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A Feasibility Trial of a Video Intervention to Improve Informed Consent for Parents of Children with Leukemia

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Abstract

Background—Research on parental understanding of informed consent for pediatric randomized clinical trials (RCTs) has highlighted weaknesses in understanding of key aspects of informed consent. The goals of the current study were to assess the feasibility of and parental satisfaction with a video intervention to improve informed consent for pediatric leukemia RCTs and to compare parental question asking during informed consent conferences (ICCs) for parents in the current study with historical control data.

Procedure—A 20-minute video was produced. Utilizing the principles of anticipatory guidance, it included information delivered by nurses and physicians about leukemia and key aspects of informed consent. Parents were encouraged to be active participants in ICCs. Participants included 12 parents of children newly diagnosed with pediatric leukemia. The video was viewed by local pediatric oncologists prior to utilization with families.

Results—Ninety-two percent of parents reported that the video made it easier to understand information that their child's physician later provided; 83% of parents reported that it helped them to think of questions to ask the physician; and 67% of parents indicated that the video made them feel more comfortable with asking questions of the physician. Results of a *t*-test comparing question asking during ICCs revealed that parents who participated in the intervention asked a higher rate of questions than parents from a historical control sample ($t = 1.95$, $p = 0.05$).

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Conflict of Interest Statement

The authors do not have any conflicts of interest to disclose.

Discussion—Our study supports the feasibility and potential efficacy of a brief video intervention employing anticipatory guidance to prepare parents for future discussions about RCTs.

Keywords

informed consent; pediatric leukemia; ethics

Introduction

The time period surrounding an initial diagnosis of pediatric leukemia represents a significantly stressful time for most families [1,2]. During this time, families are faced with extensive information that they must try to understand and use to make decisions about their child's care. In addition, most children with pediatric leukemia are offered the option of participating in a clinical trial, which necessitates additional discussions with physicians about clinical trials, known as informed consent conferences (ICCs). Given the additional demands on families' abilities to understand and assimilate information, it is not surprising that parents often have difficulty with understanding key aspects of informed consent. Indeed, research suggests that many parents have difficulty understanding the multiple fundamental aspects of informed consent, including randomization, the role of choice in participation, and differences between clinical trials and off study treatment [3,4].

These difficulties with understanding basic elements of informed consent highlight the importance of interventions to improve informed consent for pediatric leukemia trials. Research on interventions to improve informed consent have been used with a variety of patient populations, and have included enhancing the readability of consent documents [5,6], testing for understanding [7], and providing additional information through the use of multimedia [8,9]. Unfortunately, in a recent review of interventions to improve informed consent across many different populations, Flory and Emanuel [10] concluded that there are limited data supporting the effectiveness of these interventions, but this review also noted that the use of neutral educators in extended discussions of key aspects of research is a promising area of intervention.

One technique that provides education to families and has demonstrated promise in other areas such as injury prevention, infant sleep, and child rearing practices, is anticipatory guidance [11]. Anticipatory guidance prior to ICCs may be particularly beneficial for parents of children with pediatric leukemia who are asked to process an abundance of information presented during the ICCs. The guidance might help parents to focus on key elements of doctor-patient communication. Additionally, our research group believed that technology might be useful to supply the anticipatory guidance.

There are major challenges related to providing anticipatory guidance to parents of children very recently diagnosed with leukemia. First, there is the constraint of time and the constant influx of friends/family when a family is receiving this devastating news. Second, pediatric oncology treatment teams are extremely busy when a child is first diagnosed with cancer. One goal of this work was to determine whether it was feasible to integrate this approach into clinical care in a manner that was helpful to families and not disruptive to pediatric oncology treatment teams.

The intervention described in the current paper was created as a result of experience gained during data collection for a clinical trial that examined the efficacy of two interventions in improving parental understanding of informed consent for children diagnosed with pediatric leukemia [12]. One of these interventions utilized nurse educators in an anticipatory

guidance intervention. The second intervention focused on training pediatric oncologists 1) to deliver information in the ICC in a specific order, 2) to encourage parental involvement, via open-ended questions, and 3) to encourage parents to ask questions [12].

The content of the anticipatory guidance intervention was aimed at preparing parents for communication with physicians in ICCs and educating parents about the goals of research and treatment; voluntariness of participation; confidentiality; randomization; and other essential aspects of informed consent for clinical trials. Additional details regarding this nurse-delivered intervention have been previously reported [13]. During recruitment for the nurse-delivered intervention, it was noted that approximately 50% of parents declined participation, which represented a marked contrast to previous experience of recruiting families of children with pediatric leukemia [3]. Evidence suggested that it was too difficult or overwhelming for some parents to schedule a separate meeting with a nurse educator [13]. It was decided that the development of a DVD that conveys similar information to what was delivered by the nurses may allow families to access the intervention more readily and would be more cost effective. The goal of the intervention was to improve not only understanding of clinical research but also to encourage and empower parents to be active during discussions with their child's physicians and to ask questions about areas that were unclear to them.

