



I Wasn't Trained for This: Designing Decision-Making Aids to Assist Families Considering High-Risk Pediatric Clinical Trials

Michael Schmidt

Center for Multimedia Arts
The University of Memphis FedEx Institute of Technology
365 Innovation Drive, Memphis, TN 38152 USA
901-678-1777
mschmidt@memphis.edu

ABSTRACT

How does a graphic designer come to find himself contributing to new initiatives in bioethics and palliative & end-of-life care at St. Jude Children's Research Hospital? Moreover, why is this designer co-leading a team that is responsible for imparting ethically, and some would say morally, imperative information to parents considering experimental medical treatments for their sick and dying children? I'm that designer, and I'm telling you, I wasn't trained for this.

Nevertheless, a graphic designer is needed in this case because parents, and certainly the patients, have a very difficult time deciphering the thirty-page, single spaced "informed consent" documents that explain what kind of cancer they're facing and just what the doctors (physician researchers) propose to do about it. While the physicians and non-physician caregivers act as advocates and interpreters, they don't have the means to explicate complex concepts as an information designer or graphic designer might.

Unfortunately, this is only the tip of this very complex situation. Like I said, I wasn't trained for this. However, by bringing together a diverse and multidisciplinary team of medical doctors, psychologists, technical communicators, management information systems experts, software designers, and engineers, my team has developed a novel approach to design for informed consent.

I propose to set the stage with this case study, where understanding through graphic design truly is a high-stakes matter. I will discuss the ways in which the design team had to transmogrify into a small multidisciplinary army to cover the complex areas of user needs requirements. I will discuss how design decision-making, in its various disciplinary manifestations, had to adapt, give-way, and eventually reinstate itself anew over the course of three years of research.

Finally, I will share the prototypes we have created for both parent and patient communication tools, both of which deal with end of life decision-making.

KEY WORDS

Decision-Making, Experience, Multidisciplinary

INTRODUCTION

For better or worse, graphic designers—and I have good reason to believe designers of many other stripes, too—receive opportunities they weren't trained for but nonetheless felt qualified to take on, either for reasons of hubris, an honest desire for a challenge, or temporary insanity. And as designers are popularly defined more by the products they create than by their immaterial stock in trade, it's far less a mystery why a doctor, who has grown frustrated with the opacity of his thirty-page, single-spaced, black & white, text-only informed consent documents might look to people with expertise in multimedia for a more comprehensible way to relate crucial decision-making information to his patients. And so while I was just as assuredly insane as I was trained in various forms of media when I met this physician, I wasn't experienced in how to help people use design to make difficult treatment decisions—a process he wanted to better facilitate.

Not surprisingly, I found myself making very little at all. Instead, I was soon ensconced in the challenges of building a multidisciplinary team to tackle the complex questions implicit within this physician's medical research context. Eventually, I became determined to find the points at which design methods and media could be of greatest relevance to patient family treatment decision-making if, in fact, we were to finally provide an additional resource—an augmentation to the existing informed consent process—to help families cope with, comprehend, and participate in their treatment decisions. Informed consent is a legally and ethically mandated process wherein patients are informed of the risks, benefits, and alternatives to a physician's recommended treatment. Other than emergency situations, patient consent must be obtained, in writing, before treatment can be conducted.

The following case study relates a series of insights for augmenting informed consent by designing decision-making aids to assist families who are considering high-risk pediatric clinical trials. This research initiative is a collaborative effort between St. Jude Children's Research Hospital in Memphis, TN, USA, Drs. Ray Barfield

and Justin Baker lead investigators, and the University of Memphis. This work has been funded in part by the Greenwall Foundation, an organization dedicated to advancing research in bioethics. Further support has been provided by St. Jude, the University of Memphis Faculty Research Grant Program, and by the University's Center for Multimedia Arts.

THE PROBLEM(ATIC) CONTEXT

Patients have to be expert decision-makers if they are to convert the ever more complex information regarding the advances of medical technology, as they pertain to their care, into informed choices regarding courses of action that will leave them, prospectively and retrospectively, satisfied with their decisions.

Decision-making challenges become harder still when it's not the patient consenting or dissenting to a clinical trial, or choosing among a set of standard-of-care options, but a family. This challenge is particularly painful, overwhelming, and anxiety-inducing when that family's child is facing a catastrophic illness.

