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CONLEY ESSAY

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Pediatric Assent in Clinical Research: A Patient-Centered Perspective Using Motivational Interviewing

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After experiencing morning headaches, vomiting, and increasing lethargy for about 3 months, Joey, 12 years of age, was found to have a medulloblastoma. He had surgery to remove as much of the tumor as possible. Joey had a postoperative MRI that showed no focal metastatic sites. His treatment plan called for radiation immediately following the surgery and then chemotherapy.

Joey's oncologist, Dr. Burnet, told his mother that an ongoing study was investigating the use of lower-than-standard doses of craniospinal radiation in a subset of children like Joey. The study was testing the hypothesis that the lower radiation dose followed by high-dose chemotherapy would produce the same survival rates as the standard high radiation dosage while reducing the neurocognitive side effects of the radiation.

When Joey and his mom met with Dr. Burnet, his mom told Dr. Burnet that she did not want Joey to participate in the experimental treatment regimen. Joey didn't say anything during the meeting, but on the way home he told his mother that he wanted to be a part of the experimental treatment study. She asked him why. Joey, who had always been a curious kid, loved school, and was proud of his ability to excel at his studies, said, "Mom, they think this is going to be better than what they're doing now. I don't want to be a cancer-free dummy..."

Joey's mother and father were separated, and, although Joey lived with his mom, his father remained close to both of them and involved in his son's life. When Joey's mother told him about the treatment decision they were being asked to make, Joey's dad said, "I think we should let Joey decide. He's old enough to understand what the risks and possible benefits are. It's his life." The mother and father were alone, and Joey's mom was fighting back tears. "I can't say yes to this experiment; I just want our son to live," she said.

The three of them went to Dr. Burnet together so that they all could hear what Dr. Burnet had to say. In the meantime, they learned as much as they could from the Internet, and what they were able to find just confirmed what Dr. Burnet had said. This time Joey spoke up in the office, telling Dr. Burnet that he wanted to participate in the lower-dose radiation study.

"Because this regimen is experimental," Dr. Burnet told Joey's folks, "Joey's assent is really important, but it's best for everyone if all of you to agree to the treatment.

I'm sure you can see why it's critical that everyone be on board when you're facing a possibly life-changing decision. We have a physician-ethicist on staff," Dr. Burnet continued, "who might be able to help you sort out some of the questions you have. The key one, as I see it, is who gets to decide what is in Joey's best interest. Would you like to meet with our physician-ethicist, Dr. Klein?"

Response

Joey's dilemma disrupts the typical framework of ethical research practices because the concepts of autonomy and informed consent do not apply in pediatrics. Instead, they are replaced by parental authority and patient assent. However, strong parental authority without the child's assent undermines the developing capacity of the child to engage in decision making. As a result, clinical ethicists must strive to reach consensus within the family. Motivational interviewing provides techniques that the ethicist can use to facilitate a patient-centered, semi-directive discussion in attempt to break down the communication barriers among the patient, parents, and healthcare team.

The Problem of Autonomy

Clinical bioethics in the United States revolves around the concepts of autonomy and, by extension, informed consent. Medical autonomy is the ability of an individual to direct his or her own decision making. Due to the complexities of many medical therapies, autonomy is manifested in informed consent, the process of providing the patient with adequate information to make medical decisions free from coercion.

Capacity, the ability to understand the risks and benefits of a proposed treatment and choose a treatment plan that corresponds to his or her values, is a prerequisite for autonomy. Determining medical capacity is a key aspect of many ethical consultations in adults due to the wide range of decision-making ability. Following this model, an adult with decision-making capacity has the autonomy to direct his or her own care and involvement in research.

However, this model does not hold in pediatrics, namely because children lack full decisional capacity. It is generally understood that children slowly gain capacity as they develop and mature from an infant with no capacity to a young adult with nearly full capacity, but it is difficult to determine where on the spectrum of capacity an individual child exists. Therefore, children are not fully autonomous, but they become more autonomous as they develop [1].