In this paper, we describe the development, feasibility, and satisfaction with a DVD-based video intervention to improve parental understanding of informed consent and communication with their child's physicians during ICCs. A secondary goal was to assess the potential effect of the intervention on active parental involvement in ICCs by comparing data from the current study regarding parental question asking during ICCs with data from historical controls.

Methods

Research participants were recruited from Children's Hospital of Pittsburgh. IRB approval was obtained from the local IRB prior to study recruitment. The video was shown to the pediatric oncologists at the Children's Hospital of Pittsburgh to ensure they were supportive of the material on the video, and they could support the suggestions on the video. Their support and involvement was critical since the oncologist on service had to remember to ask the family about their interest in this study and call the research team on very short notice

After obtaining informed consent, participants watched the video on a portable DVD player in the child's room with a research assistant shortly after their child's diagnosis. Subsequent ICCs were observed and audiotaped by a research assistant. Research assistants were trained to observe and document the fact that the parents watched the video but did not answer any questions after parents viewed the video. Research assistants did tell the families prior to watching the video that their child's doctor had seen the video and approved of its content. All questions were deferred to subsequent ICCs. Following the ICCs, parents participated in an interview that included questions about satisfaction with the video intervention. The research assistants were instructed to interview the parent who watched the video and who was the most active during the ICC. The most active parent during the ICC could not be interviewed for 3 cases, and instead the less active parent who watched the video was interviewed.

Parental question asking was assessed by count of the number of questions asked by parents during ICCs. Data about question asking from the current study were compared to historical data that were collected in a descriptive study that assessed communication during ICCs [3].

The script for the video was written by one of the authors (M.E.), and produced and developed at the facilities of another author (A.R.) [14]. A Sony DV Cam digital camcorder equipped with a Sennheizer lavalier microphone was used. Editing was carried out using Adobe Premier non-linear editing software on a Windows-based microcomputer. The video was distributed during the study using a DVD, but it can also be viewed via the internet by COG members at: <https://members.childrensoncologygroup.org/DISC/bioethics/default.asp> and by the public at: <http://www.veoh.com/browse/videos/category/family/watch/v18851732PP8mHFhF>. The video features actual doctors and nurses presenting the information rather than actors. Text (accompanied by voice over) was also presented on the screen at various points during the video to highlight central points that were being delivered by the nurse. Table I displays excerpts from the script that highlights the key areas targeted. Briefly, the video targeted key aspects of informed consent, such as randomization, voluntariness, and the right to withdraw. In addition to providing general information about clinical research, parents were also encouraged to be active participants during ICCs and to ask questions. Examples of effective communication during ICCs, role-playing of parent-physician communication, and common questions were also provided. Parents were also encouraged to communicate their preferences about the ICC to their child's physician. For example, parents were encouraged to ask for a break during the ICC if needed; to communicate their preferences for the location of the ICC; and to communicate who they would like to be present at the ICC. Parents were provided with blank paper to write down questions or take notes while watching the video. At the conclusion of viewing the video, which lasted approximately 20 minutes, printed material was provided that included a written information sheet about research studies and a one page description of pediatric leukemia [15].

Results

A total of 21 parents of children with pediatric leukemia who were offered a clinical trial were approached and 17 (82%) agreed to participate in the current study. The primary reason given for declining participation was that parents were too overwhelmed or busy to participate. Scheduling problems prevented four of the 17 parents from inclusion in the study (research assistant not available). In addition, one case was excluded from data analyses due to insufficient ICC data, resulting in a sample size of 12.

The following results were obtained from these 12 parent interviews designed to assess the feasibility of and satisfaction with the video intervention. Parents were generally interviewed within 72 hours after the intervention and ICC.

Demographics

Demographic characteristics for the sample are shown in Table II. Parents included 9 women and 3 men, with a mean age of 34.8 years (SD = 5.7, range 25–43 years). Socioeconomic status (SES) was measured using the Hollingshead Index of Social Position [16], which is derived by combining education level and occupation type, with scores ranging from 1 to 5, with 5 being the lowest SES category. Fifty percent fell in the highest range (1–2), and 1/12 (8%) of the parents was of racial/ethnic minority, specifically Asian American. The video intervention was presented in English and interviews were conducted in English.

Subsequent Communication with Physicians

Table III displays parental responses to questions about communication with their child's physicians. Ninety-two percent of parents reported that the video made it easier for them to understand the information that their child's doctor later provided. Sixty-seven percent of

parents reported that watching the video made them feel more comfortable asking questions of their child's doctor. The majority (83%) of parents reported that the video helped them to think of questions to ask their child's doctor. Finally, 83% of parents indicated that the video had an effect on the way they later communicated with their child's doctor. In an open-ended question about how it affected their later communication, 7 of the 10 parents indicated that it either helped them to think of questions to ask their child's physician or enhanced their comfort level with asking questions.