Each year, four thousand pediatric patients are treated at St. Jude Children's Research Hospital, where my colleagues and I work within ethics and palliative care initiatives housed in the Oncology and Nursing Research departments, respectively. St. Jude patients and their families are fighting cancer and other catastrophic illnesses within one of the World's premiere pediatric research institutions. Patients come to St. Jude from all over the globe presenting symptoms of serious illness. Four hundred of these children each year are newly diagnosed with cancer, an infectious disease, or other life-threatening malady. They and their families (abbreviated "patient families") are coping with the emotional and physical toll of illness along with the cognitive burden of comprehending the operational details of a disease, specifically what it's doing to their child's body.

St. Jude is a research hospital, and as such its patients are chiefly enrolled in research protocols. Therefore, while new patient families try to emotionally absorb and cognitively process a harrowing diagnosis, they must also decide on a course of treatment from a set of options usually predominated by a state-of-the-art medical research protocol proposed by a physician researcher. And the decision-making doesn't stop there. Many St. Jude patient families go through years of clinical trials, with decisions to be made at critical junctures throughout. So critical are the decisions, and so heavy are the hopes for their outcomes, it is not the least exaggeration to say that making these decisions is an intrinsic part of the illness experience—a family illness experience.

The treatment decision-making process within pediatrics is obviously distinct from that of standard medicine. The choice to consent or dissent to treatment is not solely the purview of the patient. And depending on age and other circumstances, the decision may not be at all that of the child. Yet, as my colleagues and I learned from interviewing pediatricians, children as young as five years old demonstrate that they understand what is going on with their bodies, disease, and their healthcare. These pediatricians, we found, purposefully and

meaningfully include children as young as six year old in treatment decisions, one doctor citing her desire to involve children in their healthcare as her primary reason for becoming a pediatrician in the first place. And this same group of doctors described the decisional authority of teenage patients as, “driving the [treatment decision-making] process.” The field of pediatrics is, in fact, increasingly recognizing the family—parents and child—as a decision-making unit. This definition recognizes the decisional authority of the parents while remaining inclusive of the child-patient’s priorities & values. This distinction further acknowledges that decision making in pediatric catastrophic illness is a cognitive and emotional challenge to the entire family, one that engages the unique values inherent in each family’s beliefs, the priorities of the pediatric patient, and the internal and external pressures on each mother and father to be “the good parent.”

Yet the emotional and intellectual consternation of this problem context is not owed exclusively to the affective and cognitive challenges facing the patient family. For an accounting of at least half of this problem area’s complexity, we can turn to the prickly legal and ethical particularities of research in human subjects. Clinical trials are regulated in the US by the Food and Drug Administration (FDA) and overseen locally by institutional review boards (IRBs). Title 45 of the Code of Federal Regulations (Part 46, Subpart A to be exact, but then you already knew that), states the *Common Rule*, which explicates the rules of ethics that all study protocols must meet in order to receive FDA and IRB approvals.

THE PROBLEM(ATIC) APPROACH

The *Common Rule* states that subjects must give their informed consent to research. The informed consent documents for research protocols are challenging to follow, even for a college graduate. If the patient family does not ask questions of the care team or seek out other information resources, their decision may not be fully informed, not only violating the *Common Rule*, but leaving open the possibility for serious misunderstandings during treatment, particularly when serious side effects occur. We have here, then, a significant chunk of the rationale for the design of a decision-making intervention to promote informed decision-making. This rationale resonates on five levels: (1) with the needs of parents to feel and to know they have made a decision truly in the best interest of their child; (2) with the needs of children to live out their priorities and yet to feel and to know they have not disappointed their parents, e.g., by rejecting a high-risk, almost certainly non-curative treatment option; (3) with the ethical and professional requirements of physicians and caregivers; (4) with the requirements placed upon local IRBs; and (5) with the risk-averse procedures of boards of healthcare institutions. All of these levels must be addressed if a design intervention is to be tested, approved, and eventually implemented within a healthcare institution.

The *Common Rule* further lays down the content requirements for informed consent: “A statement that the study involves research, an explanation of the purposes of research, . . . a description of the procedures to be followed, and identification of any procedures which are experimental.” (Breault) These statements provide

obvious reasons to employ media beyond text to the practice of treatment decision-making and informed consent. Given the clear and obvious need, our prototyping of a decision-making aid to augment informed consent started here, with content authoring. We created animations illustrating how an experimental drug, once introduced into the patient, will live out its intended purpose. And we developed an interactive presentation explicating the steps in a randomized trial (Fig. 1)—a process that is extremely cumbersome to communicate and comprehend using verbal means only.

