The International Center for Health, Law and Ethics

Faculty of Law, University of Haifa, Israel

The UNESCO Chair in Bioethics

Informed Consent

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Informed Consent: Case Studies

Introduction

The ever-increasing power of modern medicine and the complex, sociological settings in which it is practiced raise new ethical questions concerning what is just, what is good, and what is right in the behavior of doctors and patients, of individuals and of society.

The tremendous advances in medical technology, the high costs of health care, the scarcity of resources, the rise in public expectations and demands and the shift in values require intensive consideration of the future of the health system and reconsideration of certain old ethical principles, or rather, of their applicability to novel situations.

Beyond political issues, it is necessary to understand the principles that call for decisions involving medicine and what guides the way these decisions are made today. It is the responsibility of each of us to assume that there are contradictions and conflicts between these principles.

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A person's basic rights are established on recognition of his human status, the inviolability of his life and the fact that he was born, and will always be, free. Respect for the values and wishes of the individual is a duty which becomes even stronger if the individual becomes vulnerable. Since the autonomy and responsibility of every person, including those who need health care, are accepted as important values, reaching or participating in decisions concerning one's own body or health must be universally recognized as a right.

The ethical problems arising from the requirement of patients' informed consent are so diverse that it seems fit and proper to devote the first of a series of manuals for training in ethics to this subject and to familiarize students of medicine with cases which demand ethical, as well as medical or surgical decisions after the initial diagnoses of patients' ailments and long before the students themselves assume personal responsibility for the practice of medicine. It is intended that "Informed Consent" shall be the first of a series of companion text books for training in ethics. Each of them will deal with ethical problems which face the doctor in those different spheres of medicine in which the experts who have agreed to edit the books specialize.

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Finally, it is my pleasure as well as obligation to acknowledge the debt of gratitude which I owe to the many supporters of the UNESCO Chair whose names and functions are recorded at the beginning of this work. The diversity of countries where they engage in their professional activities and the expertise which distinguishes their contributions to the manual have most definitely added a highly international flavor and hopefully a worldwide appeal to its contents.

A. Carmi

Case Report No. 1

A 72- year -old male farmer with three children had been suffering from colon cancer. He described his illness as a "mass in the intestine" but he did not know what kind of a treatment modality would be used.

The day after the surgery, the assistant surgeon on duty visited the patient for routine inspection and treatment of the surgical wound. The patient, expecting to see a closed wound, was scared when he saw the opening of his colostomy. He asked the surgeon about "the hole in his abdomen". The surgeon, in a serious manner, replied: "The end of the intestine that was operated on was sutured to your abdomen. You are now to defecate through this hole and into the bag I will place at the end of it."

Surprised and angered by the response, the patient asked:" Whom did you ask before opening that hole?" The surgeon told the patient that they had informed his son about the procedure. The patient shouted in anger: "Who was to be operated on and have a hole in his abdomen? Is it me or my son? How dare you perform that without asking me? I will sue all of you!" The surgeon, unprepared for such a reaction, slowly started to explain the reason why colostomy had been performed and referred to the patient's disease as a "bad" one. After the explanation, the patient said: "If you had told me this earlier, I would not have shouted at you. I am not that illiterate, you know! I could understand."

Associate Prof. Dr. Nermin Ersoy
Turkey

Medical treatment has become a joint venture combining doctor and patient. A decision to treat medically can only be determined by co-operation between the treater and the treated, both parties being linked together by mutual trust and reciprocity. The principle is based on the concept of self-determination, enjoining that each individual take responsibility not only for his own actions, but also for his own body and what he allows to happen to it. Hence, any decision with regard to the choice of treatment is that of the patient, his doctor acting as his adviser.

The purpose of the informed consent principle is to enable the patient to consider, weigh and balance the benefits and disadvantages of the proposed medical treatment in order to make a rational choice either to undergo or refuse it. The proper use of this principle prevents or diminishes the possibilities of errors, negligence, coercion and deception, and encourages the doctor's self-criticism. But its main purposes are to assert the patient's autonomy, to promote his right of self-determination, and to protect his status as a self-respecting human being.

Case Report No. 2

Mr. N., 46 years old, is the father of two children. The oncologist was keeping him under observation in connection with his adenoma of prostate for three years. In due course the tumor became malignant. Consequently Mr. N. was admitted to hospital for prostatectomy. Before the surgery he was informed about the state of his health and about forthcoming surgery. Informed consent was obtained.

In the course of the surgery a seminoma was found. The surgeon decided on prostatovesiculectomy. As a result, Mr. N. sued the surgeon because the treatment was harmful to him and his right of reproduction was affected.

Prof. Gallina Ermolaeva
Russia

Was the rule of informed consent fulfilled in this case?

1. Yes. Informed consent was fulfilled because it was not medically reasonable to expect the seminoma. Once it was identified, extension of the field of surgery was proper.
2. No. The rule of informed consent was not fulfilled because the right of reproduction is a fundamental right and the surgeon could have delayed the second surgery in order to obtain the patient's informed consent. The situation was not an emergency and surgical access to the seminoma is easy.

What is the meaning of "informed consent"?

In order to be fully legal, the patient's consent must be informed.

Being informed implies cognition, willingness, consideration, intention and understanding.

Opinion and choice cannot be final and acceptable unless they are based on knowledge. No consent will be valid which does not depend on willingness.

A patient should be able to comprehend the meaning of the information, balance pros and cons, draw inferences from the data with reasonable rationality, assess the circumstances, appreciate the aspects of the situation, and reach a deliberate decision on the basis of the available information. Hence, information must be communicated to the patient in a manner that is consistent with the patient's capacity to understand and in a form that maximizes such understanding.

Various factors may diminish a patient's ability to understand, evaluate and decide, undermining his competency to consent. Illness can impair his usual ability to think and act in a responsible manner.

*

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

A patient does not have to comprehend more of the disclosed information than is necessary for the nature and range of the decision at hand.

Case Report No. 3

A 17-year-old girl fled from home with her boyfriend some time ago and then was found. The boy was put under custody. The girl's family is totally opposed to their marriage. The girl considers the possibility that her big brother could kill her boyfriend in case he finds out that she is no longer a virgin. The police officer who comes to the physician eligible and responsible for a virginity test would first like to talk to him alone. He informs the doctor that the girl does not know that her boyfriend is already married. The doctor then talks to the young girl and tells her that as she is under 18 her family legally has the right of requesting a virginity test (perineal examination); the physician adds, however, that such an investigation cannot be performed without her consent, but also says that he cannot sign a health certificate without first making the necessary examination.

