

CASEBOOK ON

BENEFIT AND HARM

2

Casebook Series

**BIOETHICS
CORE
CURRICULUM**



United Nations
Educational, Scientific and
Cultural Organization

Social and Human Sciences Sector
Ethics Education Programme

BIOETHICS
CASEBOOK ON
CORE
BENEFIT AND HARM
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FOREWORD

The *Framework for Action* of the 1999 *World Conference on Science* in Budapest, under the aegis of UNESCO and the International Council for Science (ICSU), states that ethics and the responsibility of science should be an integral part of the education and training of all scientists, and that they should be encouraged to respect and adhere to basic ethical principles and responsibilities of science. During the 32nd UNESCO General Conference (2003), Member States expressed the need to initiate and support teaching programmes in ethics, not only in bioethics but in all scientific and professional education. In response to these statements, and to *The Teaching of Ethics* (2003) report by UNESCO's *World Commission on the Ethics of Scientific Knowledge and Technology* (COMEST), the Organization launched its Ethics Education Programme (EEP) in 2004 to reinforce and increase the capacities of Member States in the area of ethics education.

A dimension of the EEP is the establishment of the *Advisory Expert Committee on the Teaching of Ethics*, composed of members of COMEST and UNESCO's International Bioethics Committee (IBC), as well as representatives of the UNESCO Chairs in Bioethics, the Academy of Sciences for the Developing World (TWAS) and the World Medical Association (WMA). The first task of this ad-hoc committee was to develop the *UNESCO Bioethics Core Curriculum*, launched in 2008, which sets out to introduce the bioethical principles of the 2005 *Universal Declaration on Bioethics and Human Rights* (hereafter referred to as the Declaration) to university students.

The Declaration embodies a set of bioethical principles that has been agreed upon by the Member States of UNESCO after an intense elaboration and consultation process involving independent and governmental experts from all regions of the world. This set of bioethical principles provides a common global platform by which bioethics can be introduced and strengthened within each Member State, and UNESCO is mandated to promote, disseminate and elaborate these principles for practical purposes.

Since bioethics teaching has not been introduced in many universities in many countries, the UNESCO Bioethics Core Curriculum can provide an incentive to start introducing such teaching. Furthermore, its content does not impose a particular model or specific view of bioethics, but articulates ethical principles that are shared by scientific experts, policy-makers and health professionals from various countries with different cultural, historical and religious backgrounds.

The casebook you have before you is part of the *UNESCO Bioethics Core Curriculum Casebook Series*, launched by UNESCO in 2011, and designed to be used with the core curriculum, or as stand-alone study material for one of the bioethical principles in the Declaration. The casebook series is intended to reinforce the introduction of ethics teaching, especially in developing countries. In order to encourage wide dissemination and usage of this series, the casebooks are freely available in hardcopy as well as for electronic download through the UNESCO website (www.unesco.org).

On behalf of UNESCO, I would like to express our gratitude to the *Advisory Expert Committee on the Teaching of Ethics*, especially to Professor Amnon Carmi, the Coordinator of the working group, as well as to the other members of the working group responsible for this casebook, for their commitment and voluntary assistance to the work of UNESCO in the strengthening of ethics education around the world.

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INTRODUCTION

Article 4 of the *Universal Declaration on Bioethics and Human Rights* (2005) on ‘Benefit and Harm’, emphasizes that in applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefit to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized. Article 4 follows from Article 3 that refers to ‘Human Dignity and Human Rights’. Both articles treat dignity as an inherent property of being human. Recognition of the central place of dignity in human rights and ethics takes into account the obligations of the human species for other human beings.

In ancient medical ethics, an important moral principle was: *above all do no harm*. This notion continues to be used as an important ethical principle in contemporary health care. Absolute protection against all harms is not attainable, even in ideal circumstances. On the other hand, in the case of ordinary medical practice, beneficence is the first moral percept of professional ethics. Benefits are of several kinds: advancing the interests of a patient or a society, or producing new knowledge of value to future patients. Risks are the estimates or the probabilities or possibilities of injuring a patient or a society. Harms may be physical, emotional or financial. The moral sanction for tolerating exposure to risks is the intended benefit that follows from the treatment.

In health care practice it is important to evaluate benefits and harm. Treatment choices have to be made among patients: an assessment has to be made between risk of harms and potential benefits. This is particularly important for resource allocation, when time and material resources are scarce. Conformity to the obligations of Article 4 requires a combination of prudential judgments and technical competence. Estimates of probability and projections of the expected impact on the individual patient and the society of a proposed treatment must be made.

This casebook, as part of the *UNESCO Bioethics Core Curriculum Casebook Series*, is intended to reinforce the teaching of the ethical principle

of ‘Benefit and Harm’ as enshrined in the *Universal Declaration on Bioethics and Human Rights* (2005), taking into account the intricacies of recent scientific developments and the safeguards which are required in the form of educational innovations which will insemminate ethical values into the students, in spite of this materialistic age in which we live.

This casebook contains 33 case studies. Every case has been dealt with by a high judicial instance and offers a description of the type of ethical problems involved. Each case is followed by general guidelines for the edification of students who must themselves, under the guidance of their lecturer, study the case, discuss the possible solutions and reject what they consider unsuitable before reaching their own decision. The aim of the project is to produce a tool and a platform for active participation of the students in the decision-making process.

Combined efforts of teaching, educating and training by the use of such a methodology may plant and root in the hearts of the students ethical values that should guide any physician providing patient care.

At this point, I would like to thank my colleagues of the working group for this casebook for their perseverance and commitment to this project, as well as the editorial assistants from the International Center for Health, Law and Ethics at the University of Haifa and from the UNESCO Secretariat.

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CASE STUDY 1

Treatment without consent – Refusing medical treatment

Miss EB is a 28-year-old woman. Since birth she has been afflicted with severe cerebral palsy and is a quadriplegic. She is now a patient at a public hospital.