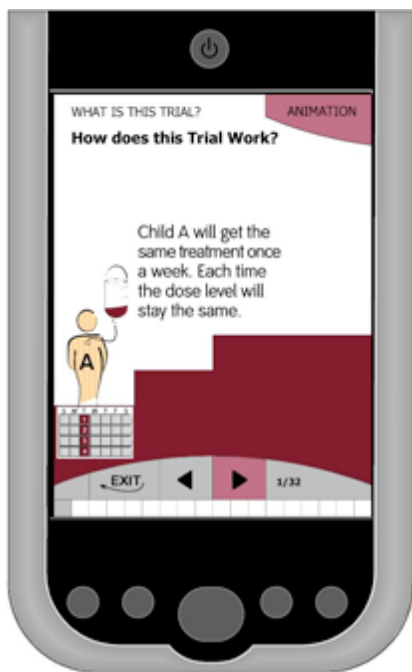


Figure 1. Interactive animation of a randomized trial.

Our animation of a randomized trial is where we had the most success depicting not only the treatment process, but also its inherent risks. This may seem like a simple enough use of visual rhetoric. Yet it's an important accomplishment for the parent who would not otherwise understand that if she consents, her child could receive the same dose of an experimental drug that sent the child right before hers to the ICU. That's the risk, and it's one that's difficult to fully grasp from just the physician's standard informed consent document. And legally and ethically, informed consent must include "a description of any reasonable foreseeable risks or discomforts to the subject." (Breault)

The highest risk research trials are categorized as phase I, meaning they represent the first phase in clinical trials as conducted in human subjects. These are generally therapies tested in humans for the first time. Phase I studies often test for the maximum tolerated dose (without unacceptable side effects) of a new drug therapy. Phase II studies test therapies for signs of potential effectiveness in fighting their intended disease target. And Phase III studies compare the efficacy of new, promising therapies against current standards-of-care. (Getz and Borfritz 2003)

Our prototypes have been developed for phase I studies (Fig. 2). These studies are very common, involve only a small number of participants in each trial, and are typically not high-risk. However, phase I studies of cancer treatments, particularly in children, the ones we're involved in, are most definitely high-risk. These studies are developed, evaluated, and overseen with extreme rigor and are typically carried out only on terminal patients, with at least one exception being patients in phase I stem cell transplantation studies. Without this subset of high-risk studies, there would be far fewer advances in research medicine and treatment options for catastrophic illnesses, particularly cancer. Because phase I studies typically do not emphasize health-related benefit, and because this subset of phase I studies can be highly toxic and even deadly, these choices are considered against other non-curative options, such as comfort care (pain management and hospice), therapy attempts at relatively short life extensions, or even other phase I protocols. Therefore, the phase I study option, available to patients with at least eight estimated weeks to live, is grouped with other end-of-life care options.

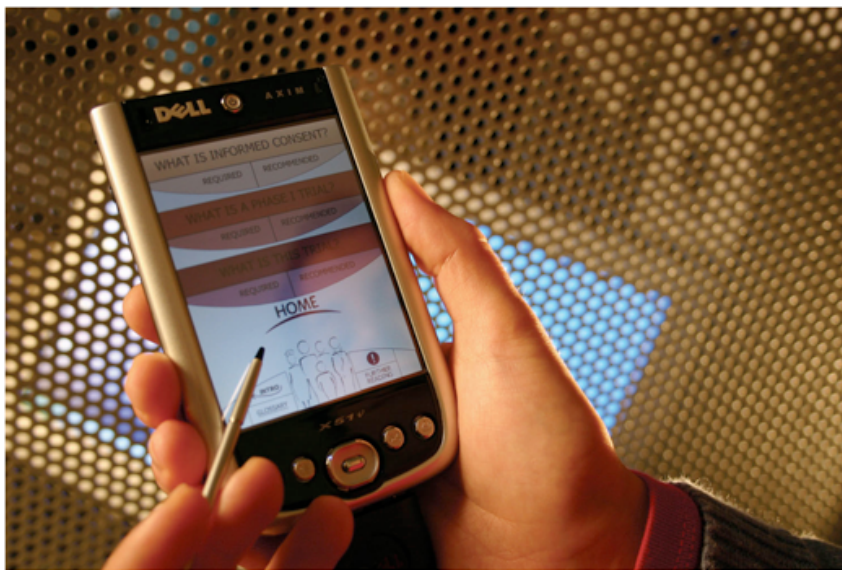


Figure 2. Working prototype for mobile, interactive media guide to informed consent.

Given the remoteness of curative potential in phase I studies, quality-of-life must be considered a major determining factor in this particular decision-making process, expanding the patient family's deliberations beyond a singular consideration of consent/dissent to a proposed clinical trial. In other words, the patient family is making a decision regarding how, where, and potentially with what degree of strength the patient will spend her last months and weeks of life.