Dr. Berna Arda
Turkey

Should the physician tell the girl that her boyfriend is already married?

1. The physician should not tell the girl that her boyfriend is already married because the information is not medically relevant and disclosure would invade the boyfriend's right of privacy.
2. The physician should tell the girl, in view of the trust between the physician and the girl as well as because of the boyfriend's dishonesty.

The information that should be conveyed to the patient

The doctrine of informed consent requires that the physician convey to the patient any information that would be viewed as material in permitting the patient to make a knowing and intelligent decision regarding medical care and treatment.

For the purpose of obtaining the patient's decision on informed consent the treater should supply him with the following medical data.

Diagnosis and prognosis of the patient's medical health status

Case Report No. 4

Mrs. A.B. is 39 years old, a popular dressmaker who has been happily married for twelve years but distressed and deeply depressed by her inability to conceive. She has undergone stressful and expensive treatment for infertility, which was unsuccessful probably due to her endometriosis, a condition which has also caused her increasingly disabling pelvic pain. Eventually, she accepted her specialist's advice that she would be unable to have children, and should have a hysterectomy to relieve her pain and bleeding caused by endometriosis and to enable her to enjoy life with minimum impairment. She was referred to a local gynecologist and admitted to hospital for hysterectomy.

The gynecologist requested a house surgeon, an intern, to undertake pre-operative examination and obtain consent for surgery. The intern read Mrs. A.B.'s medical record, noting her severe depression and the absence of a recent pregnancy test, and on examination confirmed serious endometriosis but found her uterus enlarged. The intern asked the gynecologist if a pregnancy test was indicated. The gynecologist replied that pregnancy was not expected and testing would not be in Mrs. A.B.'s best interests. A fetus might be seriously impaired due to the patient's condition or age, and either an impaired child or an abortion would aggravate Mrs. A.B.'s depression. The intern was directed to obtain consent for the hysterectomy.

Prof. Bernard Dickens
Canada

What information should the intern disclose to Mrs. A.B.?

1. He should disclose no additional information because of the clear direction by the attending gynecologist and considering the fact that Mrs. A.B. previously accepted the advice to have hysterectomy. Further, such disclosure would not be in the best interest of Mrs. A.B.
2. He should disclose to Mrs. A.B. that her uterus is enlarged and that she may be pregnant. He should recommend a pregnancy test before the hysterectomy is performed. He should not follow the contrary directions given by the attending gynecologist.

   His obligation to provide material information (relevant) for informed consent overrides his obligation to act in accordance with the attending gynecologist's orders.

*

A description of the nature, process, purpose and expected benefit from, and prospects for, the proposed treatment.

*

The hazards involved in the proposed treatment, including side-effects, pain and discomfort.

Case Report No. 5

Mrs.C.S., a teacher who is also a lead singer in a choir, consulted an otorhinolaryngologist for a nontoxic multi- nodular goitre which was growing larger. She had been advised to have surgery 5 years earlier but had declined until the possibility of cancer was raised by her doctor. She was admitted to hospital for thyroidectomy and was seen first by the otorhinolaryngologist and subsequently by a general surgeon.

At surgery a subtotal thyroidectomy was performed by the general surgeon with the otorhinolaryngologist assisting.

Immediately postoperatively the patient developed difficulty in breathing and was re-intubated.

On the following day a tracheostomy is performed by the otorhinolaryngologist. On day 6, she is extubated and is discharged the following day. On follow- up the otorhinolaryngologist notes "sluggish movement of both cords". One year and 3 months later she is seen by another doctor for "bronchospasm". Two days after that she is noted to be having stridor and the doctor consults another otorhinolaryngologist who gives an opinion over the phone that the recurrent nerves were damaged at surgery. The second otorhinolaryngologist sees the patient a month later and states that "the vocal cords are fixed in the midline with very little air space". An operation is advised to separate the cords; the operation is carried out but is not successful.

Prof. E.R. Walrond
J. Ramesh, M.S. Fais
West Indies

Was the rule of informed consent followed in this case?

1. No. The rule of informed consent was not followed because the doctor should have informed C.S. of the material risk of vocal cord injury and should have allowed her to make a decision in the light of these risks.
2. Yes. The rule of informed consent was not violated. This was an emergency case, because of the possibility of cancer, and the doctor acted in the patient's best interests.

Case Report No. 6

Mrs. Ch. B. is a 55-year-old nurse, married, with one adopted son. She has a medical history of rheumatism in childhood, complicated with endocarditis that led to mitral stenosis and aortic insufficiency as a sequel. For this reason, she had a successful surgical intervention 8 years ago. Since the operation, she has started anticoagulant therapy. Meanwhile, about 3 years ago, she was diagnosed with a cold thyroidal spot. Several months ago some compressive complications appeared (dysphagia and spastic cough) with progressive decline. The GP assigned her to a consultation with an endocrinologist and a cardiologist. The results confirmed that her complaints were due to the enlarged thyroid gland, but after a medical consultation in the hospital, the primary idea of operation was not agreed to by the doctors, because of the risk of malignant degeneration (5 % risk) and / or profuse bleeding during the intervention, due to the anticoagulant treatment. These threats and concerns were shared with the patient but she unbendingly and hopefully insisted on operation as soon as possible.

Prof. Dr. Mariana Ljochkova, M.D. Ph. D
Dr. Rumen Stefanov, M.D.
Bulgaria

What should be the doctor's approach to this patient?

1. The doctor should allow the patient to assume the risks and proceed with the surgery after obtaining full and informed consent.
2. The doctor should refuse to perform the surgery because to do so would violate the recognized clinical standard of care.
3. The doctor should refer the patient to another surgeon.

Case Report No. 7

Mrs. R.B., 25 years old, Gravida 2, Para 1, a housewife, married for the last 3 years came for antenatal check -up at 6 weeks of gestation.

