

Ethical Issues of Informed Consent

Introduction

The doctrine of informed consent represents a shared decision making between a patient and a health care provider. *“Informed consent happens when a patient authorizes a medical procedure or intervention based on understanding of the risks, benefits, and alternatives”* (Bester, Cole, Kodish, 2016). The patient’s informed consent is currently an essential part of any provision of health services. The doctrine of informed consent and the associated right of the patient to be informed about the planned procedure is one of the most frequently discussed areas of bioethics and medical law. The history of informed consent can be traced back to the post-World War II Nuremburg Code which prohibits unethical medical treatments to be carried out (Murray, 2012). Along with expanding individual rights, the relationship with the patient and ethical standards have undergone considerable development in recent years. The relationship between a patient and a health care provider can be characterized by an information deficit on both sides and can be thus perceived as unequal.

This essay examines the ethical issues and principles underlying informed consent. The aim of the essay is to present the ethical dilemmas arising from the information deficit and inequality of both parties involved in the process of informed consent.

The essay is divided into four chapters followed by a conclusion which summarizes the findings. Each chapter is devoted to an explanation of one of the ethical dilemmas underlying informed consent.

Individual Autonomy

Autonomy is one of the four foundational principles of medical ethics along with beneficence, nonmaleficence and justice and it is the main ethical consideration underlying informed consent. Informed consent as a form of autonomous authorization represents a decision to make a certain kind of medical treatment (Pugh, 2020). Simply put, the patient has the right to choose what happens to his body. Furthermore, the ethical principle of justice needs to be considered while making decisions about treatments offered or withheld from patients (Selinger, 2009). Informed consent can be considered as an expression of freedom and autonomy of will, but it also represents the recognition of the individuality of existence of a patient. On the other hand, informed consent can be criticized for being a formal intervention that destroys the trust between the patient and the doctor.

The concept of autonomy varies in different countries based on several cultural aspects of decision-making. In Western nations, respect for individual autonomy is much stronger than in non-Western cultures that tend to have a more collectivist decision making process that involves their families and loved ones (Van Norman, 2011). In the Czech Republic as well as in other post-communist countries, more patients with higher degree of passivity and

dependence on doctors' recommendations can be expected. These patients are typically reluctant to think independently and co-decide about their treatment.

The importance of the concept of autonomy stems from the need of the active involvement of the patients in their diagnosis and treatment. The patient has the ultimate decision making-responsibility, and a health care provider cannot impose a treatment on the patient. The ethical importance of informed consent is often more elementary: "*It provides reasonable assurance that a patient (research subject, tissue donor) has not been deceived or coerced*" (O'Neill, 2003).

However, the ethical dilemma arises when the patient acts as a passive recipient of the medical care. Some patients are more prone to self-preservation approach and authorize the health care provider to make serious medical decisions without asking for their justification. This approach represents the paternalistic type of a relationship between a health care provider and a patient. The aim of a health care provider is to serve as an educator and illustrates the modern cooperative type of a relationship where the patient participates in the choice of care and treatment and no procedure can be performed without his will. Patients should be able to reflect their own values and preferences and actively participate in formulating the plan for medical care. This is a key element in an effective treatment of the patient. Ideally, the patient should believe in the best possible outcome of the treatment but should also consider all risks and problems that may occur during the treatment.

Overwhelm and Information Overload

Typically, patients have a limited understanding of their medical condition and of medicine in general. It must be considered that a patient is in an existential situation when coming to the doctor. From this point of view, the patient is a weaker party that comes to the doctor to seek help and relief from his pain and hardship. Therefore, the patient can be more easily manipulated and mistreated. On the other hand, it is very difficult for the health care provider to find a balance between sufficient information and too little information for the patient to be able to participate in shared decision-making process.

Overwhelm is a situation in which the capacity of a patient is overwhelmed by the amount of the information at hand or by the nature of it. In this situation, it is impossible for the patient to provide informed consent. Overwhelm is very typical for the clinical settings and is based on patient's emotional state. Apart from the obligation to respect patients' autonomy, health care providers also have other ethical obligations, such as beneficence and nonmaleficence. For this reason, health care providers should take action to prevent patients from becoming emotionally overwhelmed and provide them with support. The clinician can enable the patient to be supported by a family member or loved ones or by a various members of medical care team or can extend the decision time for the patient to feel more comfortable to make the decision.

Information overload arises when the patient is exposed with a large volume of complex and uncertain information and is usually connected to new technologies. The patient is

incapacitated by the information itself, so the true informed consent is not possible in this case (Bester, Cole, Kodish, 2016).

Informed Consent and Capacity

One can give an informed consent only if the person is competent to do so. An informed consent to be valid requires four things:

- Voluntariness (which means, that the patient's decision does not involve coercion and excessive influence),
- Disclosure (the health care professional shares important information with the patient),
- Understanding (recognizing the risks and advantages of the treatment),
- Capacity (Bester, Cole, Kodish, 2016).

„Capacity describes a person's ability to a make a decision. In a medical context, capacity refers to the ability to utilize information about an illness and proposed treatment options to make a choice that is congruent with one's own values and preferences“ (Karlawish, 2022).

There are three main factors that influence capacity: patient-related factors, information related factors and communication-related factors.

Patient-related factors include situations where the patient is unconscious or under the influence of drugs or alcohol. Young children also lack capacity to make medical decisions. Unconscious patients can make no decisions at all. Old patients with dementia or disabled patients with cognitive impairment can only make certain types of medical decisions and need help of others. Moreover, the stress created by illness may affect the patient's decisional capacity as mentioned in the chapter regarding overwhelm above.

