20 (14)	11 (8)	14 (10)	13 (10)
Other	19 (13)	25 (19)	16 (12)	15 (12)
Length of stay, % (n)				
One day	46 (32)	43 (33)	34 (25)	40 (31)
2-3 days	31 (22)	33 (25)	45 (33)	38 (30)
4-7 days	4 (3)	16 (12)	18 (13)	14 (11)
More than a week	19 (13)	8 (6)	4 (3)	8 (6)
FCR length, mean (sd), minutes	10.2 (4.6)	10.4 (3.4)	9.9 (3.6)	11.2 (4.6)
Main Outcomes				
Family engagement[b]				
Relationship building, mean (sd)	43.7 (31.1)	42.6 (18.7)	36.0 (22.5)	41.6 (24.1)
Information giving, mean (sd)	32.1 (34.4)	23.4 (19.2)	33.1 (28.8)	28.3 (23.6)
Information gathering, mean (sd)	3.3 (3.3)	3.0 (2.5)	3.1 (3.2)	3.3 (3.6)
Decision making, mean (sd)	3.2 (3.0)	4.0 (3.2)	2.9 (2.2)	4.4 (4.2)
Parent perceptions of safety climate[c]				
Overall safety, mean (sd)	4.1 (0.7)	4.1 (0.7)	4.2 (0.8)	4.1 (0.7)
Staff communication openness, mean (sd)	3.9 (0.7)	3.9 (0.7)	4.0 (0.6)	4.0 (0.8)
Family communication openness, mean (sd)	4.5 (0.6)	4.5 (0.6)	4.5 (0.6)	4.6 (0.6)
Handoffs and transitions, mean (sd)	3.9 (0.8)	3.9 (0.9)	4.0 (0.9)	4.0 (1.0)
Checklist Elements				
Total checklist elements performed, mean (sd)	4.6 (1)	4.9 (1)	4.3 (1)	5.9 (1.2)
Nurse present, % (sd)[d]	86 (29.8)	88 (27.7)	88 (23.8)	88 (26.5)
Introductions made, % (sd)	29 (41.6)	39 (41.1)	21 (34.1)	47 (42.9)
Assessment provided, % (sd)	58 (42.5)	64 (40.5)	48 (40.9)	69 (41.9)
Plan summarized, % (sd)	97 (11.5)	100 (2.8)	96 (18.2)	98 (8.6)
Family was asked for questions, % (sd)	71 (37.2)	73 (36.2)	67 (37.9)	88 (26.1)
Healthcare team was asked for questions, % (sd)	24 (35.2)	28 (35.4)	23 (33.8)	59 (41.3)
Discharge goals discussed, % (sd)	82 (26.9)	85 (24.8)	76 (33.8)	83 (31.1)
Orders were read back, % (sd)	9 (20.9)	17 (29.7)	7 (20.1)	52 (42.8)

[a]Values may not add to 100% due to rounding.
[b]Mean and standard deviation of the number of utterances or decision-making events that families engaged in during
[c]Mean and standard deviation of parents' safety climate domain scores, in which all of the domains' elements were rated on a five-point scale (1, strongly disagree, 5, strongly agree) with higher scores indicating more favorable
[d]For each checklist element, the mean and standard deviation of the average percent of rounds during which the element was performed during a patient's stay.

The intervention significantly improved the number of FCR Checklist elements performed (β=1.2, p<0.001). Specifically, the intervention significantly increased the likelihood that families were asked for questions (OR=2.43, p=0.05), the HCT was asked for questions (OR=4.28, p=0.002), and orders were read back during FCR (OR=12.43, p<0.001). Performance of the other checklist elements was not impacted significantly. (Table 2)

Table 2. Adjusted Odds Ratios and 95% Confidence Intervals (95% CI) for the Intervention's Effect on FCR Checklist Element Performance (n=668 rounds)[a]

FCR Checklist Element	Odds Ratio (95% CI)
Nurse present	0.63 (0.23, 1.74)
Introductions made	1.62 (0.70, 3.76)
Assessment provided	1.92 (0.69, 5.31)
Plan summarized	0.22 (0.02, 2.08)
Family was asked for questions	**2.43 (1.01, 5.85)**
Healthcare team was asked for questions	**4.28 (1.73, 10.60)**
Discharge goals discussed	1.96 (0.79, 4.87)
Orders were read back	**12.43 (4.62, 33.47)**

Bolded values indicate p<0.05.