Para.1 was a male baby born with congenital heart disease. The baby died at the age of 6 weeks. The patient was very anxious about the foetal outcome in this pregnancy and went through all the investigations like torch profile, VDRL, RBS and all were found to be normal. She had an uneventful first trimester. She was put on Tab Folic Acid 5 mg at her first antenatal visit. In the 2nd trimester the ultrasonography was done at 16 weeks of gestation and reported to be normal. Patient had a regular and uneventful antenatal check-up till 35 weeks, when another ultrasonography was advised and occult spina bifida was reported.

Occult spina bifida may or may not give rise to eventual problems of micturition control or problems in the lower limbs. The standards of neurological management and operative intervention are also available nowadays.

Dr. S.C. Ahuja
Dr.(Mrs.) Kumkum Avasthi
India

How much and what information should be given to the patient and her husband?

1. The patient and her husband should be provided with all relevant information regarding the occult spina bifida and its implications for the baby.
2. The husband should be provided with all relevant information regarding the occult spina bifida and its implications for the baby. The husband will then decide how much information to disclose to his wife.

The prospects and dangers involved in alternative medical treatment, or in no treatment at all.

The fact that the treatment may be of innovative nature.

In the typical treatment context, physicians must provide their patients with more and more specific information. On the other hand, physicians must strike a delicate balance between submerging their patients in information, thereby diminishing a patient's ability to make rational choices and restricting the information, to simplify decision making.

Lack of valid informed consent: To treat or not to treat - that is the question

Case Report No. 8

Mrs. X. was a 30-year-old woman, married for 10 years, nulliparous, unable to conceive for 10 years, She also had a history of menorrhagia, congestive dysmenorrhoea and dyspareunia for 2 years. Pelvic examination revealed a 10- week-sized regularly enlarged uterus, which was slightly tender. Ultrasonography by a senior radiologist in a Medical College diagnosed 3 intramural fibroids 2x3 cms.each. Her husband's semen analysis was normal.

The patient was offered myomectomy after a course of antibiotics. Pre-operatively, the couple was informed of the necessity for doing a hysterectomy in a few cases due to profuse intra-operative bleeding. The couple however refused to give consent for hysterectomy as they were very keen on pregnancy. Since no major problem was anticipated in view of the small size and number of fibroids, stress was not laid on obtaining consent for hysterectomy.

At laparotomy, under general anaesthesia, the uterus was found to have adenomyosis and not fibroids. No plain of cleavage could be found around the intramural lesions. The patient could not be informed as she was under general anaesthesia.

The physician contacted the husband to explain his findings. He recommended total hysterectomy and asked for consent from the husband. Consent was given.

Dr.(Mrs.) Alka Stija
India

Should the doctor perform the operation?

1. No, because the doctor must respect the woman's autonomy and self-determination. The husband's consent is invalid.
2. Yes, because the husband has authority to consent to the operation, which the physician believes is medically indicated.

Case Report No. 9

A 38-year-old construction worker was admitted to the hospital after 3 weeks of worsening symptoms of a respiratory infection. He was found to have severe pneumonia, and within 48 hours of admission was transferred to the Intensive Care Unit in respiratory failure. He was treated aggressively with antibiotics, ventilatory assistance, and other measures. Over the next 3 weeks his condition did not improve, and he deteriorated into multi-system organ failure without a bacteriological diagnosis. When his wife was informed that it was likely he would not survive, she asked if it would be possible to obtain some of his semen so that she could have his baby.

She reported that they had been married for 14 years and had been unable to conceive. After much resistance, he had agreed just a few months earlier to see an infertility specialist. After initial testing had shown no soluble problem, they had consented to begin their first cycle of in vitro fertilization that very month, but had not been able to follow through because of his illness.

She made the request because she was convinced that he would want very much to have a child. He was the only son of his parents, and he wanted his family name to continue into the next generation. His sister, who accompanied his wife confirmed these social and attitudinal facts.

Robert D. Orr
USA

Should her request be honored?

1. No, because the husband has not expressly granted informed consent for the performance of the procedure.
2. Yes, because the husband previously granted implied consent for the procedure by virtue of his willingness to undergo in vitro fertilization.
3. Yes, but only following a judicial order based on the best interests of the child to be conceived, the clear desires of the woman and the goal of respect for parenthood.

Case Report No. 10

Mr. J.B. is 52 years old. He is married and has two children 12 and 14 years old. He is suffering from unstable hypertension and chronic obstructive pulmonary insufficiency and suffered an acute myocardial infarction nine weeks ago. He was treated by stenting the two main coronary arteries. From that time he has constantly been on a small aspirin dose once a day. He was admitted to hospital a week ago with acute left femoral artery thrombosis. On admission, since he refused an agreement for proposed interventional treatment,only medical treatment with heparin, streptokinase and vasodilating agents was ordered. It gave no results and eventually necrosis of the distal part of the left leg developed. He was consulted by a surgeon and left leg amputation was proposed. He refused the proposed treatment despite warning of the possible lethal outcome. His wife is asking doctors to perform the operation regardless of lack of consent from the patient.

Prof. Krystina Orzechowska Juzwenko
Poland

How does the surgeon respond?

1. The surgeon informs the wife that her husband is competent and has the right to refuse treatment, even if the refusal results in his death.
2. The surgeon informs the wife that her husband's decision to refuse treatment will result in his death. Such a decision demonstrates her husband's incompetence. Accordingly, the surgeon will proceed with the amputation despite the husband's express opposition.
3. The surgeon informs the wife that he will proceed with the amputation, despite her husband's express objection, because it is in his best interests.
4. The surgeon will seek judicial enforcement for countermanding the patient's decision.

Case Report No. 11

Mrs.E.D. is a 69-year-old retired bank manager. She has been suffering from poorly controlled diabetes for the last 18 years. For the last 6 months she has needed hemodialysis twice a week for end-stage renal disease. Three days ago, she was hospitalized because of an infected non-healing wound at the amputated stump of her left leg. Two days later gangrene set in. Following a meeting of her diabetologist, infectious disease specialist, surgeon, and family it was decided to amputate. Her eldest son, a physician, agreed to the amputation but announced that no one should tell her about it. She would only be told that the wound would be "surgically cleaned". Last year when the foot was to be amputated, Mrs. E.D. refused to give her consent. They did it without her consent and after her initial anger for a few days, she appeared to understand the need and no longer blamed them. Her son anticipates the same reaction and feels informing her will only add more stress. Her husband and other children agree to the plan.

Angeles Tan Alora, MD
Philippines

Should the surgeon follow the son's request and operate on Mrs.E.D. without obtaining her consent?