Miss EB's physical handicaps of palsy and quadriplegia have progressed to the point where she is completely bedridden. Except for the ability to move a few fingers of one hand and to make some slight head and facial movements, she is immobile. She is physically helpless and wholly unable to care for herself. She is entirely dependent upon others for all of her needs; these include feeding, washing, cleaning, toileting, turning, and helping her with elimination and other bodily functions. She cannot stand or sit upright in a wheelchair. She lies flat in bed and must do so for the rest of her life. She also suffers from degenerative and severely crippling arthritis. She is in continual pain. She receives automatic injections with periodic doses of morphine through a tube permanently attached to her chest. These injections relieve some, but not all, of her physical pain and discomfort.

She is intelligent and very mentally competent. To eat, she must be spoon fed. Because of her previously announced resolve to starve herself, the medical staff fears her weight loss may reach a life-threatening level. Her weight seems to hover between 65 and 70 pounds. Accordingly, they inserted a feeding tube against her will.

Miss EB is not terminally ill; she is anticipated to live another 15 to 20 years.

→ Should the medical staff force-feed Miss EB?

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.

NO Miss EB has a fundamental right to refuse medical treatment. Therefore, the medical staff must not force-feed her.

YES Food is a basic need and not a medical treatment. By not force-feeding Miss EB, the medical staff will be helping her commit suicide, which is counter to the interest of the public. In balancing Miss EB's right to refuse treatment against the damage caused to public policy by her suicide, the medical staff must act to prevent suicide. Miss EB is trying to starve herself to death and the State will not be a party to suicide.

Notes about the case study

Court decision

This case came before the country's Court of Appeal who concluded that if Miss EB is force-fed, she faces 15 to 20 years of a painful existence, endurable only by constant administration of morphine. Her condition is irreversible. There is no cure for her palsy or her arthritis. Miss EB would have to be fed, cleaned, turned, bedded, and toileted by others for 15 to 20 years. Although she is alert, bright, sensitive, perhaps even brave and feisty, she must lie immobile, unable to exist except through physical acts of others. Her mind and spirit may be free to take great flights but she is imprisoned and must lay physically helpless, subject to the ignominy, embarrassment, humiliation, and dehumanizing aspects created by her helplessness.

It is not the policy of the State (of the Court of Appeal deliberating this case) that all and every life must be preserved against the will of the sufferer. It is incongruous, if not monstrous, for medical practitioners to

assert their right to preserve a life that someone else must live, or more accurately, endure for ‘15 to 20 years’. The Court of Appeal cannot conceive that the policy of the State is to inflict such an ordeal upon anyone.

As a consequence of her changed condition, it is clear that she has now merely resigned herself to accept an earlier death, if necessary, rather than live by feedings forced upon her by means of a nasogastric tube. Her decision to allow nature to take its course is not the same as deciding to commit suicide with real parties aiding and abetting.

Miss EB’s right to refuse medical treatment, even of the life-sustaining variety, entitles her to the immediate removal of the nasogastric tube that was involuntarily inserted into her body. The hospital and medical staff are still free to carry out a substantial, if not the greater part of their duty, i.e. of trying to alleviate Miss EB’s pain and suffering.

The right to die is an integral part of our right to control our own destinies so long as the rights of others are not affected. That right should include the ability to enlist assistance from others, including the medical profession, in making death as painless and quick as possible.

Discussion Refusing medical treatment

The first issue we have to deal with is whether provision of nutrition and hydration is a clinical procedure. By common standards it is of course not. A parent who provides food and liquids to his/her offspring is not engaging in clinical treatment even though these are necessary to sustain the health of the child. However, matters become rather blurred when dependent patients who cannot feed themselves are forced to be nourished and hydrated. In simple cases, a third party, a nurse or relative or nurse auxiliary could spoon-feed the patient. This is more like a parent feeding a child than an application of a clinical procedure. On some occasions, because of the labor-intensive nature of this mode of feeding, tube-feeding and hydration is adopted. These involve clinical procedures such as inserting lines and tubes which are invasive. Insofar as this is so, they are clinical interventions – or at least their initiation is a clinical intervention. But these are more commonly adopted as a convenience and not as a clinical necessity.

Where patients have lost the swallowing reflex, such interventions are a requirement if the patient is to have his or her life sustained. Insofar as this is so, nutrition and hydration become a necessary medical treatment.

However, once they become an indicated treatment, they are to be regarded as any other clinical treatment. They are to be offered to patients who have a right to refuse them. As surely as people might refuse potential life-saving interventions such as chemotherapy or radiotherapy in cancer cases, or blood transfusions in liver surgery, or heart transplants or any other life-saving intervention, so they might refuse nutrition and hydration. The right to refuse any medical treatment or intervention is an elementary right of every individual. When treatment is offered, the patient must assess the benefits of treatment and the consequences of non-treatment from the perspective of his/her own religious beliefs, opinions and life experience.

The right to die is not a new idea in medical ethics. For centuries, doctors have been provided with the guidance *‘Thou shalt not strive officiously to keep alive.’* The problem is that the use of extraordinary means employed in striving officiously today becomes a standard procedure tomorrow. Once this occurs, doctors may feel obliged to treat without regard to the patient’s wishes. Since providing some of these treatments may be considered essential to life, it is easy to start down the slippery slope and neglect the rights of patients. In this case, while not providing nutrition and hydration does result in allowing the patient to die, this is not tantamount to killing the patient as she has refused permission for the doctor to rescue her.

Even where there is no such refusal, the non-provision of nutrition and hydration might be justified on the basis that the alternative is an inevitable, imminent, and prolonged painful death. Extending dying in such cases, as would be achieved by the application of artificial nutrition and hydration, is not considered to be equivalent to saving the patient’s life and, as such, is not clinically indicated. However, it must be noted that in some countries, not providing hydration to patients, even if they are at the end of their life, is forbidden.

It should be emphasized that even in cases where the patient’s choice to refuse treatment has extreme consequences (such as death) the patient still cannot force the doctor to act contradictory to the doctor’s own conscience and beliefs.

CASE STUDY 2

Treatment without consent – Imposed medical treatment despite patient’s refusal

B joined the Jehovah’s Witnesses in 1963. Since then, B has firmly refused blood transfusions under any circumstances because it is prohibited by her religious beliefs.