Furthermore, using the informed consent model in pediatrics is problematic because informed consent implies a sense of self. Informed consent by proxy is technically misleading since the patient remains uninformed. Because of these ethical distinctions, pediatricians do not utilize the language of autonomy and informed consent but instead refer to parental authority and patient assent [2].

Parental Authority

Parental authority stems from the traditional role of parenting. Our culture grants parents the responsibility of decision making for their children and does not morally

oppose a parent's decision to direct most aspects of their children's lives. This is comparable to the principle of respecting patient autonomy in adults. From an ethical standpoint, parental authority is based on the principle of beneficence, acting in the best interested of their child [1].

At times the parental authority conflicts with the child's wishes. For example, very few children want routine vaccinations. They cry. They yell. They scream. They may become aggressive, verbally denounce their parents and physician, and attempt to flee. If any healthy adult behaved like this, the clinician would immediately stop treatment. However, since the child lacks the capacity to understand the future benefit of vaccinations, he or she is exposed to temporary pain against his or her wishes.

This does not mean that parental authority is absolute. In 1944, the United States Supreme Court ruled that parental authority could be limited for the protection of children [3]. In regards to medical treatment, the American Academy of Pediatrics states that "all children are entitled to medical treatment that is likely to prevent serious harm, or suffering, or death" regardless of parental desire to do otherwise [1]. Children are also protected from being enrolled in clinical research that has no direct benefit to them or puts them at high risk. Finally, the emerging autonomy of adolescents is often respected in the sensitive discussions of sex, smoking, drugs, and alcohol, since parental involvement may decrease trust in the physician.

Patient Assent

Although children lack full capacity for informed consent, they should still be involved in their medical decision making whenever possible using the model of patient assent, the process of agreeing to a treatment plan chosen by an outside authority. This respects the relative capacity of the child and centers care on the patient. Even at a young age, allowing a child to make simple decisions such as deciding in which arm to get a vaccination helps them understand and participate, even if they are not responsible for the actual decisions.

Pediatric patients should not be excluded from decision making without specific reasons. Explanation of medical care to the child should be developmentally appropriate for the child's understanding, include the risk and benefits of treatment and entail an assessment of the comprehension and response of the child. For the best outcomes, parents and physicians should seek the assent of the patient for all medical decisions [1, 2].

Patient-Centered Approach to Decision Making

Tension occurs in pediatric decision making when the child disagrees with the parents' plan. The American Academy of Pediatricians proposes three models for decision making in pediatric research that balance paternal authority and patient assent based on the patient's age [2, 4]. Decisions with infants and young children center on parental authority accompanied, if possible based on the age of the patient, by assent. For school-aged children such as Joey, parental permission with assent is used to account for the increasing capacity of the child. As patients become

adolescents, parental permission continues, but informed consent can be used in specific situations as the patient nears adulthood.

Irresolvable disagreement between parents and the child inevitably occurs. Ultimately, parents have the power to select care for their child provided that care is in the best interest of the child. However, physicians should withhold treatment, even if only temporarily, in order to assess the values of a noncompliant patient. Coercion should only be used as a last resort. Continued treatment without assent can undermine the child's trust in both the physician and the parents, causing problems in the therapeutic and family relationships. Finally, legal action including court-appointed guardianship or emancipation should be reserved for only the most severe cases when all other means of reaching consensus have failed [2].

Motivational Interviewing in Ethical Consultations

From a patient-centered perspective, the role of the ethicist, Dr. Klein, is to facilitate conversation between the individuals involved with the final goal of reaching rational consensus for the patient and parents. Dr. Klein cannot make the decisions for Joey's family. Instead, he must expertly mediate a discussion that helps the family solve the dilemma for themselves. This can be a difficult task since individuals are often resistant or ambivalent to decision making, but the principles of motivational interviewing may help resolve these barriers.

Motivational interviewing is a semi-directed and patient-centered approach to physician-patient communication that began in the 1980s as a technique to help alcoholics quit drinking. It has been successfully applied in numerous health care settings to help patients adjust behavior, especially addiction. More recent studies have shown that motivational interviewing techniques help in difficult conversations with patients, such as palliative care consultation, even though not all of the concepts of motivational interviewing apply because no behavioral changes are involved [5].