1. The surgeon should not operate without her consent because informed consent is a fundamental, ethical and legal right.
2. The surgeon should operate without her consent because consulting her may lead to a negative response resulting in her death. Further, she was pleased with the previous amputation decision and its results, which may be interpreted as implied consent.

Case Report No. 12

You are a forensic surgeon on duty. Policemen bring you a man suspected of being a rapist; there are absolutely no witnesses and no evidence that could confirm his guilt, but they tell you that they have found some traces on the victim's body that could lead to the identification of the culprit.

Before the consultation, the suspect drank a glass of water and smoked some cigarettes outside.

You inform the suspect of your mission: take painless samples of cells from mouth or blood to perform a genetic identification to be compared with traces found on the body.

The suspect refuses this examination and goes out with the policemen.

A few minutes after he leaves, policemen come back and bring you the glass and the cigarettes, expecting you to test for genetic evidence left on these items.

Thierry W. Faict,
Yves Dousset,
Roger Letonturier,
Stephanie Neel -
France

Are you going to test for genetic evidence?

1. Yes. Such test is an integral part of my official work.
2. Yes. I am employed by the Government, the suspect is not my patient, and I do not owe any duty to him.
3. No. As soon as you advised the suspect of the test, a bond of professional trust was established between both of you and you are expected to respect his refusal.

Therapeutic Privilege

Information may be withheld from patients in exceptional cases only when there is good reason to believe that the disclosure of certain information would endanger the patient's life or detrimentally affect his physical or mental health.

Case Report No. 13

Mr. S.R. is a 28-year-old former graduate academic scholar at a prestigious Catholic university who left school to work full time with the poorest of the poor. He engaged in carrying heavy sacks of rice for some time in his new task. Eventually he developed moderate to severe low back pains which could not be relieved by resting and medications. He consulted an orthopedic surgeon who investigated, discovered a protruding disc and suggested surgical correction but he informed S.R. that the operation carried a risk of permanent disability. S.R. was unhappy, apprehensive and decided to forgo the procedure and confined himself to chiropractic treatment. There was no benefit. S.R. consulted a second orthopedic surgeon who told him that under a skilled surgeon's hands the risk of surgery would be minimal. The second surgeon urged Mr. S.R. to ask him all the questions he wanted. But S.R. did not ask anything about the risk of permanent disability. As S.R. was an obviously anxious patient, the second surgeon held back information about this possibility; he did not go any further into the description of the risks.

Dr. Francisco A. Woo
Philippines

Did the second orthopedic surgeon act properly?

1. No, because the surgeon is obliged to disclose major risks.
2. Yes, because the surgeon has the discretion to consider the patient's state of mind in deciding how much information to disclose.
3. Yes. Because the patient did not ask any detailed question about the nature of the risks he would encounter due to surgery.

One of the most difficult social, moral and medical problems is the issue of the appropriate approach to a patient suffering from an incurable disease. A patient's right to know or be informed of the seriousness of his illness needs to be balanced with the right not to know, when knowing might cause a traumatic state of helplessness and collapse, since active problem-solving behavior is necessary for survival.

The right not to know

Patients have the right not to be informed on their explicit request. The right not to know provides an instrument to prevent the receipt of unwanted information.

Case Report No. 14

Mr.D.A, is a 55-year-old salesman, married, with 3 children. He has been a heavy smoker for the last 30 years. He has a chronic productive cough, with moderate exercise dyspnea, both of which led to medical tests that resulted in a diagnosis of COPD 5 years ago. He has no other known medical disorders and does not take any regular treatment. During the last month, he has been suffering from hemoptysis. After some hesitation, he told this to his family, and they persuaded him to inform his family physician, who knew him well.

Upon meeting with his family physician, he agreed to be referred to a pulmonologist and to undergo tests, such as a chest roentgenogram, but he requested that if a severe disorder was found, such as lung cancer, he not be informed. He explained this request as due to his preference to be spared the heartbreak involved in such bad news, and he was not willing to discuss related treatment, such as surgery, radiation therapy or chemotherapy. The family physician explained to him the variability of prognosis of different types of lung cancer and the importance of the patient's knowing the diagnosis, as he can then decide in an informed and perhaps more rational manner on treatment, but Mr. A. persisted in his request to waive the breaking of bad news.

Dr. Rami Rudnick,
Israel

How should the family physician proceed?

1. He should inform Mr.D.A. that, based on his refusal to hear bad news, the physician will decline to refer Mr. D.A. to the pulmonologist because it will be futile.
2. He should inform Mr.D.A. that he will refer him to the pulmonologist, with the understanding that he will respect Mr. D.A.'s right to refuse to hear bad news.
3. He should inform Mr. D.A. that he will refer him to the pulmonologist with the understanding that, when the test results are available, Mr. D.A. will reconsider the question of whether or not he will listen to bad news.
4. He should decline to refer Mr. D.A. to the pulmonologist if there is possibility of major complication following an invasive diagnostic procedure.

The right not to know is important, for instance, when examination generates knowledge about genetic predisposition, genetic risks and early prediction of still latent diseases which could become manifest sometimes many years after they are diagnosed (such as Huntington's disease). On the other hand, this right not to know is not applicable when a person should be given information allowing him/her to protect other people by an adapted behavior. For instance, the positive result of a sexually transmitted disease investigation should not be held back from a patient. The possible result of the investigation and the consequences of this result should be anticipated with the person before they are performed.

The right to refuse treatment

Case Report No. 15

A 57-year -old man, affected by a throat cancer with widespread metastasis, at the last stage, is hospitalized. The medical staff realizes the serious condition of the patient and that his lucidity from time to time seems compromised. The medical team feels he may need an intubation in order to support his life functions and breathe better. They ask the patient about the intubation in the morning and he agrees. During the afternoon, when the man is conscious, he seems unsure about his previous agreement, refusing the intubation support. The next day the situation repeats itself.

Dr. Francesco Masedu
Prof. Ferdinando di Orio
Italy

To intubate or not to intubate, that is the question.

1. Intubate based on the principle of beneficence in the clear and continuous absence of stated opposition by the patient.
2. Do not intubate because the last stated preference of the patient is to refuse the intubation support.
3. Intubate in the morning.
4. Do not intubate now, nor intubate in case of life-threatening obstructive respiratory failure. (The person would die in this case.)
5. Do not intubate now, but (try and) intubate in emergency if a severe respiratory failure threatening the patient's life functions occurs.