Parents who have been through several clinical trials, self-described “veterans” of the treatment decision-making process—and thus people with the same tenure as those considering high-risk phase I studies—have told us that they just want to know what's different about the newly proposed trial from the dozens their child has participated in already. They want to see, explicitly, what content resides in this informed consent

document, or decision-making aid, that they haven't seen scores of times before. Given the risks associated with phase I trials, the non-curative focus of these studies, and the information parents have told us they want to see first and foremost, we believe it is imperative that the decision making aid foreground not only the difference in content but also the difference in concept from the patient family's previous deliberations (Fig. 3).

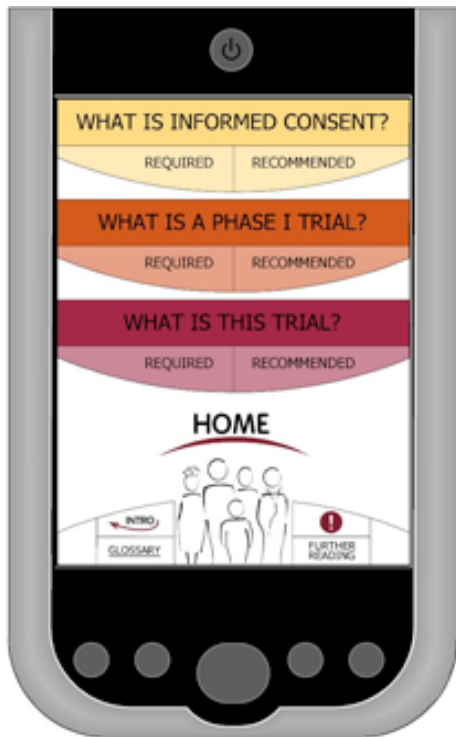


Figure 3: "Phase I" is visually emphasized.

ASSESSMENT

Ironically, and despite having two physician researchers leading our team, we didn't make the patient the intended emphasis until our second prototype, which we've just begun. And herein lies the pitfall of not being trained for this: we made two key mistakes. First, we let ourselves become overwhelmed by the rules of policy rather than remaining clear-sighted about the spirit behind those policies. The federal regulations and local IRB requirements eventually came to dictate, in the case of our first prototype, both the conceptual mapping of information and the resultant information architecture. While we achieved a user interface design that has thus far been rated very favorably for aesthetics, usability, and comfort by our evaluation participants, heuristic evaluations point out clear missteps, bringing me to the next mistake. Second, we knew too little at the outset about how to employ user-centered design. While we eventually garnered much of the information and insight we needed, we lost considerable time, funding, and essentially ran our prototyping effort into the ground—temporarily.

We also recognized, at the conclusion of our first prototyping phase, that we still understood too little about how a family's drive for a cure could become part of a decision-making process where the proposed study is a non-curative trial which might, maybe, advance the science of medicine towards cure for future patients. How, we asked, could this reality for which the physician and institution have an ethical obligation to impart be paired in a decision-making process with the powerful emotion of hope? After all, the first time a family receives a phase I proposal is soon after—and often right after—they learn the previous, curative trial failed. In our interviews regarding the informed consent process in general, parents and caregivers have both acknowledged that parents sometimes hear what they want to hear, or process only what they can through the stress of the moment, or for other reasons recount a very different version of what was said in the informed consent meeting from what actually happened.

REALIGNING FOR A BETTER APPROACH

We had to get some clarity regarding the main elements driving both the decisions patient families were making and the consequent realities patient families and their care teams were facing. Upon further investigation of the problem context, two intertwined imperatives emerged: ethics and hope. The imperative to promote an ethical decision-making process in which choices are truly informed is especially crucial in decisions regarding phase I trials, where, in spite of receiving all medical information to the contrary, parents and patients still state “hope for a cure” as their primary reason for consenting (Barrera, D'Agostino, Gammon et al. 2005). Yet this situation does not necessitate that the imperatives of ethics and hope form an irresolvable binary opposition, or that the ethical imperative to truly inform must forcibly oust the patient family's hope for a cure, however unlikely that outcome. If this were the case, then we can imagine the design guidelines would call for brute force use of explicit visual media to drive the unfortunate reality home.