Motivational interviewing has three main principles: collaboration, autonomy, and evocation. Collaboration occurs when the ethicist and patient work together to make decisions. Dr. Klein is the expert on the application of ethical principles, but Joey's parents, and ultimately Joey himself, are experts on the patient. The ethicist must also respect autonomous decision making, or, in Joey's case, parental permission with patient assent. Dr. Klein cannot have preconceived notions about Joey's decision. In directing the conversation toward consensus, he must be careful not to direct it toward a specific decision. Finally, evocation involves eliciting information from the patient and family about their internal motivations. Evocation benefits everyone involved because people often have not processed their own values on complex dilemmas. The family is encouraged to reflect on the spoken values of the patient and each other.

Dr. Klein has a number of motivational interviewing techniques at his disposal. He can ask open-ended questions to explore each individual's values. He can summarize and restate each individual's values for the benefit of Joey and his parents. He can encourage Joey to reflect on his values and ask his parents to do the same. Instead of working to overcome resistance from the family, he can acknowledge the difficulty

of decision making and reframe the discussion. This avoids an unproductive series of arguments and counterarguments while encouraging further discussion. Throughout this process, he should keep the conversation civil and query any extreme remarks that may lead to unnecessary confrontation.

Application to Joey's Case

Based on Joey's age, the decision-making model in this case should be parental permission with patient assent. It is clear that Joey wants to participate in the trial. The research trial is deemed ethical even though it is high-risk because of the possibility of direct benefit to Joey. However, it is certainly not clear if participating in the trial is in Joey's best interest because the efficacy of low-dose radiation is not known. His parents would not be abusing their parental authority by either allowing or refusing his participation. Still, Joey's parents disagree. His mother wants to refuse Joey's participation while his father supports his decision. Not just the parents but the entire family needs to reach consensus because this will help Joey engage in his care, whether he participates in the trial or not.

Joey did not voice his opinions during the initial appointment with Dr. Burnet. While there could be many reasons for this, Dr. Klein needs to overcome that by first focusing on Joey and evoking his values and emotions. Joey excels in school and told his mother that he doesn't "want to be a cancer-free dummy." Dr. Klein should discuss Joey's desire to retain full neurological function, validate his values, and restate them aloud. Dr. Klein should also ask about Joey's fears of participating in the trial to assess if Joey comprehends the risks involved.

After focusing on Joey, Dr. Klein should direct his attention to the parents, using motivational interviewing to prompt them to name any resistance or ambivalence they have toward the decision-making process. Both parents are likely motivated by fear and the desire to protect their child, and rightly so. A majority of parents claim they would rather participate in a similar trial themselves than allow their children to participate [6]. The discussion should focus on common themes parents encounter with enrolling their children in clinical trials such as the stress of living in a tragic event, desiring the best for their child, wanting to help future children with cancer, accepting the potential consequences of their decisions without regrets, feeling overwhelmed by the sheer number of serious decisions in a short period of time, and navigating relationships with the health care team [7].

Joey's mother wants her son to live but does not describe the values that motivate her to refuse the trial. Dr. Klein should validate her concern but explore her emotions and reasoning. She displays resistance toward accepting Joey's opinion, admitting "I can't say yes to giving him less treatment." Motivational interviewing techniques can help her name her resistance and reframe the issue.

Dr. Klein should explore why the father claims Joey is "old enough to understand what the risks and possible benefits are." What informs that judgment? Does the mother agree? Or is he being ambivalent by allowing Joey to decide?

No method guarantees that a consensus will be reached, but motivational interviewing techniques emphasize the importance of finding agreement. Caring for a child with cancer is stressful, and Joey's parents need to be able to support each other and their child. Joey needs to feel his opinions are valued throughout this process. Failure to do so may result in regret, resentment, and distrust among the members of the family and the health care team. This patient-centered approach seeks to avoid those consequences while respecting the concepts of parental authority and patient assent in pediatrics.

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