

CASE STUDY 17

Informed consent

Mr. S, a 56-year-old male, consulted his family physician due to respiratory problems. After X-rays revealed patchy infiltration of the lung, Mr. S was referred to a respiratory specialist, who determined that the condition was bilateral and recommended an open-lung biopsy, which Mr. S refused to undergo.

After Mr. S's condition further deteriorated, he was referred to Dr. D, an internist specializing in respiratory diseases. Dr. D observed that Mr. S was exceptionally anxious upon examination. The doctor's initial diagnosis was progressive pulmonary fibrosis of the interstitial pneumonitis type, probably involving fibrosing alveolitis. A biopsy was required to confirm this diagnosis, but Mr. S continued to refuse to undergo an open-lung biopsy.

Dr. D then suggested an alternative procedure, known as a trephine lung biopsy. This procedure was inferior to the open-lung method, but in view of Mr. S's refusal to undergo the open-lung biopsy, it was an appropriate alternative. Dr. D explained to Mr. S that the procedure involved administering a local anesthetic and then inserting a special needle into the lung while the patient sat on the edge of his bed. He also told the patient the needle would be attached to a drill. Dr. D then outlined the procedure's risks, advising Mr. S that the procedure was usually virtually painless, but did have two possible complications. Dr. D did not mention to Mr. S that the procedure also involved risk of perforating the spleen or the liver, an uncommon risk but not as uncommon as death. Apparently Dr. D was not aware of this risk.

Mr. S consented in writing to the trephine biopsy procedure. Prior to the procedure, Mr. S was anxious, apprehensive, and nervous. He told Dr. D he could not afford to die. He was given atropine and sedated with normal and accepted doses of morphine. Once Mr. S had been sedated, Dr. D gave him instructions and demonstrated the equipment to him. After a local anesthetic was administered, the operation began.

At a critical juncture, Mr. S was directed to hold his breath. Instead, Mr. S winced and moved, causing his spleen to be perforated.

Dr. D told Mr. S that the required tissue sample had not been obtained, but did not yet disclose that the spleen had been perforated. When Mr. S asked Dr. D what he had obtained from the biopsy, he answered 'something else.' It soon became painfully obvious that Mr. S's spleen had ruptured and had to be surgically removed.

▶ **Taking into consideration that Mr. S was an extremely anxious patient, should the doctor have acted differently with respect to the explanations he gave to Mr. S?**

Here are a few, but not all, possible answers. Discuss them, as well as other possible answers. Identify ethical issues and decide which answer applies to you most, giving your reasons.

YES Dr. D should have acted differently than he did. The patient was inadequately prepared psychologically for his required role in the procedure. Since Mr. S was recognized as an unusually anxious person, Dr. D should have won Mr. S's confidence through better and more effective communication. Dr. D gave instructions and demonstrated the equipment only after Mr. S had been sedated. The procedure should have been explained and the equipment demonstrated when Mr. S was in an un-sedated state. Furthermore, this particularly anxious patient should have been prepared for this procedure through careful rehearsal to teach him how to hold his breath and refrain from moving. The statement Mr. S made to Dr. D immediately before the procedure, that he could not afford to die, was a clear indication of his apprehension. At that point, Dr. D should have evaluated Mr. S's willingness to proceed, which could have been tested only when Mr. S was alert and not under sedation.

NO Dr. D acted properly and did not breach his obligation to provide Mr. S explanations about the procedure. All the

explanations that should have been given before the procedure were provided. Determining that this behavior constitutes a breach of a physician's obligation to his patient would increase the liability on physicians to an intolerable level.

Notes about the case study

Court decision

Mr. S sued Dr. D for negligence. The alleged acts of negligence included a failure to obtain informed consent, a failure to perform the biopsy in accordance with a reasonable standard of care, and falling below a reasonable standard of post-biopsy care.

The court ruled that Dr. D failed to provide a reasonable standard of medical care. This very anxious patient had not received adequate psychological preparation for his required role in the procedure. His required cooperation should have been explained to him before he was sedated and should have been carefully rehearsed. Mr. S's expression of acute fear, even under sedation, should have led Dr. D to discontinue the procedure. Discussing the procedure further while the patient was not sedated might have elicited his agreement to undergo it.

