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CASE STUDY

Adolescent assent in research: a relational ethics approach

HAPPY INDRI HAPSARI, MEI-CHIH HUANG

Abstract

Researchers often neglect adolescents' willingness to participate in research. The granting of permission by parents is sometimes not in accordance with the unwillingness of adolescents. Relational ethics is the right approach to overcome inconsistencies between legal and ethical agreements in granting parental permission and adolescent's assent. This is because relational ethics is based on building relationships among many parties. The focus of this case study is to improve understanding of the assent of adolescents through intensive study of research conflict, reinforced using existing research and to understand how relational ethics can be used as an approach in decision-making, especially in conflicts between parental permission and assent from adolescents.

Keywords: consent, assent, adolescents, parents, research, relational ethics

Case scenario

Daniel, aged 14, had a medical diagnosis of osteosarcoma. He underwent hospitalisation to undergo the induction phase of chemotherapy treatment. Daniel experienced some side effects of chemotherapy, including nausea, vomiting, fatigue, and mucositis. He said that due to this mucositis, he had difficulty chewing and swallowing food. Daniel's mother expressed concern about the condition experienced by her child. The mother always tried to provide him with suitable food, even in small portions, so that his nutritional needs were fulfilled.

Due to the side effects he experienced, Daniel was selected as one of the prospective participants in a study aiming to determine the effectiveness of gargling with honey to overcome mucositis. The incidence of mucositis is a symptom that is often experienced by patients undergoing chemotherapy. Researchers explained the study's objectives, procedures to be carried out, and side effects that might occur because of this intervention to Daniel's mother. She was very enthusiastic about this research, and gave her permission for Daniel to participate in the study. However, when asked, Daniel refused to participate, saying he could not withstand the pain of gargling according to the research procedure described. He worried that this research would increase his fear of the pain he was experiencing. Daniel's objection frustrated his mother. She then discussed this with Daniel's father, who insisted that Daniel participate in the research. This raises the ethical challenge for the researcher: "Do I have to follow the parents' decision, or do I have to grant Daniel's request not to participate in the research?"

Introduction

Consent of parents for adolescents to participate in treatment or research sometimes does not reflect the

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wishes of the adolescents themselves. One study stated that adolescents experience pressure from parents, relatives, doctors, nurses, or research teams to participate in research [1].

Research is required to abide by the four ethical principles, one of which is autonomy [2]. Any involvement with research must be an autonomous choice of the individuals themselves. Informed consent is used to protect the welfare of participants by promoting both the instruments of their autonomy and autonomy as a right in itself [3]. Based on Good Clinical Practice, informed consent is a process in which people state their willingness to participate in research after they have received information related to the research to be carried out, such as demographic data, the procedure to be carried out, and data related to research variables [4].

Informed consent in children's clinical trials is more difficult to realise when compared to that in clinical trials for adults because the children's parents or guardians act as proxies in giving parental permission, and present it as an informed consent. It is related to the duty of parents or guardians to protect the welfare of their children. This causes parents or guardians to feel uncomfortable or afraid of making "wrong" decisions [5]. Parental permission acts as a legal document used by researchers to ensure the involvement of adolescent research participants. However, there is one more requirement to be obtained from children or adolescents by researchers, namely assent. Assent is an embodiment of the ethical principle of autonomy [6]. Decision-making as outlined in consent, legally, refers to the development of competence in which an individual must reach a certain age to be able to give valid consent. On the other hand, capacity, which is one of the elements of consent, refers to the ability of the person to understand what is being explained, which in this case, is the understanding of adolescents involved in research. This gives rise to a dilemma when researchers try to involve adolescents in research. As a marginalised population in decision-making, adolescents are able to be fully involved in research. Thus, assent is essential for an adolescent's decision on involvement in research, without overriding dissent if adolescents do not want to be involved in research. Researchers can hold an open dialogue with adolescents and their parents to understand each other's views on the research to be undertaken. Such dialogue helps researchers explore their own values and beliefs.

This case study has two objectives. First, to improve the understanding of assent by adolescents. Second, to understand how relational ethics is used as an approach in decision-making, especially in a conflict between parental permission and adolescent assent.

Consent and assent in clinical trials

Informed consent is an autonomous authorisation by an individual permitting their involvement in research studies or in receiving medical care [7]. Informed consent has three

critical and essential elements: voluntarism, full disclosure of information, and decision-making ability. These three elements must be present when informed consent is given so that the informed consent becomes ethically valid.