Rating of Video Intervention

All parents indicated that it was somewhat easy or very easy to understand the information provided in the video (Table III). When asked if they watched the video after first seeing it with the research assistant, 3 parents (25%) indicated that they viewed it 1–2 more times with others, including the father, the child, and the grandparents. In response to a question about whether there was anything that they did not like about the video, 3 parents (25%) indicated that there was something that they did not like about the video. When asked what they did not like about the video, one parent indicated that it was too slow; one parent indicated that the people in the DVD appeared to be too happy; and one parent indicated that if the video had been more interesting, her child may have watched it.

Use of Written Materials

Descriptive statistics regarding the use of written materials that accompanied the video intervention revealed that all parents indicated that they were given written materials. When asked how much the written material helped them understand the treatment options available, 84% indicated that it helped a lot or some, while 16% indicated that it only helped a little or not at all.

Anxiety After Watching Video

Responses to an interview question assessing the effect of the video on parents' anxiety levels indicated that the majority of parents (75%) reported that the video either had no effect on their anxiety or decreased their anxiety. Twenty-five percent of parents indicated that the video increased their anxiety a little ($n=2$) or a lot ($n=1$).

Question Asking Compared with Historical Data

Question asking during ICCs by parents in the current study ($n=12$), as assessed by observation during the ICCs, was compared with question asking that was assessed similarly in a previous descriptive study ($n=133$). Results of a t -test comparing parent question asking revealed that parents who watched the video in the current study asked a higher rate of questions per minute ($M = 6.9$ questions per 10 minutes of conferences, $SD = 3.3$) than did parents from the historical study ($M = 5.1$ questions per 10 minutes, $SD = 3.1$; $t = 1.95$, $p = 0.05$, two tailed test).

Discussion

The results of this pilot study support the feasibility and possible efficacy of an anticipatory guidance intervention using a video presented via DVD to improve informed consent in phase 3 pediatric oncology trials. Parents reported high levels of satisfaction with the video and results based on both parental report of later communication during ICCs and comparisons of question asking during ICCs to historical data also suggest that the video intervention had a positive impact on subsequent discussions with physicians during ICCs. Adverse events were minimal.

Although a review by Flory and Emanuel [10] suggested limited effects of multimedia presentations on understanding of informed consent, the multimedia intervention developed for the current study was unique in two respects. First we used anticipatory guidance as a theoretical framework, and second, the members of the pediatric oncology faculty watched the video prior to the families and explicitly endorsed its content.

The intervention developed for the current study provided education about key elements of clinical trials and pediatric leukemia, and it encouraged more active participation in the ICC. Providing families of children with pediatric leukemia with a copy of the video and short term access to a portable DVD player also allows families flexibility in deciding when and how often to view the video, although the majority did not report watching the video a second time. Nonetheless, flexibility in when to view the video may be important for this population due to the high levels of stress, potential for feeling overwhelmed, and time demands for families of children with newly diagnosed pediatric leukemia. While parents consistently declined a similar intervention with a nurse providing the guidance, the video seemed more attractive and we obtained greater participation. Distribution of the video intervention via the internet may provide a useful and more cost-effective approach compared to use of a portable DVD player.

Additionally, the video was watched by all members of the pediatric oncology faculty prior to initiation of the study locally. They were aware of previous documented problems with informed consent [3] and were enthusiastic to try to improve the process. This helped enormously with local recruitment and may have influenced how the attending pediatric oncologist led the ICC.

Of note, the time required to obtain the informed consent and to show the video to families often required more time than actually observing the video. Parents did appear to appreciate the brevity and focus of the video message. Additionally, multimedia interventions such as the one described in the current paper offer the advantages of little demand on healthcare professionals' time, low cost, and ease of dissemination.

Despite the promising results from the current study, there are limitations that should be addressed in future research. Specifically, the small sample size and limited inclusion of racial/ethnic minority families and families with lower SES suggests that future research with larger and more diverse samples is needed before generalizations can be made about the effectiveness of such an intervention in improving communication during ICCs. This is especially relevant since previous work has documented less understanding of fundamental elements of informed consent by low SES minority families [4]. Additionally, the current study did not contain a concurrent control group. A randomized trial that includes a control group and other types of interventions would allow for a comparison with other strategies to improve informed consent. It should also be noted that three parents indicated that their anxiety increased after viewing the video. One possible explanation for this is that much of the information provided in the video was provided to parents for the first time. Based on the concept of goodness of fit [17], information may decrease anxiety for some parents, while other parents may feel overwhelmed by being provided with information. Thus, it may not be that the video itself increased anxiety for some parents, but rather that information (which would later be provided during ICCs) may at least temporarily increase anxiety for a minority of parents. Nonetheless, this phenomenon should be carefully monitored.