The patient is under no obligation to stay healthy or to receive any kind of treatment. He has the right to refuse or to stop a medical intervention. He is free to choose treatment or no treatment at all, or just partial treatment.

Case Report No. 16

A 69 -year- old male, married, with 2 adult children, is very active. His medical history includes renal transplantation and 2 myocardial infarctions.

With his wife he discussed the possibility of another heart attack; he told her when it came to dying, he wouldn't want a long period of suffering, he wouldn't agree to life-prolonging therapy. He subsequently suffered cardiac arrest with 2 hours of resuscitation, leading to a persistent vegetative state. After 8 weeks of rehabilitation, there was no change in the patient's status. There was complete dependency on nursing staff, tracheotomy, feeding via gastric / duodenal tube; his wife was entitled to care for his personal and official needs and he was brought to a nursing home. During the following weeks, there was recurrent dislocation of the duodenal tube with haematemesis, following by gastroscopy and relocation.

Five days later, there was haematemesis again. The GP called for an ambulance to get the patient to the hospital again. Following admission, the patient's wife refused another gastroscopy, telling the doctor that her husband was willing to die. She asked for a reduction of the medication and for termination of feeding and fluids.

Dr. Birgitt van Oorschot,
Germany

What should the doctor do?

1. The doctor should refuse to discontinue feeding and fluids because they are considered necessities of life.
2. The doctor should honor the request of the wife, who is functioning as the surrogate decision maker for her husband.
3. The doctor should honor the wife's request because it is based on the husband's personal instructions, as previously communicated to his wife.
4. The doctor should not honor the wife's request, as the husband's personal instruction was not documented.
5. The doctor should not perform the gastroscopy, and he should stop gastro-duodenal feeding, as both appear to be out of proportion and futile. Bur he should continue cardiac medication and fluids as he knows that death would occur very rapidly otherwise.

However, one can be under an obligation to receive necessary treatment according to existing statutory regulation.

Incompetent patients

A person is regarded as competent if he has the ability to understand the nature of his illness for which treatment is recommended, and has the ability to appreciate the consequences of giving or refusing consent. A person who is termed incompetent is one whose insanity or mental deficiency deprives him of the ability to control his own interests.

There are various criteria for examining and determining the fitness of the mentally deficient such as their ability to understand given information, to appreciate the nature of their situation, to assess the relevant facts, to exercise choice, to use understood information for realistic, reasonable and appropriate decisions, to understand the nature of the disease and the proposed treatment, and to appreciate the consequences of giving or refusing consent. Competence may be found in degrees, and one's decision-making abilities can vary over time and in different circumstances.

Case Report No. 17

A woman, 28 years of age, attends an occupational therapy day program at a local psychiatric hospital. She has mild, mental retardation (IQ 65) and for the past month has been diagnosed with AIDS. According to her psychiatrist, she was able to give informed consent for HIV testing after proper counseling had taken place. She has proven herself to be very promiscuous and in spite of ongoing psycho-education about her illness, the availability of condoms and her promises to practise safe sex, she just cannot act according to her knowledge. At the day program it is possible to 'shadow' her, but according to her mother her promiscuous behavior poses a threat to herself and others in the community. Efforts to curb her sexual behavior by means of an SSRI (Serotonin Reuptake Inhibitor) have failed. She is verbally quite strong, commutes to the hospital on her own by train, has many friends and lives with her mother and siblings within the community. The mother contacts her therapist and asks whether her daughter should not be institutionalized for the sake of her own safety and the safety of others.

Prof. W.P. Pienaar
Holland

What should the psychiatrist do?

1. The psychiatrist should initiate action to involuntarily hospitalize the woman because of potential danger to herself or others.
2. The psychiatrist should inform the mother that he cannot institutionalize the woman because she is not mentally ill but will report the case to the public authorities of the country, which may take action including the imposition of a quarantine, with a written

certificate that she carries a potential public health danger.

3. The psychiatrist should inform the mother that he will take no action but that the woman should continue with her day program, with intensive education to understand her disease and to engage in safe sex.

Health professionals are required to respect the views of incompetent patients. Respect for the patient whose ability to act autonomously is impaired implies that the patient's right to self-determination and the right to participate in the process of decision-making is to be respected as long as it is not presumed to harm himself or someone else. Consideration of the patient's wishes is fundamental even with regard to decisions that for a longer or shorter time have to be taken by someone other than the patient.

Not every example of disturbed judgment or unbalanced thinking cancels a person's mental capacity. Hence, patients suffering from dementia should not automatically be assumed to have lost their ability to consent, since this ability becomes gradually and progressively limited as the disease takes its course. Patients must be associated to the greatest possible extent with their treatment plan, even when the consent of their legal representative is required.

A patient may be competent to consent or refuse one treatment, but incompetent to accept or refuse another treatment.

Refusal of treatment

A person who is mentally deficient, as a human being and as a patient, is not denied his right to refuse treatment because of his mental illness. Every case must be examined in the light of its circumstances and every patient's decision must be examined in the light of his illness, his condition and fitness at a relevant time.

In general, a patient who opts for hospitalization will be given no type of treatment to which he does not agree, except in cases of emergency.

Case Report No. 18

A 46-year-old engineer with acute relapse of paranoid schizophrenia calls at the emergency room of the local psychiatric hospital kindly requesting admission to the closed ward. He is reporting vivid delusions of persecution (e.g. being attacked by cosmic rays sent from satellites driven by the extramundane creatures which bring him to the state of "mental and physical paralysis") and hallucinations (e.g. hearing the warning voices of those creatures, feeling the painful penetration of his body with the rays). After entering the ward the patient rejects the proposition of psychopharmacology stating he feels safe and comfortable staying in the closed ward, behind the grated windows and without handles, as his persecutors are not able to get at him there.

Prof. Krystina Orzechowska Juzwenko
Poland

What is the right solution of the conflict between the physician (who wants to treat the patient) and the patient (who refuses the proposed therapy)?

1. To provide the patient with comprehensive information regarding his condition, possible methods of treatment (including psycho-, socio- and pharmaco-therapy) and the consequences of refusing treatment, patiently trying to convince him to accept the therapy.
2. To initiate competency proceedings with a view to seeking authority to treat the patient involuntarily.
3. To treat the patient immediately to attempt to achieve mitigation of his psychosis.