On 17 June 1992, B was admitted to Hospital F and on 6 July 1992, she was informed that she had a malignant liver angioma. Because the doctor told her that it was impossible to perform surgery without a blood transfusion, B left the hospital on 11 July 1992 in search of a medical institution where she would be able to be operated on without receiving a blood transfusion.

E worked as a doctor at Hospital D where he was known for his expertise in performing surgery without blood transfusions. B was admitted to Hospital D and on 16 September 1992, she was operated on to remove a hepatic tumor. B signed a hold-harmless statement stating her refusal to receive a blood transfusion and indicating she would not hold the doctors or other hospital employees liable for any damage arising from not providing a blood transfusion.

Hospital D’s policy for performing surgery on patients who belonged to the Jehovah’s Witnesses stated that the hospital would respect the patient’s intention to refuse blood transfusions and would refrain from providing blood transfusions to whatever extent possible. However, in the event that there was no means of saving a patient’s life other than through a blood transfusion, the hospital would give the patient a blood transfusion irrespective of whether the patient or his/her family had approved such treatment.

During the operation to remove B’s tumor, the amount of bleeding reached about 2,245 milliliters. The doctors determined that it was

highly likely they would be unable to save B's life without a blood transfusion, so a blood transfusion was given to B during the surgery.

After the surgery, B was discharged from the hospital. She died four years later on 13 August 1997.

→ Should the doctors have given B the blood transfusion during the surgery?

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.

NO B's desire not to receive a blood transfusion was very clear. By giving her the transfusion, the doctors violated her religious beliefs and her right to determine the course of her treatment.

YES If the blood transfusion had not been given, B would have died. It is doctor E's duty to save her life. In balancing B's right to determine the course of treatment against the possibility of being saved by a blood transfusion, it is obvious that being alive is more beneficial for her.

Notes about the case study

Court decision

This case came before the Supreme Court of the country. The court concluded that when a patient has expressed the intention of refusing to receive any medical treatment involving blood transfusion because it is against his/her religious beliefs, the right to make such a decision must be respected as part of the patient's personal rights. The facts are that B's firm intention was to refuse a blood transfusion regardless of the consequences due to her religious beliefs, and that she went to Hospital D with the hope of having surgery to remove a liver tumor without receiving a blood transfusion. Given these facts, it is reason-

able to think that the doctors, in determining that they could not rule out the possibility that there would be no way to save B's life during the operation other than through a blood transfusion, should have explained to B that Hospital D's policy was to give a blood transfusion under such circumstances. B could then have decided whether or not to be operated on by the doctors at Hospital D.

Due to their failure to explain, the doctors should be deemed as having deprived B of the right to decide whether or not to have the surgery and they should be held responsible for having violated B's personal rights in this respect and therefore liable to compensate B for the mental distress she suffered due to said violation.

Discussion Imposed medical treatment despite patient's refusal

A person has a right to refuse treatment that is medically indicated, if the individual judges the treatment to be harmful based on their overall worldview and values. This is one embodiment of the individual's right to decide what is done to their body, and therefore caregivers and general society must respect this assessment of potential benefits and harms in light of the patient's personal outlook, rather than paternalistically dismissing the individual's judgment.

Medicine cannot determine by scientific means, what is a successful outcome of a treatment, without reference to the views of the patient. For some patients there are states worse than death. Though the surgery was successful in extending the life of this patient, it does not follow that it achieved a successful outcome in the patient's eyes even though she wanted to survive. For her, the damage caused by the procedure might well be thought to be both irreparable and fundamental. Not all lives are equally valuable to people and she might well now feel condemned to live a life not worth living.

Therefore, in some countries, we must often refrain from giving medical care, even when it can improve a person's condition, because we respect the person's right to refuse treatment. However, even when treatment has been explicitly refused, it would be ethical to override the patient's wishes in extreme cases where the immediate and

significant benefits of medical intervention, and the threat of severe injury, indicate that the patient would greatly benefit from treatment. If possible, this should be explained to the patient beforehand.

It should be emphasized that this should be a rare occurrence, applying only in extreme situations. The decision to act in these cases should be made in consultation with an ethics committee or other impartial body, whose members can express various perspectives.

CASE STUDY 3

Treatment without consent – Treatment despite patient’s opinion

Mr. HS’s hand was badly injured in a motor-car accident and he was taken to the local hospital.

Dr. M, a physician and surgeon duly qualified to practice, was called to the hospital. Mr. HS, being a stranger and unacquainted with Dr. M, asked the doctor to fix his hand but not to cut it off as he wanted to have it looked after in his home city.

Later on, in the operating room, Mr. HS repeated his request that he did not want his hand cut off. The doctor, being more concerned with relieving the patient’s suffering, replied that he would be governed by the conditions found when the anesthetic was administered. Mr. HS said nothing.

As the hand was covered by an old piece of cloth and it was necessary to administer an anesthetic before doing anything, the doctor was not yet in a position to advise what should be done. Upon examination, the doctor decided an operation was necessary to amputate the hand. Dr. M said the wounds indicated that surgery was necessary, as the condition of the hand was such that delay would mean blood poisoning, putting the patient’s life at risk. The two other attending physicians supported this decision.

→ Should Dr. M have amputated Mr. HS’s hand under these circumstances?

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. M had to amputate Mr. HS's hand. If the surgeon had not amputated the hand, the patient would have been at risk of blood poisoning, which could threaten his life. In any case, the hand could not be saved.

NO Amputation is an irreversible treatment. Mr. HS was very clear in his instructions when he asked explicitly not to cut off his hand.

Notes about the case study

Court decision

This case came before the Supreme Court of the state. The court concluded that the operation had been necessary and was performed in a highly satisfactory manner. Indeed, there was no suggestion otherwise. The damage and loss and the cost of an artificial hand are the results of the accident and not the unauthorized operation. However, Mr. HS is entitled to damages because of the trespass to his person.