[a]Random effects models include a random intercept to account for the association in the repeated measures across the stay for a given patient and were adjusted for child age, length of stay, parent education, and health status. Missing survey data for these elements occurred in 5 instances, resulting in 668 rather than 673 observations.

Adjusted models demonstrated no significant intervention effect on family engagement. However, performance of four of the checklist elements significantly impacted family engagement. (Table 3) Specifically, when the HCT provided a summarized assessment of the child's progress, families engaged in significantly less relationship building (4.22 fewer utterances; p=0.04), information gathering (0.86 fewer utterances; p=0.005), and decision making (0.57 fewer instances; p=0.04). During FCR in which the families were asked for questions, families engaged in significantly less information giving (12.15 fewer utterances; p<0.001). When the HCT discussed goals for discharge, families engaged in significantly more relationship building (5.30 more utterances; p=0.03).

When the HCT read back orders, families engaged in significantly more information giving (8.20 more utterances; p=0.002), information gathering (0.86 more utterances; p=0.02), and decision making (0.66 more decision-making activities; p=0.04).

Table 3. Adjusted Regression Coefficients (β)[a] and 95% Confidence Intervals (95%CI) for Association of FCR Checklist Element Performance with Family Engagement in Communication Tasks (n=668 rounds)[b]

FCR Checklist Element	β (95%CI)			
	Relationship Building	Information Giving	Information Gathering	Decision Making
Nurse present	-1.30 (-6.98, 4.39)	0.06 (-6.34, 6.46)	-0.77 (-1.60, 0.06)	0.24 (-0.49, 0.97)
Introductions made	2.52 (-1.92, 6.96)	-2.11 (-7.14, 2.93)	-0.01 (-0.66, 0.63)	0.27 (-0.30, 0.84)
Assessment provided	**-4.22 (-8.33, -0.11)**	-4.44 (-8.88, -0.005)	**-0.86 (-1.45, -0.26)**	**-0.57 (-1.10, -0.04)**
Plan summarized	4.36 (-6.45, 15.18)	-11.09 (-23.52, 1.34)	0.95 (-0.63, 2.54)	0.38 (-1.03, 1.78)
Family was asked for questions	-4.22 (-8.64, 0.20)	**-12.15 (-17.06, -7.24)**	-0.22 (-0.87, 0.42)	0.01 (-0.56, 0.58)
Healthcare team was asked for questions	-0.38 (-4.55, 3.79)	-1.41 (-5.99, 3.17)	0.23 (-0.38, 0.84)	0.08 (-0.46, 0.62)
Discharge goals discussed	**5.30 (0.63, 9.96)**	-3.58 (-8.91, 1.75)	0.54 (-0.15, 1.22)	0.13 (-0.48, 0.74)
Orders were read back	4.08 (-0.76, 8.93)	**8.20 (2.97, 13.43)**	**0.86 (0.16, 1.56)**	**0.66 (0.04, 1.29)**

Bolded values indicate p<0.05.

[a]Beta describes the change in the number of utterances or decision-making events associated with a 1% increase in the percentage of FCR in which the checklist element was performed.

[b]All models were adjusted for child age, child health status, parent education, and length of hospital stay. Missing survey data for these elements occurred in 5 instances, resulting in 668 rather than 673 observations.

Adjusted models demonstrated no significant intervention effect on parent perceptions of safety. However, the performance of FCR Checklist elements improved parent perceptions of two safety climate domains (Table 4, next page). Specifically, parent views of staff communication openness significantly increased with the proportion of FCR in which the family was asked for questions. In addition, parents' perceptions of the safety of handoffs and transitions significantly increased with the proportion of FCR in which the HCT gave an assessment of their child's progress or asked the family if they had any questions.

