Parent Participation and Physician-Parent Communication During Informed Consent in Child Leukemia

WHAT'S KNOWN ON THIS SUBJECT: Physician partnership- and rapport-building behaviors have been shown to be related to parent participation during informed consent conferences (ICCs). These positive physician behaviors may facilitate communication and enhance parent participation and understanding.

WHAT THIS STUDY ADDS: This study expands our understanding of physician-parent communication during ICCs for pediatric leukemia research and evaluated the effectiveness of a physician-directed intervention at improving physician behaviors during ICCs.

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KEY WORDS

informed consent, pediatrics, leukemia, communication, research ethics

ABBREVIATIONS

RCT—randomized clinical trial
ICC—inform consent conference
SES—socioeconomic status
PDI—physician-directed intervention
MUSIC—Multisite Intervention Study to Improve Consent
PAGIC—Parent Advisory Group on Informed Consent
RA—research assistant
RIAS—Roter Interaction Analysis System

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www.pediatrics.org/cgi/doi/10.1542/peds.2010-3542

doi:10.1542/peds.2010-3542

Accepted for publication Aug 10, 2011

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

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FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

Funded by the National Institutes of Health (NIH).

abstract

OBJECTIVE: In this study we evaluated the effectiveness of a physician-directed intervention at enhancing positive physician behaviors and communication strategies during informed consent conferences (ICCs) for pediatric acute leukemia clinical trials.

PATIENTS AND METHODS: Physicians at 2 large pediatric hospitals were recruited to participate in a physician-directed intervention (PDI), which included 1 full-day seminar and successive half-day booster sessions. ICCs were then observed, audiotaped, coded, and analyzed to evaluate the effectiveness of the intervention. Data also were collected at 2 control sites. Between 2003 and 2007, 59 ICCs were observed and analyzed.

RESULTS: Significant group differences were found in physician rapport-building behaviors. Physicians in the PDI + booster session group engaged in greater rapport-building than did physicians in the PDI group who did not attend booster sessions and physicians in the control group. No group differences were detected for physician partnership-building. In addition, parents in the PDI + booster session group engaged in more general communication and study-related communication, and mothers in the PDI groups asked significantly more questions per minute than did mothers in the control group.

CONCLUSIONS: These results provide support for the effectiveness of the PDI at enhancing positive physician behaviors. Booster-session attendance is a critical component of physician-directed interventions to improve parental participation and physician-parent communication during ICCs. *Pediatrics* 2011;128:e1544–e1551

Pediatric cancer mortality rates in the United States have decreased dramatically; the current 5-year survival rate is nearly 80%.¹ Despite this success, the diagnosis of childhood cancer remains a difficult and stressful family experience.² When parents are given news of the diagnosis, many are presented with complex information about participation in randomized clinical trials (RCTs) during informed consent conferences (ICCs). High levels of parental distress, coupled with medical and research terminology, may limit parental understanding of RCTs or treatment options for their child.³ Previous research found that although randomization was explained by physicians in 83% of cases, only 49% of parents actually understood randomization.⁴ Other pediatric and adult oncology studies have demonstrated similar limitations in parental understanding and physician-parent communication.⁴⁻⁹ Furthermore, physicians report that delivering bad news and discussing RCTs can be especially difficult.¹⁰ A lack of emphasis on communication skills and training contributes to these difficulties.^{11,12} Recognition of the important need for communication training for physicians has stimulated efficacious interventions to improve communication during ICCs about adult clinical oncology research.¹³⁻¹⁷

However, few researchers have examined the nature of this communication during ICCs for pediatric research. Drotar et al¹⁸ found that physician partnership and rapport-building behaviors were associated with active parental participation (eg, question-asking, words per minute) in ICCs, even after controlling for parent socioeconomic status (SES) and ethnicity. Using this same data set, Miller et al¹⁹ found that physicians employed fewer partnership-building behaviors with families of lower SES. These and other studies highlight the importance of

developing interventions to improve physician-parent communication in pediatric settings and enhance partnership- and rapport-building in the informed consent process for pediatric care. Many have called for future studies of the effectiveness of pediatric interventions to improve informed consent²⁰⁻²² and physician-parent communication.²³ Furthermore, the importance of patient- and family-centered care^{24,25} underscores the need to improve physician communication.