Information is provided by researchers to prospective respondents. The information is provided (Table 1) in the forms of the procedures to be undertaken, on risks that may arise in the study, the duration of the research, and whether the research will hinder the daily activities of participants, in this case, adolescents [8].

Competence and capacity, two other elements of decision-making ability, describe the ability of individuals to make decisions. The terms "competence" and "capacity" are often interchanged. However, these two words have different meanings. Competency is the ability of someone who has the natural or legal qualifications needed to engage in an action. In other words, competency implies having the legally recognised mental and cognitive abilities needed to perform an action [9]. This competency is based on age limits decided under the law (Table 1) and based on the stages of cognitive development of children and adolescents [10, 11].

Meanwhile, capacity is based on assessment of the abilities possessed, viewed from a psychological perspective, to be able to make rational decisions, especially on one's ability to understand, appreciate, and process information which results in rational decision-making. This assessment is carried out by the people who work in health and social care, such as physicians, nurses, and psychologists, but not the judiciary [9, 12]. If someone is declared by a doctor to be a person who lacks the capacity to make rational decisions, then he/she is considered as *de facto* incompetent, but this is not determined through legal procedures. There are four standards for determining capacity in decision-making, namely "the ability to evidence a choice," "the ability to understand relevant information," "the ability to appreciate the situation and its likely consequences," and "the ability to manipulate information rationally" [9].

The rights of children and adolescents are set down in several regulations in the ethical principles of research. Based on the Helsinki Declaration of the World Medical Association, it is said that children, including adolescents, are vulnerable individuals or groups. Research involving adolescents must provide benefits that are responsive to their health needs, or it cannot be conducted with adolescents as participants. If a research study cannot provide health benefits, then it is permitted to involve adolescents as respondents on the condition that the risks anticipated in the study are minimal, ie its risks are not greater than those normally encountered in everyday life or during the conduct of a physical or psychological examination. This condition was added to the International Covenant on Civil and Political Rights which states that no human being should be subjected to medical or scientific

research without the consent of that person, especially in children. The General Comment No. 3 in the Rights of Children with HIV/AIDS issued by the United Nations Committee on the Rights of the Child states that children must be involved in making decisions about their participation in paediatric research [13,14,15].

Adolescents provide assent to their participation in research even though they have not yet met the competency requirements (Table 1). Assent is an affirmative agreement from a child to participate in a clinical trial [16]. The involvement of adolescents in the provision of assent is not only a form of respect for their opinions but is also able to improve their decision-making skills [17]. One study revealed that most adolescents agreed to participate in research out of altruism and some hoped for more personal gain [18]. However, dissent by adolescents must be respected by researchers [19].

Parental permission as informed consent in paediatric clinical trials

By law, adolescents are considered not yet competent to take autonomous decisions related to their participation in clinical trials, so parental permission is used to replace informed consent. In the research ethics of "person autonomy", parental permissions granted by proxies and assents given by adolescents are used as valid documents according to the Institutional Review Board (IRB) to participate in research [14].

Parental permission is an agreement given by a parent or legal guardian, in this case called a proxy, for a child or adolescent to participate in a clinical trial. Parental permissions are valid if the proxy is given adequate information and is voluntarily giving permissions [21].

Relational ethics: An approach to decision making for adolescents in research

The ethical principle of "respect for persons" is the most important ethical principle, in which researchers must prioritise the welfare of the participants over the interests of research or science. Researchers, according to this ethical principle, must carry out strategies to reduce the harmful effects of research, one of which is related to the emotional well-being of participants [22]. The conflict that arose between Daniel and his parents at the time of granting the research consent and assent was a conflict that had to be resolved by the researcher. The researcher must decide on the continuation of the research, because legally the parents had given parental permission. On the other hand, researchers must also uphold the principle of "respect for persons", in which researchers respect adolescents' decisions not to participate in research. For resolving this ethical problem, the researchers in this study can use a relational ethics approach.

Relational ethics emphasises understanding what constitutes moral agency and illustrates how decision-making is done in the context of a relationship. The focus in relational ethics is

on the relationship itself and relationships that involve adolescents, parents, researchers, and the healthcare team [23]. Relational ethics is based on four interrelated elements: mutual respect, engagement, embodiment, and environment [23].