Table 4. Adjusted Regression Coefficients (β)[a] and 95% Confidence Intervals (95%CI) for Association of FCR Checklist Element Performance with Parent Perceptions of Safety (n=298 admissions)[b]

FCR Checklist Element	β (95%CI)			
	Overall Safety	Staff Communication Openness	Family Communication Openness	Handoffs and Transitions
Nurse present	-0.03 (-0.33, 0.27)	-0.01 (-0.31, 0.29)	0.20 (-0.06, 0.45)	0.07 (-0.32, 0.46)
Introductions made	-0.15 (-0.36, 0.06)	-0.14 (-0.35, 0.07)	-0.12 (-0.30, 0.06)	-0.11 (-0.38, 0.17)
Assessment provided	0.17 (-0.03, 0.36)	0.18 (-0.02, 0.38)	0.06 (-0.11, 0.23)	**0.27 (0.02, 0.53)**
Plan summarized	0.03 (-0.67, 0.73)	0.39 (-0.32, 1.10)	-0.19 (-0.79, 0.41)	0.04 (-0.87, 0.95)
Family was asked for questions	0.07 (-0.17, 0.31)	**0.38 (0.14, 0.62)**	0.09 (-0.11, 0.29)	**0.32 (0.01, 0.62)**
Healthcare team was asked for questions	0.00 (-0.21, 0.21)	0.01 (-0.20, 0.23)	-0.02 (-0.20, 0.16)	0.07 (-0.20, 0.33)
Discharge goals discussed	0.12 (-0.23, 0.47)	-0.05 (-0.40, 0.31)	0.02 (-0.28, 0.32)	0.23 (-0.23, 0.68)
Orders were read back	-0.04 (-0.27, 0.19)	-0.01 (-0.25, 0.22)	0.08 (-0.11, 0.28)	0.03 (-0.27, 0.33)

Bolded values indicate $p<0.05$.
[a]Beta describes the change in parent perceptions for each of the 4 safety domains associated with a 1% increase in the average percentage of FCR in which the checklist element was performed during the child's stay.
[b]Adjusted for child age, child health status, parent education, and length of hospital stay.

With regard to how family engagement is related to patient safety, as might be expected, families who engaged in more information gathering during rounds were significantly more likely to report frequently asking the HCT about medications ($p<0.001$) and asking about the name or dose of a medication ($p=0.02$). Families who had greater participation in decision making were also significantly more likely to report frequently asking the HCT questions about their medications ($p=0.01$). Engagement in relationship building had no significant effect on performance of recommended safety behaviors. Although greater engagement in information exchange was associated with more frequent performance of these recommended safety behaviors, higher levels of engagement did not appear to create greater feelings of safety. In fact, families who engaged in more information giving during FCR perceived less overall safety during the stay and felt their children were less safe during handoffs and transitions ($p<0.05$ for each). Similar results were found for families who engaged in more information giving.

In our investigation of how FCR can be used by families to influence medication safety, 83 (55%) of the 150 families raised 318 medication topics during 347 video-recorded FCR. Characteristics (demographics and health-related factors) were not different between families who initiated dialogue about medications and those families who did not. However, families of children hospitalized with asthma initiated more dialogue about their children's medications, compared to families of children hospitalized for other conditions. Most family-initiated dialogue focused on inpatient medications (65%), with home medications comprising 35%. Anti-infectives (31%), analgesics (14%), and corticosteroids (11%) were the most commonly raised medications. The most common medication topics raised by families were scheduling (24%) and adverse drug reactions (11%). Although most HCT responses were provision of information (74%), appropriate changes to the child's medications occurred in response to 8% of family-initiated dialogue, with most changes preventing or addressing adverse drug reactions or scheduling issues. More detailed results can be found in our paper.[39]

5.B.2 Discussion
Implementation of the FCR Checklist intervention succeeded in increasing the likelihood that key FCR elements, as defined by patients, families, and staff, were performed. Although the intervention did not alter family engagement or perceptions of safety, performance of specific checklist elements significantly influenced both of these outcomes. Thus, implementation of the FCR Checklist has implications for the delivery of safe, high-quality pediatric inpatient care. The FCR Checklist also offers a way to structure delivery of FCR to meet the needs of families, learners, and the HCT while also supporting future research comparing the effects of FCR on other healthcare and educational outcomes.

Teams using the FCR Checklist were significantly more likely to ask families and HCT members for questions. The act of asking for questions allows FCR to leverage the expertise of families as the primary caregivers for the child and also provides other team members, such as nurses, pharmacists, and case managers, an opportunity to share their expertise. Nurses in particular can present issues or questions families may have raised to them but which families may not feel comfortable speaking up about during FCR.