This research extends the findings of Yap et al,²⁶ who examined the effectiveness of a physician-directed intervention (PDI), which was aimed at improving physician communication and the delivery of informed consent via didactic and skills training. Primary outcomes included physician adherence to the sequenced approach (Fig 1) emphasized in the PDI and physician question-asking. In this secondary data analysis the effectiveness of the PDI at improving physician rapport and partnership-building behaviors and parental participation in the ICC is examined. We hypothesized that

physicians in the intervention group would engage in more rapport and partnership-building than would controls and that parent participation would be greater in the PDI group.

PATIENTS AND METHODS

Description of the Multisite Intervention Study to Improve Consent

The Multisite Intervention Study to Improve Consent (MUSIC) was a large clinical trial in which 3 separate interventions aimed at improving parental understanding and participation in the informed consent process for children diagnosed with acute leukemia were examined. MUSIC researchers evaluated the feasibility and effectiveness of a parent-directed DVD-based intervention,²⁷ a parent-directed, nurse-delivered intervention,²⁸ and a PDI.²⁶ In this article we report additional findings from the PDI.

Description of the PDI

To learn ways to improve the informed consent process, the Parent Advisory

FIGURE 1

PAGIC model: a sequenced approach aimed at improving the delivery of information and communication during ICCs.

Group on Informed Consent (PAGIC) was formed.²⁹ This group of parents of children with leukemia facilitated interpretation of data and formulation of plans to improve the delivery of information. This collaboration with parent stakeholders resulted in the PAGIC model (Fig 1); a sequenced approach for physicians to follow in ICCs.²⁹ The model served as the foundation for the PDI, which was designed to (1) emphasize a sequenced approach to information delivery during the ICC, (2) improve communication techniques for discussing key concepts, and (3) provide strategies for gauging parental understanding.

Each of the 4 study sites were selected because they are high-volume pediatric medical institutions where our team has established collaborative research partnerships. Letters of invitation and consent were sent out to physicians who treat patients with pediatric leukemia to inform them of the study. Co-investigators at the sites also approached physicians to provide additional information about the PDI. Data were collected at 2 comparable control sites. Informed consent was obtained from all participating physicians. Parents of children diagnosed with acute leukemia at each of the sites were eligible. Research assistants (RAs) working at these sites established surveillance mechanisms (eg, contact with nurses, residents, fellows, and physicians) for new leukemia cases. A trained RA explained the study and requested consent from parents after the disclosure of the leukemia diagnosis, but before the ICC transpired. Parental participation involved observation and taping of the ICC by an RA. Parents were not told whether their physician took part in the intervention. RAs recorded information about any conversations the family had with the physician before the recorded ICC, but information

about conversations that might have happened after the official ICC(s) were not recorded. Data from the parent interviews were not used for this analysis. The study was approved by each of the 4 sites' institutional review boards. Data collection began March 2003 and ended October 2007.

Initial day-long seminars were conducted at both PDI sites by a physician who specialized in pediatric oncology and ethics and 2 pediatric psychologists. Research staff and PAGIC members assisted. Physicians were taught listening skills (eg, summarize parents conversation and key points) and communication skills (eg, use of open-ended questions, simplified language, use of concrete illustrations). Physicians were taught to encourage parents to share their thoughts and learning preferences (eg, "Please tell me how you learn best. Do you prefer to have discussions, read from books or article, or have others read to you?"). Positive versus problematic communication styles were illustrated via audiotapes. The day-long seminars also included didactic instruction, collaborative discussion, practicing of skills, and the presentation of findings from a descriptive study on informed consent for pediatric leukemia trials.⁴ Seminar leaders stressed the importance of adhering to the stages of the PAGIC model, conducting at least 2 separate ICC meetings, and gauging parental understanding before proceeding to the next step. Teaching at the seminars was enhanced by the presence and input of parent PAGIC members.

To reinforce the lessons of the initial seminar, 2 half-day booster sessions were conducted at each intervention site. Booster-session attendance was recorded, but not required for inclusion in the study because of busy clinician schedules and a potential inability to comply with mandatory booster-session attendance. However, 40% of

physicians electively attended at least 1 booster session.