Instead, the problem calls for a dialogical strategy, where family members' perspectives & values—the patient's being foremost—are aligned into an agreed-upon course of action, resulting in a decision with which all stakeholders can live without conflict or regret. I say all stakeholders, meaning the medical care team, too, because no physician and her care team would want to administer a toxicity study on a dying child who would rather be at home than in the hospital, where his parents insisted he remain. This sort of lack of alignment of priorities between parents and child, or between spouses, is what can really tear a family apart and, not incidentally, leave the physicians and caregivers with the memory of an unfortunate situation they may never forget. In such cases, stakeholder priorities are non-aligned, leaving high potential for uncertainty with the decision among most if not all of those directly involved. It's not hard to see how this can happen, even though every person in the situation has at heart, based on what they each know at the time, the child's best interest. However, ethics and hope, in this non-aligned scenario, have a very hard time coinciding. The physician who wants to ensure that the patient's end-of-life priorities are met and the parent willing to try

anything to save her child no matter what the child wishes (a dramatic example for emphasis) have a lot to discuss.

Ethics and hope, therefore, have presently formed the foundational imperatives undergirding our approach to this research for the design of family-centered decision making aids. Our goal, then, is to design for both imperatives by promoting the mitigation of decisional conflict. Decisional conflict is the experience of not being sure which treatment course to follow, or otherwise feeling conflicted about the choice—either an option yet to be chosen or a decision already made. It can be assessed both qualitatively and quantitatively, and it is attributed to feeling insufficiently informed or supported in the decision making process. Decisional conflict is also caused by unclear personal values from which to make a decision as well as from the irrevocable circumstance of facing uncertainty. (Whelan et al. 2004)

I have been careful not to state our goal as, *to mitigate decisional conflict*. Instead I've used the cumbersome and passive phrasing, *designing for the mitigation of decisional conflict*. While I believe that design is anything but passive, I agree with psychologist and user experience designer Marc Hassenzahl that “Designers can shape, but they cannot determine. They can create possibilities but they cannot create certainties. . . . Promising that a certain set of design recommendations—if put into action—will always result in a particular set of emotions, may be promising more than can be delivered.” (Hassenzahl 2004) I cannot say, therefore, that my colleagues and I are going to mitigate decisional conflict, replete as that phenomenon is with emotion. We've chosen instead to design for needs, the fulfillment of which we hope will promote less confusion, anxiety, and uncertainty (Fig. 4).

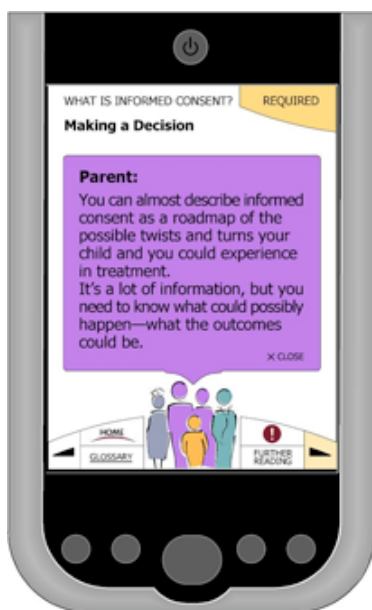


Figure 4. Perspective bubbles add supportive quotes from other patient families.

NEW GUIDELINES AND OBJECTIVES

We eventually learned from interviews with parents, patients, doctors, and non-physician caregivers, as well as from observations of medical rounds, intensive and frequent sessions with content experts, and further rounds of interviews that we should (1) build a decision making aid that can facilitate collaborative deliberations among family members and between the family and their pediatric care team; (2) respect the decision making role of children—even those quite young; and (3) provide means that promote assessment and sharing of values, priorities, expectations and fears to remove barriers to effective communication within the decision making process.

COLLABORATING ACROSS MANY DISCIPLINES

The objectives my colleagues and I have laid out are inherently multidisciplinary. Even within the healthcare context itself our team has engaged with members of multiple disciplines for their content expertise and experiential knowledge of patient families—social workers, nurses, nurse practitioners, child-life specialists, patient educators, psychologists, health communication experts, pediatricians specializing in symptom assessment and other health-related quality of life matters, and of course the lead physician researcher for whose experimental drug and phase I study we are designing the treatment decision-making aid shown in the previous figures.

Meeting the challenges of study design, study evaluation, and data analysis requirements of our initiative, we have the benefit of expertise in clinical psychology, cognitive psychology, communication, and human factors. However, the studies and measures—which we have only just begun—have been determined collaboratively between these researchers, the team's MDs, and the designers. This arrangement has enabled the designers—two graphic designers, to be specific—to engage in the entire initiative, with one designer, myself, also actively engaged in interviews and observations within the hospital. Because I became so drowned in trying to manage this new context and its multidisciplinary requirements, the other designer became the lead on media content creation and user interface design, and she supervised software engineering, which was outsourced to Flick Software, Inc. in Ottawa, Ontario, CA.