There is need for special protection for incompetent patients, who are weaker and whose right may be more easily violated or ignored. A decision in the patient's best interests is not necessarily a decision to accept treatment.

A guardian is authorized to give his consent to such medical treatment as may be necessary. Every guardian is obliged to act in the best interests of his ward.

Case Report No. 19

Ms. A.P. was a 40-year-old woman who lived in an assisted residency because she was mentally retarded. She was sufficiently autonomous to go and do mechanical jobs in a factory. The judge declared her incapable 20 years ago and appointed an uncle as her guardian. She had a male friend in the institution. As a result of new treatment for epilepsy she suffered intestinal necrosis that required emergency surgery and a colostomy. In the post-operative period she developed different complications, starting with pneumonia treated by intravenous antibiotics. She became negative, did not want to eat and asked doctors and nurses to allow her to die, to go "to meet her mother". The psychiatrist gave anti-depressive treatment and food was injected into her by nasogastric tube which she pulled out several times a week. She also fought with nurses who had to tie her to the bed in order to replace the tube. Three months after her admission to the hospital a new infection appeared in her hips with pus collection that required new surgery. She became aggressive to doctors and nurses, cried constantly and begged them to let her die. Her guardian, an old man mentally limited and incapable of making any decision, signed authorization for the operation.

Prof. Juan Vinas,
Spain

Should the doctors proceed with the new surgery?

1. Yes. They have informed consent from the legal guardian.
2. No. The legal guardian is mentally limited and incapable of making any decision. They should apply to the court for an alternative guardian.

The guardian is required to make the same decision the patient would have made, had he been competent. Evidence of past choices and attitudes may guide the guardian. If there is no such evidence, the guardian should act in the best interests of the patient.

Treatment of minors

Every human being is subject to rights and duties from the cradle to the grave. However, although the minor is not devoid of legal competency, in view of his tender age, physical weakness and inexperience, guardians are appointed to protect his interests. Since parents are the natural guardians of their children during their minority years, parental consent is required before the children are medically treated.

Case Report No. 20

R.I. is a 10- month- old infant, who has been taken care of in the NICU because of serious neonatal asphyxia and subsequent hypoxic encephalopathy. The patient was born to a 32- year- old Pigo mother and a 35-year-old father after full term gestation. The pregnancy was unremarkable. A house midwife noticed persistent bradycardia of the baby 2 hours before the delivery, and an emergency Caesarean section was performed.. The baby, weighing 2840 g., appeared severely asphyxiated. The first physical examinations showed apnea, muscular hypotonia, general cyanosis, midriatic pupils with no light reflex, and no response to pain-stimuli, suggesting his suffering from severe brain damage. He was treated initially with brain hypothermia, but the CT, 24 hours later, disclosed massive brain edema and the auditory brainstem response (ABR) documented only the first phase wave.

The repeat CT a month later, revealed serious brain atrophy. Although further intensive care was not indicated, the parents strongly requested a neonatologist to continue the treatment. The neonatologist told a NICU resident to keep taking care of R.I. as before. Therefore, the infant has been treated with nasal milk feeding, intravenous administrations of catecholamine and diuretics, and intermittent mechanical ventilation until today.

Recently, the parents have come to accept the irreparable damage of the patient. However, they appear to be confused about whether they should request a cessation of treatment.

Prof. Yoshihiro Takeuchi,
Japan

Should the neonatologist offer medical advice?

1. No. The neonatologist should continue to treat until the parents have carefully considered the situation and reached an independent decision regarding how to proceed.
2. Yes. The neonatologist should offer advice upon which the parents can make an informed choice about withholding further medical treatment.

A child who is capable of forming his own views should have the right to express those views freely, and his views should be given weight in accordance with the age and maturity of the child.

There is of course a matter for debate in deciding at what age the minor enjoys a high enough level of competence to justify his assumption of authority and rights.

Minor' refusal to undergo treatment

The refusal of a minor to undergo treatment which will save his life presents his parents in particular and the whole of society in general with a difficult dilemma. On the one hand society is interested in respecting the sanctity of life by preserving the life of the minor, but at the same time it recognizes the right of a minor approaching independent adulthood to make decisions concerning himself and his future. Policy makers are expected to examine the minor's competence to make decisions on such issues. Is the decision the product of his free will? Does the minor comprehend the implications of the proposed treatment? Is he capable of estimating the consequences of lack of treatment? Does he understand the meaning of death? Last but not least, what are the reasons for refusing the proposed treatment? However, it is quite unnecessary to obtain a minor's consent to medical treatment if he is so young that he is not yet capable of understanding his condition.

Parents' refusal of a necessary treatment

Case Report No. 21

J.B., a 5-year-old girl, is brought to hospital by her parents with symptoms of fever and weakness. Upon further examination acute lymphocytic leukemia (ALL) is suspected, but a bone biopsy is required to confirm the diagnosis. The parents are informed of the procedure for the "bone marrow pin-prick" and give their consent. When a diagnosis of ALL is confirmed, the standard chemotherapy treatment is explained to the parents as well as the probable prolongation of life for a few years. On realizing the cost involved in this treatment and that "success" is not guaranteed, the parents are distraught and feel it is not worth continuing treatment.

Umi Modan,
Indonesia

Should the doctor honor the parents' decision?

1. Yes. The parents are the child's legal guardians and empowered to make all necessary health care decisions.
2. No. The medical team should apply to the court because they are concerned about the parents' failure to act in the best interests of the child.

Parents' refusal of a necessary treatment may amount to abuse of parental powers and shall not be binding.

Case Report No. 22

T.K. is a 12-year-old boy. He was involved in a terrible car accident which crushed both lower limbs with heavy bleeding. Apparently he was going to school when the accident happened. He was immediately rushed to a hospital. He was evaluated by an orthopaedic surgeon. The surgeon's finding included severe anaemia due to acute blood loss and much devitalized tissue. His haemoglobin was 5.6 gm %. The surgeon ordered immediate blood transfusion to save T.K.'s life. T.K.'s parents, who are Jehovah's witnesses arrive just prior to the transfusion. The parents consent to all medical treatment except the blood transfusion. T.K. is taken to the operating room. There, the anesthesiologist suggests that the blood transfusion be given in secret without knowledge of the parents.