The ICCs at all sites were observed and audiotaped by RAs who were trained in silent observation, interviewing, and coding techniques. Following the RA's initial coding, audiotaped ICCs were coded twice again by additional study personnel. Reconciliations were made using a preestablished coding rulebook developed by investigators for the purpose of resolving inconsistencies.

Participants

Overall, 80 physicians were approached and 42 physicians participated, attending 1 or more training sessions. At the 2 intervention sites, 171 families were eligible, 84 were approached, and 60 agreed to participate. At the 2 control sites, 132 families were eligible, 60 were approached, and 42 agreed to participate. The most common reason for not approaching eligible families was because of scheduling issues (ie, RA unavailable). A total of 102 ICCs (60 PDI and 42 control) were eligible for analysis; however, 14 ICCs from the PDI sites were excluded because the physician(s) had not attended the intervention seminar. An additional 29 ICCs were excluded because either the RA was unable to attend the entire ICC or parents were not offered enrollment of their child in a clinical research trial because of the unavailability of an appropriate trial at the time of data collection. Therefore, a total of 59 ICCs were analyzed: 33 from the PDI sites and 26 from the control sites. Of these 59 ICCs, mother ($n = 45$) and father ($n = 14$) data were analyzed.

Measures

Demographics

Parent and patient demographic information was collected via parent interview. Parent SES was measured using the Hollingshead Index of Social Position,³⁰ which combines education and

occupation to assess overall SES. Lower scores on this measure indicate higher SES. Physicians completed a self-report demographic questionnaire.

Physician Rapport- and Partnership-Building

The Roter Interaction Analysis System (RIAS)^{31,32} is a well established, comprehensive observational measure of physician and parent (or patient) communication that includes assessment of behaviors related to the intervention. Although the original RIAS used audiotapes to code communication statements, coding for this study was done using transcripts of the ICCs to measure physician rapport and partnership-building. The RIAS method was designed to measure physician and patient communication behaviors during medical office visits across 38 categories (eg, biomedical information, psychological information, orientation and instructions). Because of the focus of the PDI, only physician statements reflecting rapport and partnership-building were coded for the purposes of our study. Authors of the RIAS report reliability averages of .85.³³ A number of studies have demonstrated high predictive and concurrent validity of the RIAS.^{34–38}

Rapport-building includes statements of worry and concern, empathy, reassurance, legitimation, and self-disclosure.³⁹ Partnership-building, in which the physician facilitates and synthesizes communication, includes asking for parents' understanding and opinions, checking physicians' own understanding, encouraging parent's response, and explaining expectations for partnership.³² Frequency counts of each type of physician statements yielded a total partnership and a total rapport-building score.⁴⁰ Fifteen (25%) of the ICCs were double-coded to establish interrater reliability. Intraclass correlation coefficients were calculated, resulting in a coefficient of 0.86 for the total rapport-building scale

and a coefficient of 0.99 for the total partnership-building scale.

Parent Communication During the ICC

Trained RAs coded mother and father questions and comments into 1 of 2 categories: general or study-related communication to physician(s). This coding system was successfully devised and used by our research team in an earlier study.¹⁸ Parent participation in the ICC was measured across 3 different indices: (1) frequency of parents' general communication to physicians; (2) frequency of parents' study-related communication to physicians; and (3) parent question-asking per minute during the ICC.

General communication consisted of parents' questions and comments that were not related to the study. Study-related communication regarding RCTs for leukemia involved (1) questions about the study (eg, randomization, nature of study agents, risks, definitions, and the consent form) or (2) comments about the decision-making and consent process for the RCT.