Easily the greatest deliberations have occurred over the text. Two technical communicators and a healthcare communicator wrote the text for our team's initial prototype. The reading level, voice, length, and content organization of the text elements were determined using focus groups investigating what patients, parents, physicians, and non-physician caregivers understood to be an informed consent process.

ANALYZING NEEDS

Since conducting a heuristic evaluation and user tests of our first prototype, we've adopted a user-centered design approach with the consultation of a cognitive psychologist specializing in human factors. This shift has

brought our design considerations more in line with the actual needs of patient families as they experience them in context.

OBSERVING BEHAVIORS

By observing behaviors, we've learned a great deal more about patient family communication preferences for decision-making and decision-making support. Tellingly, for instance, I learned from sitting in on medical rounds that parents were using online technologies to share their family's illness experience with family and friends back home. I was aware of these blogs, but I didn't stop to think St. Jude families might be using them, because I also knew the hospital doesn't provide or condone blogging for reasons of legal risk. But then I was thinking like an institution rather than observing from the vantage point of the subject. So there we sat in a room filled with MDs relating data and observations about their in-patients while the nurses outside the room were at their stations logging in to CaringBridge.com to see the latest reports from the parents of these same in-patients. This is not trivial or anecdotal information, because the actions observed were part of regular daily routine, lending just as much veracity as any validated quantitative measure could provide.

Another important series of insights has come from listening to how doctors, non-docs, parents, and children describe the roles they play in the informed consent decision-making process. Key self-descriptors from nurse practitioners, such as, "advocate" and "interpreter," for example, have helped us see not only how they too are part of the decision-making experience, but when and for what purpose.

ACCESSING INFORMATION

Accessing information is the problem component where we have found, thus far, the greatest relevance for and challenge to designing for the mitigation of decisional conflict, because this is the point where we have to recognize that stress and anxiety are going to interfere with comprehension, no matter how clear we make the information. However, the problem is temporal. The mothers we interviewed explained that the times they received the worst news about their child's prognosis were the times they felt like they were experiencing, as one mother stated, "a roller coaster [ride] with no bottom," or as another mom put it, "an emotional whirlwind." Not incidentally, it's at this moment they receive the informed consent document: the information regarding the next recommended trial for their child. Each of the parents agreed that they did come back to themselves, but the next day—not in that same session. Again, like Hassenzahl, I'm skeptical we can design information and information systems capable of facilitating knowledge acquisition in moments of serious negative affect by directly mitigating, through design, the user's feelings of anxiety, fear, or grief. Yet because we know from the literature and our own constituents that this form of high negative affect is temporal, that it is fluid, we can be reasonably confident that if we stay on task with meeting needs, other support from family members, psychologists, social workers, and child-life specialists will step in to help with the emotions. This is not at all to say affect is not an important user characteristic for design guidelines to

consider. Instead I'm emphasizing that any artifact of design is part of a greater system, and that system—consisting of other forms of support—should not be ignored but rather incorporated into design thinking as part of the approach to determining a holistic solution. It is this thinking, then, that has led my colleagues and I to stay away from recommending automated approaches to informed consent. Decision-making is an endeavor in human relationships. Disastrous decisions are the consequence of forgetting the human equation.

Despite the many challenges presented by Phase I study decisions, patient families do not have to decide right away. Depending on circumstances, they may have up to a week or more to make up their minds. One parent we interviewed stated that when she and her husband had at least one-two days before they needed to return their decision to the physician, they could “really drill down,” “pull apart,” and collect everybody’s questions to ask the doctor.

Of course their process of “drilling down” and “pulling apart” is what we’d like to keep learning more about. The informed consent documents, just simply as an inherent limitation of the artifact, are unsuitable to this task. One physician researcher stated in a recent interview that she tells her patient parents to highlight and underline things on the paper they don’t understand and to write questions in the margins. She is talking to many of the same parents who are blogging every aspect of their children’s illness experiences. Enough said.

The other major frame of reference we’re placing on the concept of accessing information addresses information architecture in general and the relationships between pieces of information specifically. This is yet another one of those areas for which I wasn’t trained. So to fill this void we’ve begun working with a systems engineer from St. Jude and a library science expert to create concept maps, which we hope, when paired with our UCD-method’s user profiles and scenarios, will provide us with a much better sense of how to organize and provide literal access to the informed consent information for phase I studies.