Mr. HS is an immigrant without much education in the local language and probably of not more than average intelligence. When he did not reply or make any objections to the doctor's statement, Dr. M took it for granted that he would be governed by conditions as he found them and that he had full power to go ahead and perform an operation if he found it necessary. On the other hand, Mr. HS probably did not understand what the doctor meant; if he had, he would most likely have refused the operation.

Under these circumstances, Dr. M should have provided a more detailed explanation and tried to get Mr. HS to consent to an operation, if necessary.

Discussion Treatment despite patient's opinion

The patient has a right to refuse medical treatment offered to him/her as part of one's basic autonomy to decide what is done to one's body. With that, such decisions must, as far as possible, be based on clear and current information; the patient's agreement or refusal should be sincere and clear since the patient must live with the outcome of the treatment. However, to make an informed decision the patient must be aware of the possible outcome(s) of the treatment, or the consequences of refusing treatment. For this reason, the claim of the surgeon that the patient's hand was not uncovered for inspection before the patient had been anaesthetized is not acceptable as an excuse.

Furthermore, the surgeon heard the patient refusing to go through the amputation and so the least he should have done was to check his hand before anaesthetizing. The doctor simply said that he would do whatever he thought necessary when he got around to examining the man's hand. If he had first observed the nature of the injury and then sought consent from the patient with the benefit of the information gained from the examination, the patient's view might have been different and there would have been no problem with carrying out the procedure. When such a procedure is possible, disabling a patient from giving an informed consent to a surgical intervention, in this case by anaesthetizing him, is bad practice.

Even if the surgeon upon inspection is persuaded that an amputation is necessary to save the life of a patient, he should not override the refusal of the patient to undergo the procedure as long as that patient is competent to refuse. In cases of incompetence, the surgeon should err on the side of life. In cases of a disagreement between the view of the surgeon and the view of the patient as to what is an acceptable treatment, the views of the patient should prevail.

The temptation faced by a doctor in these situations is to conclude that because the refusal of the patient is so contrary to what seems to be so obviously in his interest, the patient must be incompetent. This is to place the patient in a Catch 22 position where if he consents to the procedure he gets it and if he refuses he gets it anyway.

CASE STUDY 4

Treatment without consent – Treatment through a third party

A 43-year-old patient has had schizophrenia since he was 20. At the moment, he has a chronic form of schizophrenia, marked by chronic deficits, dominant negative symptoms, and the constant presence of delusions.

The patient's condition is known from reports by the patient's mother because he refuses to consult a doctor. He has never been aggressive to others and has never met the criteria for compulsory hospitalization.

Recently, his mother has noticed a worsening in his condition, including intensified positive symptoms that impair his social functioning. She asked for compulsory treatment. The psychiatrist, acting in the best interest of the patient, prescribed risperidone in liquid form to be added to his soup by the mother.

This treatment has had a good result. The patient began walking his dog for the first time in six years.

→ **Should the psychiatrist have been allowed to collaborate with the mother by assisting her in administering medication to the patient without his knowledge?**

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 benefit to the patient's health justified this action.

NO It is the patient, and only the patient, who should be treated by the psychiatrist and the psychiatrist has sole operative responsibility. The doctor is not permitted to cooperate in depriving the patient of his independence.

Notes about the case study

Court decision

In principle, a patient shall be entitled to have access to the information concerning his health. Treating a patient without his knowledge is not considered usually to be ethical. Moreover, prescribing a medication to a patient without examining her or him is not acceptable and implies legal responsibility in case of serious side effects.

Treatment without examination and full knowledge of the patient is already a wrong premise, providing it without the patient having given the benefit to know of his condition and to be an active participant in his treatment violates his autonomy, no matter how well-meaning the doctor and the patient's mother are. The utilitarian argument that improvement has taken place does not modify the fact that deontologically speaking, deceitfulness is never a good base for action.

However, there might be a number of situations where this solution can be considered: if the patient is not competent, or if the patient lives for example in a very remote area and no doctor is around, as it happens in many regions in developing countries. The right of the patient to be informed may be subject to restrictions in order to prevent serious harm to his health. However, this privilege is open to great abuse, and psychiatrists should make use of it only in extreme circumstances.

Discussion Treatment through a third party

The patient's human dignity and rights are expressed in several ways, among them: confidentiality of medical information, inclusion of the patient in decisions regarding their medical care, and others.

Sometimes a patient is not mentally competent, and is unable to take part in their therapeutic process. In these situations we can explore the possibility of caring for the patient through another person. It should be remembered that even if an intermediary is used to implement therapy, treatment decisions must consider only the patient and his/her welfare alone. We must check more carefully that the specified treatment truly benefits the patient, and that no injury may be caused to him/her.

In this case, we are not told very much about the patient's condition nor if he is dangerous to others or himself. Neither are we told whether his withdrawn state is resulting in serious harm to him. This information is important in considering whether the patient should be subject to compulsory treatment as the conditions applied in most mental health legislation provide that in such circumstances sanctions are indicated in order to protect the patient and/or others.

In the above kind of situation, of course consent is specifically not required. Therefore the competence of the patient to decide for himself is not an issue, though normally it is clear that people in such states are not able to make reasonable decisions about treatment.

The fact that the doctor didn't assess the patient first hand shows us that he assumed that the man's condition was not such that his competence to ask for or to decline treatment was impaired. If he thought that the patient was incompetent, the doctor should at least have sought permission to compulsorily examine the patient. If he thought the patient was competent, the doctor's action amounted to providing compulsory treatment in that he conspired to make sure that the patient was involuntarily taking the medication. This is not simply bad practice in that a competent patient is treated without consent; it is actually against the law. The involvement of the mother in the treatment process, by means of the doctor, was unprofessional.

CASE STUDY 5

Treatment of minors

In a certain country, the incidence of metabolic conditions such as phenylketonuria is among the highest in the world. Therefore, a voluntary test known as the PKU test is performed on newborns.

The PKU test ascertains whether a child, even one that appears healthy and well, is suffering from certain biochemical or metabolic disorders. It is a blood test in which blood is extracted from the infant by puncturing the skin, usually at the heel.