Although future research is needed, the results of the current study highlight the potential value and feasibility of a brief video-delivered intervention utilizing anticipatory guidance to prepare families of children with pediatric leukemia for subsequent ICCs with their child's

physician. These data also suggest that technology based interventions may enhance physician-patient communication in a number of standardized, but complex settings.

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Table I

Excerpts from DVD Script

Topic	Excerpts from Script
Goals of Research and Treatment	The goal of research is to develop scientific knowledge that can make a positive impact in the care of other patients in the future. The goal of treatment is solely devoted to the medical care of the individual patient. The care of each child will always take priority over the goals of research, but it is important to understand this difference.
Possible Differences Between Research and Current Therapy	Most of the drugs would be given to your child as part of current therapy whether or not you participate in a research study. In some research studies, treatment may be longer or shorter than current therapy or involve more trips to the hospital or clinic.
Voluntariness	Participation in a research study is strictly voluntary. Once you have learned about a research study and all that it involves, you and your family can decide whether or not to participate. If you decide not to participate in the treatment study, your child can continue to receive treatment at this hospital. The doctors and nurses will be just as committed to caring for your child whether you decide to participate or not.
Randomization	A participant in a Phase III research study will usually be assigned to the current therapy or one of several new groups by a process called "randomization," which is like flipping a coin or picking a number from a hat. In most research studies for childhood leukemia, the treatment for your child will be determined by chance. Neither you nor your doctor will make the exact treatment decision if you decide that your child will be in one of these research studies.
Right to Withdraw	If you decide to enroll your child in a research study, you may withdraw from that research study at any time without any explanation and without any penalty.
Communicating Preferences for ICC	If you would prefer a private room, is there a family member that you would like to stay with your child? You can also ask the doctor or nurse to arrange for someone like a child life specialist to stay in the room with your child.
Consent Document	The doctor will be giving you a packet about the research study which is called an informed consent document. We encourage all parents to read this informed consent document or ask someone to read it to you. Please feel free to write on the document and ask the doctor about anything that is unclear.
Question Asking	The doctors want you to ask questions, and they want to be sure that you understand the information they are giving you. So be sure to let the doctor know what questions you have. It may be easier to write down your questions before your meeting or jot down notes and questions as you talk.

Table II

Demographic Characteristics

	Mean (SD)	
Parent Age	34.8 (5.7) Years	
Patient Age	5.8 (4.1) Years	
	Females	
Parent Gender	9 (75%)	
Patient Gender	5 (42%)	
Patient Diagnosis	ALL	11 (91%)
Patient Trial Enrollment Status	On RCT	Off RCT
	10/12 (83%)	2/12 (17%)
Parent Ethnicity	Caucasian	11 (92%)
	Asian	1 (8%)
Parent ISP	1–2	6 (50%)
	3	2 (17%)
	4–5	4 (33%)
Parent Education	Less Than High School	2 (17%)
	Completed High School	1 (8%)
	Some College	3 (25%)
	College Graduate	3 (25%)
	Postgraduate Level	3 (25%)
Parent Religion	Protestant	4 (33%)
	Catholic	4 (33%)
	None	4 (33%)

ALL: acute lymphoblastic leukemia; RCT: randomized clinical trial; ISP: index of social position

Table III

Satisfaction with DVD Responses

	Yes				
Were you given any written information to go with the DVD video?	12 (100%)				
Did the DVD video make it easier for you to understand the information your child's doctor later provided?	11 (92%)				
Did the DVD video help you think of questions to ask your child's doctor?	10 (83%)				
Do you think watching the DVD video had an effect on the way you later communicated with your child's doctor?	10 (83%)				
Did watching the DVD video make you feel more comfortable about asking your child's doctor questions?	8 (67%)				
Did you watch the DVD video again after first seeing it with the research assistant present?	3 (25%)				
Was there anything that you did not like about the DVD video?	3 (25%)				
	Very Easy	Somewhat Easy	Somewhat Hard	Very Hard	
How easy was it to understand the information provided in the DVD video?/	11 (92%)	1 (8%)	0	0	
	A lot	Some	A little	Not at all	
How much did this written material help you understand the treatment options available for your child?	3 (25%)	7 (59%)	1 (8%)	1 (8%)	
	Increased a lot	Increased a little	No effect on anxiety	Decreased a little	Decreased a lot
What effect did watching the DVD have on your level of anxiety?	1 (8%)	2 (17%)	4 (33%)	3 (25%)	2 (17%)

/ Written material consisted of patient information pages on pediatric leukemia [15] and key aspects of clinical trials.