Mutual respect

Mutual respect is observed by researchers through engaging and interacting with participants and families. This is done based on an acknowledgment of differences in power, value, belief, knowledge, and/or experience. Researchers mitigate power between several parties and believe that we are very dependent on each other [23,24,25]. Daniel has gone through some unpleasant experiences, especially regarding chemotherapy treatment. He shared these experiences with the researcher. The researcher listened carefully, and valued his sharing of the experience. The same was done with Daniel's mother. The researcher took the time to interact with both. With both Daniel and his mother, the researcher gave them the time to discuss, identify the problems faced, and provide options for in-person discussions or by telephone. This has to do with the preferences of both Daniel and his mother.

The interaction built by the researcher with Daniel and his mother builds a bond and a sense of responsibility to appreciate every experience faced by Daniel and his mother. This improves the quality of the relationship on each side.

Engagement

Engagement reflects how the researcher has connected with adolescents and parents through a relationship of trust and openness. A practice that can be used in engagement is "sitting down and leaning in". "Sitting down" means recognising that other people's perspectives are important while "leaning in" means exploring contexts and circumstances that can affect trust, values, and motivation [23,24].

Communication is the basis for successful engagement, which consists of verbal and non-verbal communication, such as touch, gesture, and writing [25]. The researcher tried to explore what was needed and to understand the opinions and values that Daniel and his parents had. Moreover, the researcher treated Daniel as a subject and not an object, and hence structured the meaning of this situation from a perspective different from their own. Relationships built in this manner are authentic, genuine, intimate, empathetic, and reciprocal.

The researcher had to spend time building a trusting relationship and required repeated conversations with Daniel and his parents. The researcher asked various questions, listened to what they said, paid attention to the questions they asked, and was sensitive to changes in gestures and sounds. So, Daniel felt equal, unintimidated, and comfortable, as when talking to his peers.

Embodiment

The concept of embodiment is based on well-being, which has physical and emotional elements. Researchers should acknowledge the well-being of individuals in conducting research. Conflicts experienced by participants and their families will have an impact on the continuity of research and on the management of patient treatment. Recognising conflicts that arise and providing support for participants and their families will increase the sense of comfort and security [23,24,25].

In this case study, the researcher was able to explore the past experiences of Daniel and his parents. For Daniel, it might have been that medication, invasive procedures, or side effects from previous cancer treatments had traumatised him. This trauma is difficult to get over in a short time, and coupled with fear of the interventions that he said would increase the pain, he would be certain to refuse the intervention. The physical symptoms he felt would have an impact on the psychological and social aspects, which would then affect his general well-being.

Daniel's parents also experienced fear for him, as well as a sense of helplessness in going through Daniel's lengthy treatment process, as well as uncertainty about the success of the treatment. The researchers could hold open discussions with Daniel's parents in sharing their feelings, so that they could find resources within themselves to be equipped to meet Daniel's current needs.

On the other hand, researchers also have a goal to get respondents. With the limited number of adolescents with cancer, coupled with uncertain parental consent, and assent given by adolescent patients, the possibility of researchers getting a sufficient number of respondents is small. In this case, the researcher has the same goal as Daniel's parents, where both want Daniel to get a research intervention — in the form of gargling with honey in overcoming mucositis. The uncertainty faced by researchers can cause anxiety. The researchers could discuss this with research supervisors, or colleagues so that the research does not deviate from the code of research ethics. Researchers realise that it is very important to act in accordance with the patient's best interest. This is in accordance with the principle of autonomy.

Environment

An environment is not only a physical environment but also a living system where everyone is connected. Decision-making is influenced by the wider community, not only by the environment between the researcher, Daniel, and his parents. Good support is needed [25].

In this case study, the researcher provided an open and trusting environment for Daniel and his parents to explore feelings and emotions related to the research intervention offered. A safe environment — both during the process and after decision-making — should be established by researchers

so that they can respect and support participants and their families. In resolving this ethical decision-making dilemma, it is necessary to involve several parties. Healthcare providers could be involved to provide kinds of interventions that can minimise pain when gargling. Peer groups participating in research intervention sessions could also be considered as a support system for Daniel. They can share their experiences and benefits while participating in the research. This can increase insights and may encourage Daniel to have positive feelings regarding the research.

Conclusion

For informed consent to be in line with the assent given by adolescents, families who provide informed consent need to consider the adolescent's assent seriously. The relational ethics approach can facilitate a solution for researchers when facing conflicts where informed consent is not matched by assent. Relational ethics can help minimise ethical dilemmas faced by researchers.

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