Information-related factors are concerned with complex, scientifically advanced, and intellectually demanding information. These factors relate to the information overload also mentioned in the previous chapter. Most people do not understand the medical field and find it impossible to give a true informed consent.

Communication-related factors play a key role in decision making process. Health care providers can use special methods to communicate the medical information to patients in a skilled, comprehensive, and complete manner. Doctors have the option to use decision aids and extend the time for the patient to be able to understand the complex medical issues. Health care providers should be trained to communicate the information to reduce the stress of patients. The combination of patient and information factors can interact and influence the capacity of patients simultaneously which make the decision-making process of undergoing treatment and achieving informed consent more difficult (Bester, Cole, Kodish, 2016).

Informed Consent in Research

„Informed consent is one of the most important aspects of research ethics“ (Gupta, 2013). Elements of informed consent in research are in line with the general elements of informed consent and consist of voluntarism, information disclosure, and decision-making capacity. Obtaining informed consent in clinical trials represents a very sensitive and complex ethical challenge. The researcher must provide the participants with relevant information about the study and seeks their consent. There are some exceptions when the informed consent cannot be given by the subject of the trial. These situations include medical emergency and incompetent subjects such as minors and participants with mental disorders.

Emergency research includes situations when a subject is in a life-threatening and urgent medical intervention is needed. These situations are excluded from the obligation to attain informed consent prior the medical treatment and may bring ethical issues for the patient as well as medical professional delivering care. Emergency research thus involves vulnerable subjects who lack autonomy and are unable to provide informed consent. For this reason, special regulations, and responsibilities such as consultations or contacting a family member are required in these cases.

In research, informed consent is an ongoing and dynamic process because it does not end by the time the consent is given. The subject does not have the obligation to complete the research and has the right to withdraw the consent at any time. The researchers are obliged to provide the participants with important new information arising during the research because it can be detrimental to the willingness of the subject to continue with the trial (Gupta, 2013).

Informed consent in medical research represents an inevitable legal and ethical part of the clinical trial. Participants must voluntarily show their interest in the research after thorough study of all the aspects of the clinical trial. The informed consent in clinical trial consists of the description of rights of the participant, the purpose of the clinical trial, procedures that need to be followed, potential risks and benefits for the participant, expected length of the trial and extent of confidentiality of personal data. All the information is needed to ensure that the participation of the subject in the study is entirely voluntary.

There are some ethical challenges specific to informed consent given in research. The language of the documents provided to participants has to be easily understood so that participants can make the voluntary decision. The ethical principles in western countries may differ from the developing countries such as India where clinical investigations are carried out. To obtain an ethical informed consent in such countries can be very challenging because of the different social values, traditions, and level of education. Especially challenging are psychiatric clinical studies that are largely conducted in India. These studies bring ethical issues for the participants in the context of risk of worsening their illness and the validity of informed consent due to lack of capacity (Nijhawan, 2013). On the other hand, clinical trials bring new therapeutic options into the market. Each research activity must be conducted ethically with respect to rights and safety of participants and the validity of informed consent must be ensured.

Conclusion

This essay elaborated on the concept of informed consent and ethical dilemmas underlying it. The aim of the essay was to present the ethical dilemmas arising from the information deficit and inequality of both parties involved in the process of informed consent decision making.

Informed consent represents an act between the patient and health care provider formulating an acceptable plan for medical care. The clinician-patient relationship is an unequal one due to the difference of knowledge of medical information and level of stress that patients undergo while being ill. The ideas that were explored in this essay show the ethical importance of informed consent in medical practice which can be reduced to a reasonable assurance that a patient has not been deceived or coerced.

The first chapter of the essay was devoted to the doctrine of individual autonomy. Informed consent supports individual autonomy. The doctor-patient relationship should correspond to a dialogue and the patient should be a co-author of all decisions concerning his treatment. Some patients however tend to authorize the doctor to make decisions for them which places the clinicians into a vulnerable position.

The second chapter dealt with the emotional overwhelm and information overload of the informed consent process. Emotional overwhelm is caused by the stress of the unknown. Due to his physical and mental condition, the patient is very vulnerable and in a difficult life situation and trusts the help of a medical professional. In this regard, the clinician's responsibility is to understand the fragile situation of the patient and to act adequately and professionally. Such a relationship between a health care professional and a patient is a prerequisite for professional support and effective assistance to the patient in his difficult life situation. Information overload stems from the very complex, uncertain, and challenging information about patients' health and possibilities of treatment. The overload is mainly caused by the large volume of the information and the inability of the patient to process it.

The third chapter followed up with the topic of informed consent and capacity of the patient. There are three main factors that influence patient capacity such as patient-related factors, information related factors and communication-related factors. These factors also interact with each other and are connected to the information overload and overwhelm.

Finally, the fourth chapter highlighted some challenges concerning informed consent in research involving human participants.

In a sense, informed consent has become the victim of its own success due to the inability of clinicians to recognize situations of patients lacking the capacity to make an informed consent (Bester, Cole, Kodish, 2016). In many cases, the informed consent process has become a mere administrative act which has moved away from its original purpose and meaning. The aim of health care professionals should be to achieve true genuine consent. To a certain extent, the informed consent in its legal definition is an unfulfillable ideal.

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