NETWORKING FOR SUPPORT

St. Jude patient families come to Memphis from all over the world. They may stay for one week, 30 days, 90 days, or longer. Spouses are often separated by distance during these longer periods; children are away from school and friends; and extended family members are remote as well. Web services, like the aforementioned CaringBridge.com, have become popular means for keeping friends and family “up-to-the-minute” without constant cell phone calls. These networks connecting patient families to relatives and friends also serve a decision-making role. They are means to convey important treatment information from the physician, but they also can create a back channel of well intentioned but nevertheless aggravating critics. One mother complained that her father thought he was an expert on her child’s illness because he found some articles on the Web. Another mother we interviewed was still audibly upset, because her child’s grandparents had second-guessed her recent treatment decisions. She asked us if we could make her something that she could use to show her parents the decisive information that drove her decision to bring their grandchild, who was

in remission, back to St. Jude for another clinical trial. The palliative care MD on our team describes this as the “seagull effect”: where a patient family finally comes to terms with a decision only to have all their friends and relatives come in and crap all over it. This serves, too, as another example of a way to aid decision-making that we would not have thought of without participant input. Furthermore, this information gave us an idea for one way to help parents avoid, or at least cut-short, a frustrating addendum to their decision-making.

CLARIFYING AND ALIGNING VALUES & PRIORITIES

Given our goal to promote the mitigation of decisional conflict, our desired outcome is a phase I decision-making process that promotes clear recognition of the risks, benefits, and alternatives while maintaining patient family hope and yet generating a treatment action aligned with the pediatric patient's end-of-life values and priorities (Fig. 5). Distinctly, in this end-of-life decision making scenario, hope wouldn't be advanced only as “hope for a cure,” but also as hope for quality of remaining life and, eventually, even as hope for a peaceful death (Barrera, D'Agostino, Gammon et al. 2005).

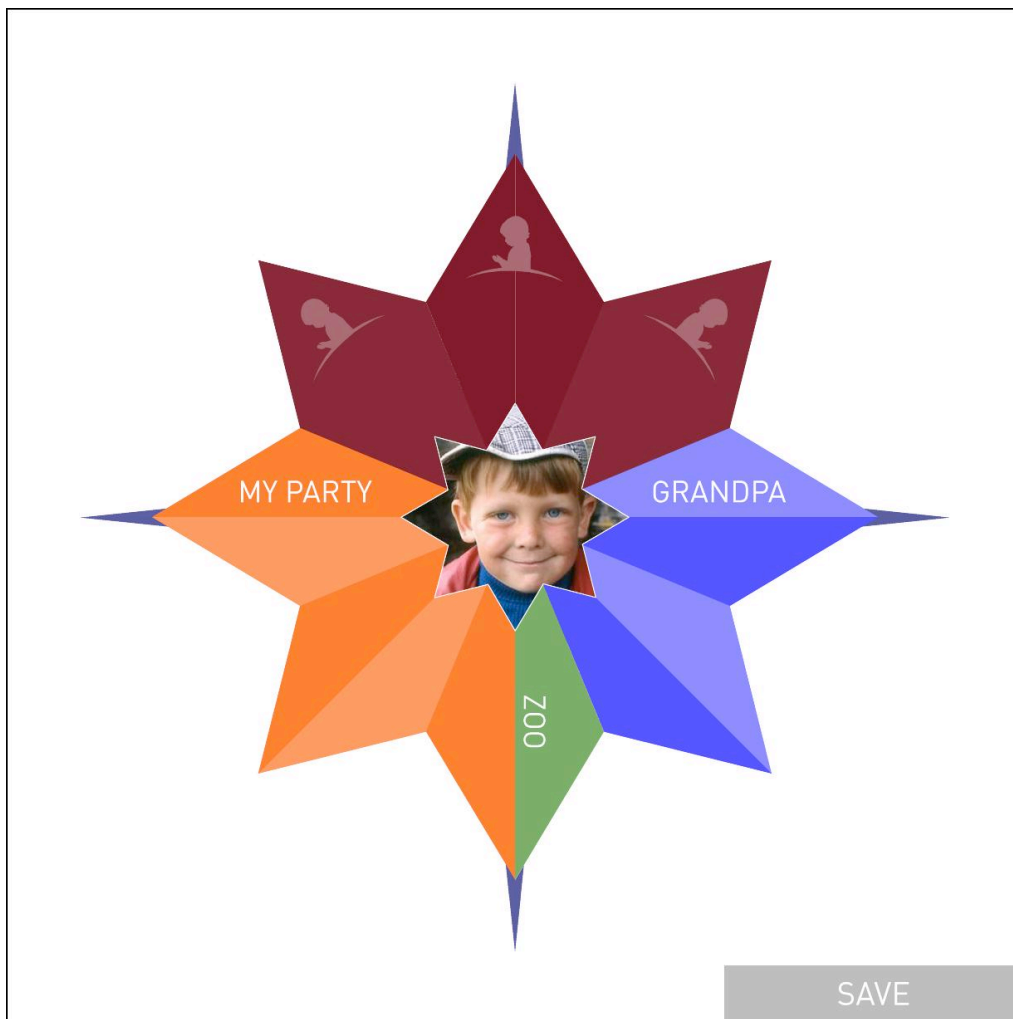


Figure 5. Early stage prototype for mitigation of decisional conflict.