The court determined that the physician-patient relationship in this case was less than satisfactory. Dr. D failed to take Mr. S into his confidence and provide him the information a patient is entitled to, as a matter of professional relations, if not a matter of law.

Dr. D had an obligation to inform Mr. S that his spleen had been perforated. Mr. S asked Dr. D what he had obtained at the biopsy. Dr. D's failure to be candid with Mr. S was a breach of obligation.

The cumulative effect of all these circumstances, even if most of them individually might be characterized as errors of judgment, is to establish liability for negligence on the part of the defendant.

Discussion What is informed consent?

Every medical treatment requires the patient's informed consent. The significance of this consent is that a person agrees to: the treatment, the 'invasion' of his body, understands the significance of his medical condition and the meaning of the treatment, the dangers and the benefits inherent in the treatment, and grants his informed consent willingly and without coercion, as determined in Article 6(1) of the *Universal Declaration on Bioethics and Human Rights*:

Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information.

Informed consent is a doctrine which was developed by courts over the years and is anchored in law in certain western countries. This doctrine strengthens mutual physician-patient trust and respect by helping the patient reach an informed decision freely with respect to the treatment to be given.

In order to obtain an 'informed' decision, three elements must be determined:

- 1 **Free will:** the patient's wish, without coercion or outside pressure.
- 2 **Information:** The patient must receive all of the information regarding his condition and the proposed treatment, including alternative treatments, side effects and the effect of not receiving treatment.
- 3 **Competence:** The patient must be competent to make an informed decision.

Consent will be valid only if it has been given in respect of the proposed treatment.

The obligation of the physician is to strictly adhere to the rules of informed consent, as part of the autonomy and respect he is obliged to his patient. Therefore, the physician must always consider the personal characteristics of the patient, such as anxiety, his special peculiarities, as much as such exist and his unique personality and relate to it by providing the relevant explanations. One of the challenges facing the medical staff is providing each patient with appropriate information.

CASE STUDY 18

Information required for informed consent

Approximately one month after her marriage, Mrs. NP went to Dr. A's clinic seeking help in becoming pregnant quickly. Shortly after being treated with ovulation stimulants, Mrs. NP conceived, resulting in a pregnancy with four fetuses. As the pregnancy advanced, the risk to the fetuses grew. Therefore, Mrs. NP was referred to the outpatient clinic of the local hospital, where her pregnancy continued to be monitored and treated.

Mrs. NP is a devoutly religious woman who prays every day. The hospital at which she was receiving treatment is also a religious institution.

The chances for such a pregnancy to reach term are low due to the risk of premature delivery and all the complications of such a delivery. To overcome these problems, several techniques have been developed in recent years to reduce the number of fetuses. Fetal reduction preserves the well-being of the other fetuses and extends the pregnancy to term. Such reduction techniques can be carried out during the first trimester and even at the beginning of the second trimester. Although this method is considered 'cruel', it has successful results. Nevertheless, fetal reduction carries a risk of killing all of the fetuses.

The hospital and the medical staff are opposed to this method because they believe it is forbidden by their religious beliefs. Therefore, the hospital does not perform such procedures.

Mrs. NP and her husband were not informed of the possibility of fetal reduction.

Due to complications in Mrs. NP's pregnancy, she delivered the four fetuses in her 25th week of pregnancy. All of the fetuses died shortly after delivery.

→ **Was the physician obligated to inform Mrs. NP and her husband about the possibility of fetal reduction, even though this procedure is contrary to their religion, contrary to the physician's conscience, and contrary to his own religious beliefs?**

Here are a few, but not all, possible answers. Discuss them, as well as other possible answers. Identify ethical issues and decide which answer applies to you most, giving your reasons.

YES The physician should inform Mrs. NP and her husband of all the possibilities even if they go against his conscience and his own beliefs. After receiving all of the information, Mrs. NP and her husband can decide what to do in accordance to their conscience. Depriving relevant information from Mrs. NP and her husband is a violation of their right to autonomy.