Asking families if they have questions was associated with both changes in communication and improved perceptions of safety. Somewhat counterintuitively, when families were asked for questions, families gave less information during FCR. It is possible that families who were specifically invited to ask questions may have been empowered to ask whatever questions they had, rather than repeating or providing additional information, in hopes that the HCT might infer their question and address it. Alternatively, HCTs may have been more likely to ask families for questions when families provided less information during the rounds. Asking families for questions also influenced parent perceptions of safety, positively impacting both perceptions of staff communication openness and of the safety of handoffs and transitions, similar to other studies of interventions to promote communication and teamwork.[47-49] Thus, implementation of this FCR Checklist element may be an appropriate intervention to improve parent perceptions of safety in children's hospitals.

The intervention also increased the likelihood that orders would be read back during FCR, and performance of this checklist element increased family engagement. When orders were read back, families both asked for and gave more information and also engaged more in decision making. Reading back orders may signal a willingness to have those orders questioned or modified. This read back also promotes a shared mental model of the orders, creating a foundation on which families and HCT members can formulate questions. In other work, we found that many families use FCR as a venue to discuss medication topics.[39] Because computerized physician order entry has not yet been able to eliminate medication errors and adverse events,[50, 51] order read back may be particularly powerful in fostering safe medication use for hospitalized children.

Our intervention did not significantly affect performance of the remaining five checklist elements. For two of these, performance rates were very high prior to the intervention. For other elements, performance improved in both intervention and control services, perhaps because FCR was a critically important hospital initiative or because the intervention diffused from intervention to control services through shared staff.

With regard to how family engagement is related to patient safety, families who were actively engaged during FCR were also more likely to report performing recommended behaviors to enhance patient safety. However, we also found that those families who gave or gathered information during rounds held more negative perceptions of safety at the time of discharge. Though this might initially seem counterintuitive, one possible explanation is that parents do more information exchange when the care plan is less clear or less accepted or even when families perceive a mistake has been made. In such situations, parents may feel as though their children were not safe during the hospital stay. Thus, we cannot simply assume that more engagement as measured by the amount of talk during FCR leads to families who feel safer. Had we measured actual errors or other harms, this relationship may have been as expected.

We also found that FCRs are crucially important venues to promote medication safety and adherence. Prior work identified potential benefits of FCR, such as greater satisfaction with care and better family understanding of treatment plans,[27, 52, 53] but our data go further, describing families' contributions to FCR and the impact on treatment and safety. Importantly, families who initiated medication-related dialogue were no different demographically than those who did not, so HCT members cannot predict which families may initiate medication topics. However, families of children with asthma were more likely to initiate this dialogue, so HCTs can anticipate and prepare for discussion of asthma medications. These discussions have a multitude of potential benefits given the high readmission rate for asthma often caused by nonadherence.[54] We also found

that some medications engendered more questions from families. Specifically, HCT members should be prepared to address questions about pain medications and antibiotics as well as corticosteroids.

Given the commonplace nature of family-initiated dialogue around home medications, having an efficient process for addressing questions about home medications is crucial. After discharge, families become responsible for administering and monitoring children's medications. Adverse drug events, defined as harm resulting from use, nonuse, or misuse of medication, occur in 14% of pediatric outpatients receiving a prescription.[55] The majority of preventable adverse drug events (70%) occur during parental administration rather than in earlier stages, such as medication ordering. Thus, discussion about home medications is crucial to partnering with families around safe medication use.

By actively raising medication topics, families contributed meaningfully to FCR in ways that mirror the medication error recovery stages of detection and correction. Without these contributions, errors in families' understanding of the medication plan may not have been detected, ultimately resulting in medication misuse, underuse, or overuse. In the end, 8% of the instances of family initiated dialogue resulted in changes to medication orders for the child. These changes typically addressed either adverse drug events or families' concerns about the scheduling of medication administration in the hospital or home.

5.B.3. Conclusions and Implications

The FCR Checklist intervention succeeded in increasing the performance of specific FCR elements. The intervention itself did not alter family engagement or parent perceptions of safety; however, the performance of specific FCR Checklist elements significantly influenced both of these outcomes. FCR is an important venue to promote patient safety, with most families initiating dialogue regarding medications during FCRs, including both inpatient and home medications. Families raised topics that altered treatment and were important for medication safety, adherence, and satisfaction. Thus, engaging families in FCR provides a regularly occurring interaction for families to influence the safety of healthcare for their child. Implementing the FCR Checklist intervention promotes consistent delivery of high-quality, family-centered, pediatric inpatient care while also improving patient safety from the perspective of parents.

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6. List of Publications and Products

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