The PKU test identifies four metabolic conditions – phenylketonuria, galactosaemia, homocystinuria and maple syrup urine disease – and one endocrine condition, hypothyroidism. All these conditions are treatable, though once damage has been caused by the condition, it is usually irreversible. Hence, it is medically considered of great importance to diagnose the condition as early as possible.

H and C are the parents of five healthy children. Their first four children were tested, with negative results. P, their fifth child, is a newborn baby. Shortly after his birth, PKU testing was offered to P as part of a public health screening program. P's parents refused to allow the test to be carried out because they strongly objected in principle to blood being drawn by invasive measures such as those used in collecting blood for PKU testing. They have no objections to a PKU test being carried out, as long as non-invasive measures are used.

The risk to the child from puncturing the heel to draw blood is minimal. Even if the test is carried out badly and incorrectly, the worst that could occur is that the little lancet used to puncture the skin might introduce infection to the skin or, at the very worst, to the bone. There is no indication that this has ever happened since the test was first adopted in this country in 1966.

There was no particular reason why P should be tested for PKU. There was no relevant family history. There were no circumstances which made it particularly appropriate to test P.

→ Should the PKU test be performed on P despite his parents' refusal?

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 PKU test is only a blood test. It is not invasive and does not cause any serious damage even if carried out incorrectly. The incidence of metabolic diseases in this country is among the highest in the world. Therefore, it is beneficial to the public interest to reduce these statistics by early diagnosis.

NO There are no indications that P might be suffering from any metabolic condition. His siblings were already tested and found healthy. No matter how minimal the harm might be, this harm does not justify performing the test. Therefore P's parents' wish to prevent their son any unnecessary harm must be respected.

Notes about the case study

Court decision

This case came before the Supreme Court of the country. The court concluded that in assessing the balance to be achieved in this case, the fact that there is no family history is important, indicating the possibility is quite remote that the child has the illness being tested for. His siblings were tested and found to be negative. Testing would be relevant if the child had a real or significant chance of having the disease being screened. Based upon the facts of this case, this is not likely. No decision should rest solely upon statistics, and every child is cherished under the Constitution in accordance with its principles.

Nevertheless, perhaps statistics can illustrate how a difficult case has the potential to make bad law. The court added that ordering the test to be carried out would be violating the separation of powers principle by, in effect, making a test compulsory which, under present circumstances, is voluntary and which the State never sought to make compulsory by introducing appropriate legislation.

Discussion Treatment of minors

Action taken by the various countries on the international level to advance health issues is manifested in a number of situations. One of these situations occurs when the national health institutes identify an irregular health problem in their country, or in parts of it, and in order to deal with it or to prevent it, certain action is taken by that country.

Usually, one consideration to be taken into account regarding treatment or tests is the refusal of the patient to have the treatment. We must respect a person's wish not to be examined, even if this involves a routine examination, and assess what harm can be caused to the patient if he/she does not undergo the examination, as opposed to the benefits he/she will receive if he/she does. We must examine this issue from the patient's point of view: his/her beliefs regarding the harm and potential benefits must be given preference over the public's viewpoint, when balancing the test's benefits against the harm which could be caused to the patient.

Nevertheless, the country acts on the general level and is not able to take into account all of the considerations relating to each individual. When we are speaking about children, the main assumption is that the parents, above all other people, have the best interests of their child at heart and, consequently, that they are the proper persons to make a *best interest* judgment on behalf of their child who is not capable of making such judgments.

Moreover, on some occasions a parent's view of what is in the best interest of the child will differ from that of the clinician. If in these situations we take the view that the clinician is best qualified to know what is in the child's best interest, then we undermine the assumption of the

right of parents to give consent for their child. Seeking such consent then becomes a relatively meaningless activity; for if they consent the child will be treated and if they refuse the child will be treated anyway, as the clinician can assume that their right to refuse is abrogated by their poor choice on behalf of their child.

However, the most important thing in every decision or act is to take into consideration the protection of the well being of the child and the avoidance of serious harm. That is why in some circumstances this assumption is questionable and most States withdraw the right of parents to decide for their children, to some extent or completely – in the latter case, the parents have no right to decide for their child.

There is another issue which arises from the execution of the neonatal blood test which has caused a good deal of discussion. This discussion has intensified as genetic tests for so many conditions have become possible and available. The major feature of these issues is the storage and use of the blood sample. There are many questions that have to be answered, such as: To what purposes, if any, can the blood spot be used without the consent of the patient? Clinical research? Population screening? Criminal investigations? Insurance applications? Paternity inquiries? Should the patient have the right to opt for the destruction of the spot at the age of maturity?

CASE STUDY 6

Treatment of minors – The patient's wellbeing

X is a 32-year-old woman. In 1990 a man with whom she had had a long relationship informed her that he was HIV-positive. She then was tested for HIV, and the result was positive.

After having discovered she was HIV-positive, X embarked upon a regime involving alternative medicine therapy, a strict diet, and healthy living. From her point of view, after eight or nine years this regime has left her very fit and well, although she remains HIV-positive. In 1997, she met a man, whom she has not married. He was tested for HIV and was found negative. They then tried to conceive a child.

Their daughter was born on 8 April 1999. They chose not to go through the normal channels of registering at a hospital for pre- and post-natal care because they were concerned that conventional medical treatment would force them to adopt what they both considered to be an unacceptable approach to the birth. The mother gave birth to her baby at home with the assistance of a midwife. She had a natural birth, and the child was born entirely fit and healthy.

Because there was a 25 to 30 per cent chance that this child would be born HIV-positive, doctors felt the child should be tested. If the child was HIV-positive, further treatment would be highly desirable. Moreover, the mother has been breastfeeding the baby since birth. If the baby is HIV-positive, such breastfeeding obviously can continue. If, however, the child is negative, the medical experts unanimously felt that the mother ought not to breastfeed. Despite the request of the medical staff, the parents refused to have the child tested for HIV.

→ Should the child be tested for HIV despite her parents' refusal?