Prof. Mengeshe A. Teshome
Ethiopia

Should the surgeon agree?

1. The surgeon should not agree. He should inform the parents that he intends to seek a court order to override their opposition and proceed with the transfusion to save T.K.'s life.
2. The surgeon should agree. He should transfuse T.K. in secret in order to protect T.K. and his parents from religious condemnation.
3. The surgeon should not agree. He should discuss his judgement regarding the medical necessity of the transfusion with the parents, but refrain from transfusing T.K. if they continue to oppose it.

Case Report No. 23

A mother from a rural area gives birth to Siamese twins, who are slightly underweight. Their heads are unattached, and they each have two hands. They are joined together from below the costal margin, and hence are sharing many organs as well as their lower extremities, with a third but rudimentary leg arising from the posterior aspect. The doctors know that an operation must be carried out for the babies to have a chance but the procedure itself is rather complicated. Furthermore, the doctors cannot determine the extent to which the vital organs are being shared. They know if an operation is to be carried out, only one of the twins will survive, and it will be a very costly procedure. The twins must be kept in the special care ward until they are fit to be operated on. They cannot survive outside the hospital. The parents are certain that someone has bewitched the twins. The parents do not care whether the twins will survive, and they just want to go home.

Dr. J. Mfutso Bengo
Rachel Mlotha
Malawi

How should the doctor respond?

1. The doctor should direct the parents to take the twins home.
2. The doctor should operate on the twins without the consent of the parents.
3. The doctor should seek a court order to authorize the surgery without parental consent.

Informed consent for euthanasia

Euthanasia is derived from the Greek words eu, meaning well and thanatos, meaning death. The word indicates the willful putting to death of persons suffering from incurable disease with the intent to prevent suffering.

Active and passive euthanasia can be distinguished as the difference between an act and an omission. Active euthanasia is defined as the taking of positive action to end the life of a terminally ill patient. Passive euthanasia is the failure to take positive action to prolong the life of an incurable patient.

Competent patients with terminal illnesses have the right to refuse life-prolonging treatment. Rejection of life-support measures by a dying patient involves the patient's right of privacy, which includes physical integrity and autonomy in deciding when death should occur.

However, although euthanasia is based upon the patient's right to die, it also includes the right to kill, as it involves the demand that another person induces death.

By the Hippocratic Oath, all doctors promise to "give no deadly medicine to anyone if asked, nor suggest any such counsel".

The major difficulty in recognizing a right to decline treatment in the case of the terminally ill is deciding who may make the decision for incompetent patients.

There is also the problem of deciding what extent of physician assistance is acceptable.

Case Report No. 24

A 63-year-old known hypertensive woman was admitted to the medical intensive care unit having collapsed at home after complaining of a severe headache and vomiting. The Glasgow coma scale (GCS) was assessed as 3 and she was placed on mechanical ventilation. A diagnosis of acute sub-arachnoid haemorrhage was confirmed on a CT scan.

There was a consultation with the neurosurgeon who advised continued ventilation for 48 hours and then reassessment of her neurological status .On day 5 post admission there was spontaneous eye opening and a cerebral angiogram was done. An anterior communicating artery aneurysm was shown and surgery was scheduled for the next operating list, 4 days later. On the day before surgery the patient registered a temperature and became more drowsy. Further bleeding was suspected and the surgery was postponed. A tracheostomy and gastrostomy were done.

The aneurysm was clipped uneventfully on day 13 after admission. The relatives were informed by the surgeon of the likely prolonged neurological recovery and the possibility of an irreversible neurologic deficit.

The postoperative course was complicated by transient diabetes insipidus, an infected gastrostomy site, pneumonia and hydrocephalus were observed on a repeat CT scan. Oliguria developed and there was hypoproteinemia with generalized edema, anaemia (requiring transfusions) and a persistent pyrexia. A tracheal aspirate grew a pseudomonas and a urine culture coliforms resistant to all antibiotics tested.

On day 65 after admission there is no improvement in neurological status with a GCS of 6 (E=4; V=1;; M=1). She cannot be weaned from the ventilator, her pyrexia persists and there has been some improvement in renal function. Her husband, who visits her regularly,explains that his wife would have wanted no

further medical treatment in these circumstances, and requests that life support be discontinued.

Prof. E.R. Walrond
J. Ramesh MS Fais,
West Indies

Should treatment be continued?

1. No, because the husband, acting as the wife's surrogate, has authorized withdrawal of life support.
2. Yes, because the patient has never expressed her views with respect to discontinuation of life support in this type of situation.

Case Report No. 25

A 34-year-old man is hospitalized in your ward for the final phase of a testicular tumor with numerous metastases (seminal cancer). Palliative care is expected. He was submitted in the previous months to numerous treatments that failed (castration, ganglion resection, chemotherapy). On his admittance, his clinical status is precarious. There is severe deterioration because of the general metastases.

His wife (who benefited from an artificial insemination before chemotherapy) and his parents are there and look after him.

After somatic treatment and psychological support, you start a morphine protocol with a strong dose that seems insufficient to relieve the patient from his pain; nevertheless, this treatment seems enough to create some impairment of consciousness.

The nurse informs you about the formal wish of the patient and of his family to put an end to his sufferings by increasing the morphine. You are already close to lethal doses. You come back to your ward to see this patient and meet his relatives.

Thierry W. Faict,
Yves Dousset
Roger Letonturier ,
Stephanie Neel
France

What does the doctor do?

1. He explains that he cannot increase the morphine dosage because it will kill the patient.
2. He explains that he will slowly increase the morphine dosage in order to relieve the patient's pain, even though it may result in the patient's death.
3. He explains that he will wait until the patient regains consciousness, ask for his consent to increase the morphine dosage, and then administer a lethal amount.
4. He explains that he can reduce the dose slightly to improve consciousness and competence, and then ask for patient's informed consent to an increase of the morphine dose to a double effect.

Informed consent for organ donation

Authorization for donation of body parts should come from the patient. When prospective donors are minors or persons who are mentally retarded or ill, judges usually apply substituted judgement and best-interest theories.

Case Report No. 26

Two brothers, M.S. and T.S., accompanied by their mother, present themselves in the out-patient service of the department for transplantation surgery. T.S. wants to donate a kidney to M.S.