Using the Observer Checklist,⁴¹ an instrument designed to code behaviors specific to cancer-related discussions and the audiotaped ICC, the RA coded behaviors by physicians and parents. Only parent question asking per minute was used for these analyses. This measure of communication has been used in previous research.^{19,31,42}

Analyses

Summary statistics were used to describe the demographic characteristics of the sample. To allow for control of possible confounder variables, analyses of covariance were used to test each of the hypotheses. In comparing individual means, pairwise contrasts of intervention groups versus controls were tested for significance by means of Fisher and Dunnett multiple comparison tests. Three groups of physi-

cians were compared: (1) PDI + booster; (2) PDI only; and (3) control physicians. In previous research^{4,19} it has been suggested that parent SES and minority status are important variables related to parental participation in the informed consent process. Therefore, the Index of Social Position³¹ and parent minority status were included as covariates. To control for experience and levels of training, physician role (ie, attending or fellow) and physician years of care were included as covariates. Physician gender has been shown to affect medical communication,⁴³ and more specifically, physician partnership and rapport-building behaviors.^{44,45} Therefore, physician gender was also included as a covariate. Research has found that mothers and fathers often differ in how they cope with their child's cancer diagnosis,⁴⁶ and communication patterns among mothers, fathers, physicians, and children with leukemia is often very complex.⁴⁷ Thus, mother and father participation was analyzed both separately and together (when both parents were present).

With 59 parent-patient ICCs and 52 physicians conducting them, the vast majority of physicians contributed 1 patient to these analyses. This number is close to complete independence, and thus it is unlikely analyses adjusted for the clustering effect of parent-patients nested within physicians would differ from unadjusted analyses. Therefore, only the results of unadjusted analyses are reported here.

RESULTS

Demographic Characteristics

Patient and parent demographics are shown in Table 1. There were no significant differences between patients and parents at the PDI versus control sites in patient-parent age, patient-parent gender, parent minority status, and parent Index of Social Position.³⁰ Phy-

TABLE 1 Patient and Parent Demographics

Characteristic	PDI Sites (<i>N</i> = 33)	Control Sites (<i>N</i> = 26)	Test Statistic	<i>P</i>
Patient age, mean (SD)	5.9 (4.6)	7.0 (5.8)	$t_{57} = .79$	.43
Patient gender, <i>n</i> (%)			$\chi^2 = .17$ (<i>df</i> = 1)	.68
Male	17 (51.5)	12 (46.2)		
Female	16 (48.5)	14 (53.8)		
Parent age, mean (SD)	36.1 (8.3)	34.2 (6.3)	$t_{55} = -1.00$	.32
Parent gender, <i>n</i> (%)			$\chi^2 = .01$ (<i>df</i> = 1)	.92
Male	8 (24.2)	6 (23.1)		
Female	25 (75.8)	20 (76.9)		
Parent race/ethnicity, <i>n</i> (%)			$\chi^2 = 1.79$ (<i>df</i> = 3)	.62
White (non-Hispanic)	18 (54.5)	16 (61.5)		
Black	6 (18.2)	4 (15.4)		
Hispanic	7 (21.2)	6 (23.1)		
Other	2 (6.10)	0 (0.0)		
Parent Index of Social Position, <i>n</i> (%) ^a			$\chi^2 = 3.35$ (<i>df</i> = 2)	.19
1–2	13 (39.4)	7 (26.9)		
3	10 (30.3)	5 (19.2)		
4–5	10 (30.3)	14 (53.8)		

Results are based on *t* tests and χ^2 analyses. *df* indicates degrees of freedom.

^a Lower scores are representative of higher SES.³⁰

TABLE 2 Physician Demographics

Characteristic	PDI Sites (<i>N</i> = 25)	Control Sites (<i>N</i> = 24)	Test Statistic	<i>P</i>
Physician age, mean (SD)	37.0 (8.1)	38.7 (8.2)	$t_{47} = .72$	.48
Physician gender, <i>n</i> (%)			$\chi^2 = 3.99$ (<i>df</i> = 1)	.05
Male	13 (52.0)	19 (79.2)		
Female	12 (48.0)	5 (20.8)		
Physician role, <i>n</i> (%)			$\chi^2 = .23$ (<i>df</i> = 1)	.63
Attending	15 (60.0)	16 (66.7)		
Fellow	10 (40.0)	8 (33.3)		
Physician years of care, mean (SD)	7.7 (8.9)	9.4 (6.9)	$t_{47} = .74$	.46

Results are based on *t* tests and χ^2 analyses. *df* indicates degrees of freedom.