NO The medical staff believes that reducing fetuses is forbidden according to their religious beliefs. Therefore, they are not obligated to tell Mrs. NP and her husband about an option forbidden by their religion.

Notes about the case study

Court decision

This case came before the District Court of the state which concluded that according to local law, a physician is not obligated to perform a procedure if it goes against his personal conscience. In this case, Mrs. NP and her husband are religious people treated at a religious institution. Hospital personnel do not consider fetal reduction to be an option because they believe it goes against their religion.

It is the hospital's right to act according to its principles and values. However, the hospital should have informed Mrs. NP and her husband that such a procedure exists and should have allowed Mrs. NP

and her husband to decide about the procedure, even if the hospital is against it.

Discussion Information required for informed consent

Although dignity has a central role in bioethics, it is not a magic word and in order for it to become functional, it requires practical norms, such as informed consent. Informed consent is regarded as a right of all human beings, stating that any medical treatment may only be administered upon obtaining the patient's informed consent. The patient's power to grant informed consent is an integral part of his autonomous right to decide what shall be done to his body.

In order to grant informed consent, patients must receive all relevant information, including details of their medical condition and prognosis, the available therapeutic alternatives, and the repercussions of treatment or non-treatment.

In many instances, patients decide on a proposed course of treatment based on personal, subjective and non-medical, factors: emotional, religious, and others.

The doctor is obligated to provide patients with all of the relevant information, enabling them to reach a well-considered decision. Relevant information includes therapeutic alternatives that are more expensive or less accessible at the given location. The doctor should not replace the patient's consideration by his own to choose between therapeutic options. Even if the doctor knows the patient and his beliefs, even if the doctor thinks he knows what the patient will choose, this does not absolve the doctor's obligation to supply complete and current information so that the patient can independently decide on the option that is best for him.

On the other hand, the physician and the medical institute are also entitled to respect their own beliefs and norms. Accordingly, one must respect medical institutions which act according to religious beliefs or cultural tradition. Thus, we cannot force such an institute to perform a procedure which is against its faith; however, this alone cannot relieve

the institution from its obligation of informing patients of the existence of alternative procedures.

Doctors are not obligated to act against their own personal beliefs. For example, one cannot force a physician to perform an abortion if he believes it is wrong, just as we cannot force him to help a patient end his life if he believes that it is considered murder.

CASE STUDY 19

Information about alternative treatments

On 28 January 1991, Ms. X, a 53-year-old woman, was examined by a doctor, who then ordered a surgical biopsy. On 14 February 1991, the results of the biopsy showed she was suffering from breast cancer.

At the time, two treatment methods were available for treating Ms. X's disease. The first method, mastectomy, entailed surgically removing all of the breast tissue, while preserving the underlying pectoral muscle. The second method, known as the conservative treatment or breast-conserving surgery, involved removing only the tumor and a small amount of surrounding tissue. The doctor advised Ms. X that while the conservative treatment for breast cancer was being implemented, this method was not yet fully and accurately understood. The doctor also told Ms. X that her breast would be totally removed, but the pectoral muscle would remain.

At the time of the operation, the conservative treatment for breast cancer was not yet prevalent, and mastectomy was the primary method used. There were not too many reported cases of implementing the conservative method, results had only been observed for a short period of time, and the method of treatment had yet to be established. Nevertheless, at the time of Ms. X's operation, the doctor was aware that a sizeable number of medical institutions were using the conservative treatment for breast cancer.

The doctor operated on Ms. X on February 28, 1991 and removed her breast. Before the operation took place, Ms. X handed the doctor a letter outlining the complex sentiments of a woman diagnosed with breast cancer and faced with a choice between continuing to live and having her breast removed.

→ **Was the doctor under an obligation to inform his patient about the conservative treatment for breast cancer which at that time had not yet been strongly established?**

Here are a few, but not all, possible answers. Discuss them, as well as other possible answers. Identify ethical issues and decide which answer applies to you most, giving your reasons.