25-year-old M.S. has been on dialysis for two years now, due to chronic pyelonephritis. He does not experience major physical trouble on dialysis. In fact, he can even drive his own car home most of the time. However, his career potential is rather limited as he cannot work for three half-days per week. He has just finished his training as a carpenter and is now looking for a job, so far without success. The response has frequently been: "If you could work full time, we'd take you on the spot." Although he is on the waiting list for a kidney, no organ is likely to be available soon, given his rare blood group. M.S. starts to get frustrated by this situation, particularly as he intends to marry his girlfriend this year and start a family. At one of his last check-ups, M.S.'s nephrologist told him about the possibility of a living organ donation. The long term results of such a transplantation are excellent, said the physician, and he would most likely be able to work full-time and live a normal life. With this prospect in mind, M.S. talks to his family. The possibility that T.S., his elder brother, might be a candidate is raised. T.S. is almost deaf and moderately mentally retarded. He has attended a special school from second grade on and currently lives at home. He is, however, not under guardianship. As he has not learned the standard sign language, only his mother is able to fully

understand what he wants to communicate. She says it is his urgent wish to donate. He keeps signaling her he wants to help and that he wants to give a kidney to his brother. M.S. is willing to accept his brother's offer and asks the transplant surgeon to accept him for further examination.

Prof. Nikola Biller-Andorno
Germany

How should the surgeon proceed?

1. The surgeon should proceed with the examination because T.S. has made his strong view known through his mother; he wants to help his brother.
2. The surgeon should not proceed with the examination while discussing the following issues:
   a. Is T.S. competent?
   b. What are the risks and benefits to T.S.?
   c. Are there other potential donors in the family?
   d. What are the opinions of the mother and other family members on this issue?
3. The surgeon should not proceed with the examination because he has no basis upon which to conclude that T.S. is competent to consent, that the benefits of organ donation will outweigh the risks for T.S., and that there are no other potential donors in the family.

Informed consent for clinical research and studies

A distinction between therapeutic and non-therapeutic types of research refers to whether or not the research may be of direct benefit to the individual concerned , and of whether only future patients can expect benefits from an increase in knowledge.

The informed consent doctrine has been elaborated primarily for medical treatment. In the context of a clinical trial it obtains additional importance. Informed consent is a prerequisite and mandatory for participation in scientific research.

Similarly, the informed consent of a patient is needed for participation in clinical teaching.

Case Report No. 27

A 75-year-old woman visits a laboratory to fill in the forms required for body organ donations. She explains that she is alone, without family and benefited a few years ago from a blood donation that saved her life.

She says that she would like to be helpful to medical research by donating her body and organs. It is likely that her body will be used during anatomy lessons for young medical students.

Thierry W. Faict,
Yves Dousset,
Roger Letonturier,
Stephanie Neel -
France

Should the woman be informed of this and all other relevant facts?

1. No. She gave an implied consent by volunteering to donate her body for medical research.
2. Yes. She is entitled to be informed of material facts, including the likely use of her body. Although her body was a voluntary donation, she could not have known how it would be used. The information would enable her to decide if hers is "a gift outright" or not.

HIV tests

In general, distinction may be drawn between cases where tests are to be carried out for the benefit of the patient and instances where tests are performed for other purposes. The patient's consent to the HIV test should be obtained, and he should know exactly what he is consenting to.

If tests are to be carried out for the benefit of third parties, the patient has to be informed about the fact that the blood sample taken from him will be tested for AIDS.

Case Report No. 28

Mrs.W.L., a 29-year-old married woman, and her husband are patients at your clinic. W.L. visits the clinic looking very sad. She lost her two children in the last three years, all before the age of three years, due to diarrhoea and severe febrile illnesses. During the illness of her last baby, the doctor attending her baby counseled that the baby and she undergo an HIV test. The test came out positive and was confirmed on further testing. She believes that her husband infected her. She has heard rumors that he was a womanizer, but he denied this when she confronted him.

Now, the husband, a prosperous businessman, is continuously insisting that she conceive again so that he may gain recognition among his friends and the child born can inherit his wealth. He further warns that if this does not happen within a year, he will divorce her and marry a younger woman. He is not aware of her HIV status nor does he know his. The wife is afraid of revealing her HIV status for fear of a divorce.

Dr. J.Mfutso Bengo,
Sekeleghe Amos Kayuni(MBBS IV)
Malawi

What action should the doctor take with regard to the husband?

1. The doctor should tell Mrs. W.L. to discuss her condition with her husband. If she refuses to do so, the doctor may inform the husband directly.
2. The doctor should tell Mrs. W.L. to discuss her condition with her husband. If she refuses to do so, the doctor must inform the husband directly.

If the patient indicates that no AIDS test may be carried out on his blood, his request must be respected.

Case Report No. 29

Mrs.M.P., 39 years of age, comes to the Gynecology Department demanding abortion. She has been pregnant for two months and does not want the baby. She has had multiple, complete sexual contact with several men in recent years and consumes heroin. The doctor requests her informed consent to an HIV test but she refuses to consent.

Prof. Juan Vinas,
Spain

Should the doctor, believing that HIV is highly probable, perform the test and other pre-operative analysis without her consent?

1. No. The rule of informed consent should not be violated.
2. Yes, as the doctor has the right to protect himself and his staff.
3. Yes, as the test is beneficial to Mrs. M.P. herself.

If the test is necessary for the diagnosis or treatment of the patient, and the patient refuses the test, the doctor may refuse to undertake the treatment.

Case Report No. 30

Mr. M.T. is a 65-year-old man who is an ex-teacher on pension. He comes to the surgical Out Patients Department with a groin swelling that has been there for 6 years. There is no complication except the discomfort the patient feels when the mass comes out. The house officer diagnosed inguinal hernia and admitted the patient for elective surgery to which the patient agreed. The surgeon did pre-operative evaluation and found herpes zoaster infection scar. The surgeon wanted to test the patient for HIV antibodies because he thought his finding was an indicator of this particular infection. The surgeon asked the patient to give blood for general pre-operative work-up without informing him that the test included HIV.

Prof. Mengeshe A. Teshome
Ethiopia

Should the surgeon tell the patient that he is being tested for HIV?

1. No, because the surgeon has authority to conduct any and all tests deemed appropriate before performing surgery.
2. Yes, because the patient has the right of self-determination and should not be tested until full informed consent has been given.