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 Usually the parents have the right to determine the course of treatment for their child. In this case, however, the parents' wish to deny their child the HIV test is not beneficial to the child and even might be harmful if the diagnosis is not made. Therefore, under these circumstances the HIV test should be performed.

NO The parents have a right to determine the course of treatment for their child, and no one should force them to act differently.

YES HIV is a contagious virus that might lead to dreadful disease. It is in the interest of the public to know who carries this virus. Therefore the baby must be tested.

Notes about the case study

Court decision

This case came before the Supreme Court who concluded that if the child's medical condition is unknown, the child is clearly at risk. The degree to which this medical test constitutes an invasion of the child is slight. The degree to which taking the child to the hospital for a medical test constitutes an imposition for the family would, for most people, be relatively slight. In this case, the parents have magnified this into a major issue because they do not accept any of the premises upon which the tests are based. Nevertheless, the welfare of the child is paramount.

This child has the right to have sensible and responsible people find out whether or not she is HIV-positive, either as a result of being born to a HIV-positive mother or as a result of breastfeeding. According to the doctors, there is a 25 percent chance that she is HIV-positive

because of being born to a HIV-positive mother. The risk is increased because of breastfeeding.

If the child is not tested, there are two possibilities. One is that she will be given aggressive treatment that would be unnecessary if she is not HIV-positive because the doctors, who are aware of her situation and do not know whether or not she is HIV-positive, feel they must treat her. The other is that she will not receive adequate treatment because her parents failed to inform the doctor of her situation and the child is in fact seriously ill. Either way, this child has her own rights, which can only be granted at this stage by testing her to determine the state of her health.

Discussion The patient's wellbeing

In every medical procedure, the patient's wellbeing must be of primary concern. When this relates to minors, infants, and adults who are unable to give their consent to the treatment or to refuse it, an evaluation must be made as to whether the decision indeed serves the objective wellbeing of the patient; in cases where it has been proven that the person who makes the decision is not acting objectively in accordance with the patient's real interest, then only the good of the patient must be taken into account and he/she must be given the most effective intervention possible.

Indeed, in the normal nature of events, procedures contrary to the guardian's instructions are not carried out, as it is assumed that the guardian acts in the patient's best interest. The harm which might be caused to the patient by not providing the treatment, as opposed to the benefit which he/she would gain from the proposed treatment, must be taken into account.

The right of parents to consent on behalf of their children for therapeutic or preventative clinical procedures is a conditional right. It is based on the presumption that the parents, above all other people, have the best interest of their child at heart and, consequently, that they are the proper persons to make a *best interest* judgment on behalf of their child who is not capable of making such judgments.

On some occasions, a parent's view of what is in the best interest of the child will differ from that of the clinician. If in these situations we take the view that the clinician is best qualified to know what is in the child's best interest, then we undermine the assumption of the right of parents to give consent for their child. Seeking such consent then becomes a relatively meaningless activity for if they consent, the child will be treated and if they refuse, the child will be treated anyway, as the clinician can assume that their right to refuse is abrogated by their poor choice on behalf of their child.

In circumstances where the patient (minor) can be exposed to serious diseases, it is ethical to take precautions, such as simple tests, in order to reduce this possibility and to give him/her the necessary treatment.

CASE STUDY 7

Treatment of minors – Medical treatment of teenagers

In December 1980, a government body issued guidelines on family planning services for young people. These guidelines stated or implied that, at least in certain cases which were described as ‘exceptional’, a doctor could lawfully prescribe contraception for a girl under the age of 16 without her parents’ consent.

The guidelines further stated that a doctor should proceed on the assumption that advice and treatment on contraception should not be given to a girl under the age of 16 without parental consent, and that the doctor should try to persuade the girl to involve her parents in the matter. Nevertheless, the principle of confidentiality between doctor and patient applies to girls under 16 seeking contraceptives. Therefore, in exceptional cases a doctor can prescribe contraceptives without consulting the girl’s parents or obtaining their consent if, in the doctor’s clinical judgment, prescribing contraceptives is desirable.

Mrs. G, the mother of five daughters under the age of 16, objected to the guidelines and sought assurance from her local area health authority that her daughters would not be given advice or treatment regarding contraception without her prior knowledge and consent while they were under the age of 16.

→ **Can a doctor ever, under any circumstances, lawfully give contraceptive advice or treatment to a girl under the age of 16 without her parents’ consent?**

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 If doctors do not do so, young people will lack guidance for safe sexual behavior. This lack of guidance will only increase the number of cases of unwanted pregnancies and sexual diseases that could have been prevented by contraceptives. Therefore, the benefit to those young people and to society is greater than the need to obtain parental consent or to inform the parents. Furthermore, if parents are informed, young people will not seek guidance from medical practitioners.

NO As long as a child is a minor, every treatment must also be consented to by the child's parents.

Notes about the case study

Court decision

This case came before the Court of the country. The court held that in view of the reality that children become increasingly independent as they grow older and that parental authority dwindles correspondingly, the law does not recognize any rule of absolute parental authority until a fixed age. Instead, parental rights are recognized by law only as long as they are needed for the protection of the child. Such rights give way to the child's right to make his/her own decisions when he/she achieves sufficient understanding and intelligence to be capable of making up his/her own mind. Accordingly, a girl under the age of 16 does not, merely by reason of her age, lack legal capacity to consent to contraceptive advice and treatment by a doctor.

The court added that once the rule of the parents' absolute authority over minor children is abandoned, the solution to the problem in this appeal can no longer be found by referring to rigid parental rights at any particular age. The solution depends on a judgment of what is best for the welfare of the particular child. Nobody doubts that in the overwhelming majority of cases parents are the best judges of their child's welfare. Undoubtedly, any important medical treatment of a child under 16 would normally only be carried out with the parents' approval.

That is why it would and should be ‘most unusual’ for a doctor to advise a child on contraceptive matters without the knowledge and consent of the parents. Mrs. G must go further if she is to obtain the first declaration she seeks. She has to justify a parent’s absolute right of veto. Still, there may be circumstances in which a doctor is a better judge of medical advice and treatment conducive to a girl’s welfare than are her parents.