TABLE 3 Physician Behaviors

Characteristic	PDI + Booster (<i>N</i> = 17), Mean (SD)	PDI, No Booster (<i>N</i> = 8), Mean (SD)	Control Sites (<i>N</i> = 24), Mean (SD)	$F_{1,42}$	<i>P</i>
Rapport-building	15.0 (7.0) ^a	10.1 (7.8)	6.2 (7.2) ^a	7.2	.002
Partnership-building	32.8 (46.5)	23.5 (52.1)	48.0 (47.7)	0.80	.46

Results are based on ANCOVAs. Means are adjusted for the following covariates: Parent Index of Social Position; parent minority status; physician role; physician years of care; and physician gender.

^a Mean differences are significant at .001 according to Fisher's least significant difference statistic adjusting for multiple comparisons.

sician demographics are reported in Table 2. No significant group differences were found in physician age, role, and years of care. However, χ^2 analyses revealed a significant ($\chi^2 = 3.99$; $P = .05$) gender difference: there was a greater number of female physicians participating at PDI sites.

Physician Behaviors

The means and SDs for physician behaviors are displayed in Table 3. Physicians

in the PDI group who also attended at least 1 booster session used more rapport-building statements during the ICCs (mean: 15.0; SD: 7.0; $F_{1,42} = 7.2$; $P = .002$) than either those in the PDI group who did not attend a booster session (mean: 10.1; SD: 7.8) or those in the control group (mean: 6.2; SD: 7.2). Contrary to our hypothesis, there were no significant group differences between the groups regarding physician partnership-building behaviors.

Parent Communication

The means and SDs for parent communication are displayed in Table 4. Parents in the PDI + booster group engaged in more general communication and study-related communication than did parents in the control group. In addition, mother question-asking per minute was significantly higher among both PDI-group parents than among control-group parents. There were no significant group differences regarding father question-asking per minute or mother and father total question-asking per minute (see Table 4).

DISCUSSION

This study adds to the science of physician-parent communication by examining positive physician communication behaviors (ie, rapport- and partnership-building) important to the informed consent process,^{18,19} general pediatric practice,⁴⁸ and the delivery of difficult news.⁴⁹ Given that previous pediatric research has indicated limitations in parental understanding and parent-physician communication regarding research studies,^{4–9} this study fills an important gap by providing support for the effectiveness of a tailored intervention aimed at improving positive physician behaviors and communication strategies during ICCs for pediatric leukemia. Our results reveal that intervening with physicians to improve communication may enhance parental participation in the informed consent process.

Results partially supported the hypothesis that physicians in the intervention group would show improvements in communication behaviors during the ICC. Specifically, the PDI improved physician rapport-building behaviors, but only when physicians attended subsequent booster sessions. These findings highlight the importance of including booster sessions in intervention designs, which seem to have an impact

TABLE 4 Parent Communication

Characteristic	PDI + Booster (<i>N</i> = 17), Mean (SD) ^a	PDI, No Booster (<i>N</i> = 8), Mean (SD) ^b	Control Sites (<i>N</i> = 24), Mean (SD) ^c	<i>F</i>	<i>P</i>
General communication	240.2 ^e (129.8)	163.5 (145.7)	148.6 ^e (133.2)	<i>F</i> _{1,42} = 2.4	.10
Study communication	35.9 ^e (27.4)	32.6 (30.7)	16.6 ^e (28.1)	<i>F</i> _{1,42} = 2.4	.10
Mother total questions asked per minute	0.44 ^d (0.23)	0.41 ^e (0.25)	0.19 ^d (0.24)	<i>F</i> _{1,42} = 5.7	.006
Father total questions asked per minute	0.26 (0.24)	0.07 (0.27)	0.26 (0.24)	<i>F</i> _{1,36} = 1.3	.27
Total mother and father total questions asked per minute	0.69 (0.37)	0.44 (0.41)	0.45 (0.36)	<i>F</i> _{1,36} = 2.1	.14

Results are based on analyses of covariance. Means were adjusted for the following covariates: Parent Index of Social Position; parent minority status; physician role; physician years of care; and physician gender.

^a *N* = 15 for father total questions asked per minute and total mother and father total questions asked per minute.

^b *N* = 7 for father total questions asked per minute and total mother and father total questions asked per minute.

^c *N* = 21 for father total questions asked per minute and total mother and father total questions asked per minute.

^d Mean differences are significant at .001 according to Fisher's least significant difference statistic adjusting for multiple comparisons.