CONCLUSION

Obviously most clinical trials are not as fraught with serious consequence and complex ethical issues as the phase I studies for which my colleagues and I have been developing decision-making aids. While we are working well within the challenges of treatment decision-making regarding new medical technologies, we are engaged in a small microcosm of research protocols. For instance, it's estimated that 80,000 government- and industry-funded trials are conducted in the US every year. (Getz and Borfitz 2003) This profusion in research has in turn created numerous advances in medical technology that have translated into clinical care, providing multiple standards-of-care where only recently a single treatment course was available (Whelan, Levine, Willan, et al. 2004). Given the increasing treatment options, the complexity of medical technology, prevalent educational and literacy challenges, and extremely limited time allowed most patient consultations, it's a little less shocking to learn that 33% of sick patients in the United States leave their doctors' offices with important questions unanswered (Woolf, Chan, Harris, et al. 2005).

However, healthcare participants are increasingly finding their own answers. And this can be as detrimental to the tenets of informed decision-making as it is helpful. Patients and their support networks are using a vast array of so-called "health communication" websites, with some of the more trafficked being WebMD, MedlinePlus, and KidsHealth, which boasts 350,000 users on any given weekday. People want to understand their increasing healthcare options and the new vocabulary and technical concepts these entail. They are demanding comprehensive expert advice, tailored to the specifics of their illness, with explanations in multiple formats—video, animation, graphics, and, of course, text.

Yet while all of this access to and demand for content portends further meaningful work for content experts, information architects, systems engineers, library scientists, and for user experience-, information-, interactive-, graphic-, software-, multimedia-, UI-, and instructional-designers, (deep breath) it also occasions the automation of informed consent and clinical trials. Now you can go online and find strictly virtual IRBs ready to review new protocols, following that service up with ready access to a subject pool. Is this what design for bioethics, for supposedly informed consent, will come to mean in the next few years? I think this is a critical moment, poised right before a tidal surge of new business plans leveraging design and media for the sake of producing even more research trials, particularly trials aimed at children. If we're already self-described healthcare consumers, shopping for clinical trials to aid our progressing diseases, than wouldn't these automated research clearinghouses be the new frontier in consumer health information as well? I could continue to guess at the implications, but the concrete fact is that design in the realm of bioethics needs to be informed about bioethics. Then I think designers will be in a much better position to see how their methods can best be leveraged to help patients and their families make sense of complex information in the midst of distressing circumstances. The solutions we designers pose should therefore arise out of a continuum of care, ethics debates, and compassion for the patient and her family & friends.

These aren't easy issues, which is why my colleagues and I have chased windmills far more often than we've nailed down design guidelines. And therefore I think more designers will need to be willing to deal with the seemingly Quixotic challenge of understanding the intricacies of bioethics, the complexities of clinical trials, and the cognitive and affective needs of patient and patient family decision-makers if we researchers and practitioners of various design fields—trained for this or not—stand to provide our fellow human beings with the beneficence and respect they deserve in their frailest moments.

References

- Barrera, D'Agostino, Gammon, et al. (2005) Health-Related Quality of Life and Enrollment in Phase I Trials in Children with Incurable Cancer, Palliative and Supportive Care
Breault. The Ochsner Journal. www.ochsnerjournal.org
- Getz and Borfritz (2003) Informed Consent: A Guide to the Risks and Benefits of Volunteering for Clinical Trials, Thomson/CenterWatch, Boston, MA
- Hassenzahl (2004) Emotions Can Be Quite Ephemeral: We Cannot Design Them, Interactions, September/October KidsHealth www.kidshealth.org
- MedlinePlus <http://medlineplus.gov/>
- WebMD www.webmd.com
- Whelan, Levine, Willan, et al. (2004) Effect of a Decision Aid on Knowledge and Treatment Decision Making for Breast Cancer Surgery: A Randomized Trial, JAMA, July 28—Vol 292, No. 4
- Woolf, Chan, Harris, et al. (2005) Promoting Informed Choice: Transforming Health Care to Dispense Knowledge for Decision Making, Annals of Internal Medicine, Vol 143, No. 4