- YES** The doctor should have told Ms. X that alternative treatments were available. The breast is located prominently on the front of the body and is a symbol of femininity. Losing a breast in such an operation changes the patient's appearance and could seriously affect her mental and psychological state. The doctor should have given the patient the opportunity to determine the course of her treatment and not deprived her of information about an alternative treatment only because it has not yet been established.
- NO** The doctor did inform Ms. X that there was a way of preserving the breast. He did refer, more or less, to the alternative treatment method and mentioned its pros and cons and the prognosis after treatment.
- NO** Since the rate of implementation of the conservative treatment was low and its safety had yet to be established, the situation had not reached the stage where the doctor should have asked whether the patient wanted to try this treatment, despite the risk in its implementation. Therefore, the doctor's explanation was not insufficient as an explanation of the available alternative method of treatment.

Notes about the case study

Court decision

This case came before the Supreme Court of the country. The court concluded that if there are several established methods that all adhere to medical standards, the doctor, as a matter of course, is required to explain, clearly and explicitly, the differences between the treatments and their pros and cons so that patient can choose between them after sufficient consideration.

However, in cases where one treatment has already been established as adhering to the standard of medicine, while the other has yet to be established, it cannot be said that the doctor is always under an obligation to explain the latter treatment. On the other hand, it cannot be denied that there are instances in which a doctor is under an obligation to explain even such a non-established treatment. In this case, the treatment had been implemented at a sizeable number of medical institutions, a considerable number of operations had already taken place, and the results had been positively assessed by doctors who implemented this treatment.

The doctor was aware that the treatment might be suitable for the patient and that the patient was strongly interested in the suitability and applicability of this treatment to herself, despite his negative view of this treatment and his own refusal to implement it himself. Under such circumstances, the doctor is under an obligation to inform the patient, within the scope of his knowledge, about the content of the treatment, its suitability, its pros and cons, as well as the name and address of the medical institutions which offer this treatment.

The mastectomy surgery for breast cancer is an operation to remove the breast. Surgical removal of the breast can seriously affect the patient's mental and psychological state as a result of the change in her appearance. Such surgery has an impact on the patient's quality of life, indeed upon the whole manner in which she conducts her life. Thus, doctors are obligated to explain the conservative treatment for breast cancer as an alternative treatment before deciding upon surgical removal of the

breast tissue while preserving the pectoral muscle. This requirement is even stronger than in general surgery that does not have such an impact on the patient's appearance and quality of life.

Discussion Information about alternative treatments

Dignity is not a well defined notion and different sources refer to it with different meanings. In order to unify the definition of dignity, some 'practical rights' call for particular definitions, such as the right to approve medical treatment without 'informed consent'.

To effectively implement this right, the patient must have all of the information relating to the medical procedure, including information about alternative treatments. According to one approach, the physician must disclose every option available to the patient, even if it is not truly feasible, only then can the doctor be convinced that the patient will be able to make a fully informed decision. Another approach says that if the patient is unable to receive the treatment either because it is unavailable or he cannot afford an alternative treatment, the physician does not have to tell him about it.

The right of informed consent is an integral part of the patients' autonomy to determine the treatment most suitable for them, based on their medical condition, their general life perception, values, beliefs, and feelings. This autonomous decision is part of one's personal responsibility and it follows from the fact that patients will have to live with the consequences of treatment – whether it succeeds or not. This principle is expressed in Article 5 of the *Universal Declaration on Bioethics and Human Rights*:

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected.

To obtain genuine informed consent, based on the patients' sincere and free will, comprehensive information relating to their medical condition, available treatment options, as well as benefits and risks involved in each of the treatment alternatives must be disclosed. Certainly, this

includes therapies that are less common or more expensive, as long as they are established and accepted medical protocols. Even if a course of treatment is infrequently applied or is highly costly, still it should be discussed with the patient, who may opt for that treatment despite its cost.

The right to informed consent is not absolute, and in situations where the patient might be harmed by the information, it is ethical to withhold certain information.