It is well acknowledged that children of both sexes are often reluctant to confide in their parents about sexual matters. The government body guidelines under consideration show that abandoning the principle of confidentiality for contraceptive advice to girls under the age of 16 might cause some of them not to seek professional advice at all, with the consequence of exposing them to ‘the immediate risks of pregnancy and of sexually-transmitted diseases’. No doubt these risks could be avoided if the patient were to abstain from sexual intercourse, and one of the doctor’s responsibilities is to decide whether a particular patient can reasonably be expected to act on advice to abstain. In a significant number of cases, such abstinence cannot reasonably be expected.

Discussion Medical treatment of teenagers

The judgment in the case produced a concept which has been called ‘Gillick competence’ in the Bioethics literature. The creation of this concept draws attention to the use of the term ‘child’ in the case description. While it is true that I am my mother’s child so long as I live, this does not entail that she has the right to make decisions for me so long as she lives in the way that a parent is entitled to make decisions for her infants. The crucial question is when does a child in the second sense become a child in the first sense only? Often the age of 16 years (although in some countries it could be the age of 17 or 18) has been used in medical law as the crucial chronological age. However, the Gillick judgment points out that, in the view of the judges, it occurs when the child reaches maturity. There is no arbitrary chronological age when this happens, even though in law generally there is a chronological age of maturity when children are expected to be treated as responsible agents for misdeeds they perform.

The word competence is often used in healthcare contexts to denote the ability of persons to make their own decisions. This is dependent on their having sufficient maturity to understand information provided to them and the emotional maturity to both perceive and live with the consequences of their decisions. For some young people this will occur much earlier than for others.

The Gillick judgment suggests that it is unethical to undermine the dignity of mature human beings by insisting that others make decisions for them when they are capable of making those decisions for themselves, however well intentioned the third parties might be.

In various declarations regarding children, there is more and more recognition of the need to involve teens in their own medical care. This trend is expressed as well in the laws of several countries.

As teenagers mature, and are more able to reach decisions on their own, we need to include them more in the decision-making process, and eventually allow the teen patients to make considered decisions about their medical treatment based on their own world view.

According to this judgment, it is the responsibility of the doctor to make a judgment about the maturity of the young patient in the above sense before deciding whether the parent/s should be involved in decision making for them. Sometimes lip service is paid to this concept, in that young people are consulted about medical matters concerning them, but more stringent criteria of competence are applied to them than are applied to adult persons. This disrespects the rights of the young person, and physicians must pay attention not to treat youngsters in such a way.

Consequential considerations with ethical import also informed the judgment. There had been great concern about the large number of teenage pregnancies. These often resulted in terminations, which occurred outside the health service with serious deleterious consequences for the young women involved, or in very young single mothers having responsibility for children, without having the emotional maturity to parent those children.

Education in sexual matters including advice about contraception was thought to be a major means of reducing these phenomena. As many young people are reluctant to discuss such matters with their parents, the intention of the authorities was to make them more willing to receive advice from their doctors. This ethical gain was thought to outweigh the apparent encroachment on the rights of parents to make decisions on medical consultation for their children.

CASE STUDY 8

Treatment of minors

Mrs. R resides together with her husband and their five children. Her house is connected to the public piped water supply and no alternative water supply is available for drinking and cooking.

Mrs. R protested that fluorine is being added to the water supply. She was aware that fluorine in the public water supply is intended to protect against dental caries in children. With regard to protecting her children against dental caries, she said she believed in the importance of sound nutrition, and that she and her husband attend to their children's diet, which consists only of healthy food.

Mrs. R objected to putting fluorine into the public water supply because she considered it an infringement of her parental rights. She believed it was her job to see to her children's upbringing and to decide what they should eat and drink as well as all other aspects of their upbringing. Her objection as an individual was that it was an infringement of her own personal integrity. She added that putting fluorine in the public water supply was tantamount to medication in the case of children, and while it was not intended to do anything for adults, she objected to it because she felt it might cause harm to herself. She also added that large doses of fluoride might cause illness, and that fluoride is found naturally as a trace element in most foods, e.g. vegetables, meat, cereals, fruit, fish, tea, etc. There are over 130 types of foods which contain fluorides.

→ Should the State continue providing fluoride through the water supply?

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.

NO Fluoride is also provided in 130 types of foods. Providing fluoride through the water supply is not beneficial because it cannot be controlled, and as indicated, large doses of fluoride might be harmful. Therefore, it is not beneficial to add fluoride to the water supply.

YES Fluoride has been proven beneficial to the public, especially for children. In children's teeth, fluoride combines with the nascent enamel and has the effect of delaying, and to a certain degree preventing, the onset of dental caries, one of the most prevalent of human ills.

Notes about the case study

Court decision

This case came before the Supreme Court who concluded that in modern life, the provision of public water supplies in cities is necessarily a community obligation, and if this water lacks some wholesome elements, it is the right, if not the obligation, of the community to correct this deficiency when this can be done without harming or endangering the public. The desirability of adding deficient elements to food or water or removing potentially harmful elements has been widely recognized and frequently exercised. Water is chlorinated, salt is iodized, vitamins are added to margarine, and flour is fortified whenever these measures are shown to be beneficial.

Dental caries disease is not new. It has adversely affected generation after generation and will continue to do so if measures are not taken. This constitutes the type of danger from which the State has not merely the right, but also the duty to protect its citizens. To deal with the problem, the government has chosen to fluoridate the public water supply. Mrs. R has failed to refute the evidence indicating that not only is this most effective method, but it is indeed the only effective method. The method undoubtedly does result in minimal interference with the constitution of the body, but such interference is not one which in

any way impairs the functions of the body or, to any extent discernible by the ordinary person, its appearance. The Court is left with no doubt that the fluoridation of water to the extent proposed in the area where Mrs. R resides will not involve physical changes which in any way affect either the wholeness or the soundness of the body of the person concerned. The ingestion of fluoridated water cannot, therefore, be said to constitute an infringement of or a failure to respect the bodily integrity of Mrs. R or her children.