^e Mean differences are significant at .05 according to Dunnett's multiple comparison statistic contrasting intervention groups versus controls.

on the retention and adoption of targeted skills and strategies.

Partnership-building behaviors were unchanged. One possible conclusion from this finding is that it may be easier to enhance rapport-building behaviors of pediatric oncologists in this emotionally challenging conversation because of a possible preference of physicians and parents to view the physician as “helper” versus “partner” in care. Alternatively, if rapport is established early in the ICC, it may obviate the need for physicians to engage in partnership-building. Nonetheless, it should be noted that Yap et al²⁶ did report that physicians in the PDI group elicited more open-ended questions, which highlights the uptake of some partnership-building behaviors. It is important to note that these possible explanations for our findings cannot be generalized to all communication skills training research, and additional research in pediatric settings is needed for purposes of replication.

Furthermore, our findings that parents in the PDI group + booster session engaged in more general communication and study-related talk during the ICC reveal the physician behaviors targeted via the PDI may stimulate greater parental participation in the ICC. This is further supported by the finding that mothers in both PDI groups asked more questions per min-

ute. No group differences in father participation were found, but the small number of fathers may have limited power to detect differences. Coupled with the findings of Yap et al,²⁶ our results reveal that physicians and parents in the PDI group engaged in more study-related discussions, which was a primary intervention target.

One strength of the current study is the direct observation of ICCs, which provides communication data that are impossible to gather by other methods. In addition, the positive impact of the intervention may have been enhanced by the fact that it was designed based on feedback from parents and previous research specific to this context.²⁹ Limitations of the study should be considered. Physicians who agreed to participate in the PDI and attend booster sessions may have had greater interest in improving their communication skills in conducting ICCs, compared with physicians who chose not to participate. However, control sites were included in our study design to mitigate this limitation. In addition, whereas the RIAS coding system used to measure physician rapport and partnership-building is well established and widely used, it was not specifically tailored to goals of this intervention. This could explain why significant differences were found

for rapport-building, but not for partnership-building.

The findings have research and practice implications. Given the importance of physician-parent communication across pediatric practice, the same techniques stressed in our intervention can help general pediatricians and those in varied settings when communicating with parents and patients. Unfortunately, many physicians have time and schedule restraints that hinder one's ability to attend day-long seminars. However, with the growing enthusiasm for Internet-delivered interventions, an interactive online physician intervention aimed at improving positive physician behaviors may prove effective for physicians interested in improving their own skills while also learning techniques to encourage parent and patient participation. Future directions also include the solicitation of qualitative comments from parents and patients to assess physician communication and engage families as active contributors to quality improvement.

CONCLUSIONS

The findings across pediatric cancer⁵⁰ and other pediatric^{9,51} literature indicate a need for improvements to the informed consent process and this is a response to that need. Results of the current study reveal that a physician-directed intervention to improve the informed consent process for pediatric

leukemia research was both feasible and effective. It is promising that physician behaviors were changed via a time-limited intervention. Our study highlights the importance of continued research to examine how similar strategies may be used to improve communication with other patient populations.

ACKNOWLEDGMENTS

This work was supported by National Cancer Institute grant R01 CA 083267.

We thank the MUISIC research team of

Anne Angiolillo, MD (co-investigator) (Children's National Medical Center, Washington, DC), Michelle Eder, PhD (Center for Health Research, Kaiser Permanente, Portland, OR), James Feusner, MD (co-investigator) (Children's Hospital of Oakland, Oakland, CA), Anita Khayat, PhD (Children's Oncology Group, Arcadia, CA), Glen Lew, MD (co-investigator) (Children's Healthcare of Atlanta, Atlanta, GA), Robert Noll, PhD (co-investigator) (Children's Hospital of Pittsburgh,

Pittsburgh, PA), Anne Reilly, MD (co-investigator) (Children's Hospital of Philadelphia, Philadelphia, PA), and Kathy Ruccione, RN, MPH (co-investigator) (Children's Hospital Los Angeles, Los Angeles, CA); Sabahat Hizlan for assistance with data management; Meral Sayir for assistance with data coding; 2 anonymous reviewers for helpful comments; and the research staff, physicians, and families for participating in this study.

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