Discussion Treatment of minors

Countries act on several levels in order to ensure the safety and health of their citizens. This activity is part of the country's responsibility towards its citizens and it is also stated in Article 14 of the *Universal Declaration of Bioethics and Human Rights*:

The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.

In a democratic and pluralistic society, the individual is entitled to protection and the ability to realize his wishes. However, on occasion, the benefit to the public is much greater than the harm to the individual in such cases, we will prefer to continue to act in such a way as benefits the public as a whole and endeavor to find a personal solution for the individual, even if this involves a certain price for the individual (for example: if he is obliged to pay money from his own pocket for this solution). We must keep in mind that the individual and the harm caused to him must be taken into account, but on the other hand, the considerable benefit of the government's intervention for the public as a whole, must not be negated.

Moreover, there are compromises to be made to individual freedoms in order to make communal life possible. These restrictions are actually the means of enabling people to live in a free society. For example, road traffic regulations restrict the freedoms of people to drive wherever they would like on the road. But as a result, chaos is avoided and it becomes possible for everyone to drive on the road.

Fluoridation of public water supplies is an example for such compromise, but there are peculiar ethical differences between this public health intervention and others. A good way to come to grips with these issues is to compare some of these other acceptable cases with the water case:

- 1 Building safety regulations. Though freedoms are restricted here to guarantee health and safety, no physical harms are visited directly on those covered by the regulations. The claim is that those drinking the public water might be harmed. This is an important distinction; however, there can be other negative consequences for those affected in the building case, too. They might be inconvenienced, will probably have to pay more for their houses or for their alteration, and so on. Similar inconveniences and expense would be encountered by Mrs. R in avoiding the use of public water by her family.
- 2 The control of infectious diseases model. Given that dental caries constitute the most common health problem in the world with major health consequences for many millions of people, compulsory loss of individual freedoms seems to be an acceptable compromise. The difference between this and the water case, however, is that the freedoms restricted in the infectious disease case are those of the person who constitutes the threat to the health of the public and not those of the beneficiaries of the intervention. Mrs. R constitutes no such threat in herself.
- 3 The whooping cough vaccination programs designed to protect the health of all members of a population depend on a sufficiently large proportion of the child population being vaccinated to produce herd immunity to the very threatening disease. Many of those vaccinated would not have contracted the disease anyway. In that sense, they have been subject to an unnecessary health intervention which carries a small risk of serious damage. This is seen as a worthwhile restriction on their freedom. Here the intervention carries a measurable risk and appears to be more like the water case. However the major difference is that individual parents are free to opt out of the program. So long as those opting out are relatively small in number the herd immunity is not compromised. Mrs. R could be such a one if this was the program under scrutiny. However in the water case there is no possibility of opting out of having public water containing fluoride in her house.

CASE STUDY 9

Treatment of minors – Cosmetic surgery on a teen minor

S is a 17-year-old boy with a condition known as bilateral gynecomastia, or enlarged breast tissue. To avoid great embarrassment and the suffering caused by ridicule from his peers, S never swam, never went to the beach, and never engaged in any activities that might expose his chest to view.

Gym days at school were particularly difficult for S. Although he eventually lost a significant amount of weight and went down eight clothing sizes, S's gynecomastia was not dispelled. S thus continued to avoid situations where his condition would be apparent to others. Moreover, although he was accepted for admission to an out-of-state university, he decided not to attend as he did not want to live in a dormitory where he anticipated being subjected to ridicule.

Dr. G, S's pediatrician, recommended surgery to eliminate S's 'deformity' and its consequent emotional pain. According to Dr. G, the procedure was medically necessary.

→ Should S undergo the cosmetic surgery?

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.

NO S is still a minor, and he should not undergo any surgical procedure that is not medically necessary. His difficulties in dealing with his deformity can be treated by mental health treatments.

YES The surgery is for S's benefit. Not only will it improve his appearance, but will offer him the possibility of functioning as a typical adolescent.

Notes about the case study

Court decision

This case came before the Civil Court of the district where S's father sought reimbursement from the defendant health insurer for a surgical procedure performed on S to remove enlarged breast tissue. The court noted that although the mastectomy was primarily intended to improve S's appearance, such an improvement was not an end in itself. Rather, it was a means to an end to enable S to function as a normal adolescent.

Analytically, the determination of whether the surgery was elective and cosmetic depends on the dimensions of any 'functional defect' which resulted from S's anomaly. S's impairment took the form of a fear of any situation that would lead to exposing his chest to others. Due to his fear, S avoided many activities associated with normal adolescence. While many adolescents avoid activities due to emotional turmoil resulting from existing or imagined abnormalities, S's gynaecomastia was an objective, tangible, and unusual source of turmoil, more akin to a clubfoot or cleft palate than to a large nose, heavy acne, or diminutive breasts on an adolescent female. These latter conditions, while objective and tangible are relatively common and often lead to elective and cosmetic treatments.

The psychological health of an adolescent plays a significant role in determining the dimensions of the adolescent's reaction to a perceived anomaly. Thus, there may be instances where the anomaly is minor and the adolescent's reaction, for psychological reasons, is major and irrational. In such cases, psychological treatment may be indicated rather than surgery. S's anomaly, by contrast, was not minor, and his reaction to it was rational, if not entirely appropriate; there was apparently no psychological reason for S's emotional impairment. Indeed, one of the

defendant's physicians recognized that it was 'certainly reasonable' to believe that S suffered from 'emotional distress' due to his condition.

For these reasons, the defendant had failed to sustain its burden of proving by a preponderance of the evidence that the mastectomy was either elective or cosmetic. Rather, the surgery constituted a treatment that was medically necessary to eliminate S's anomaly and impaired functioning.

Discussion Cosmetic surgery on a teen minor

In general, cosmetic surgery's purpose is to improve a person's appearance, rather than to save their life. However, improvement of one's appearance can noticeably improve one's quality of life, and benefit one emotionally.

In the case of cosmetic surgery on a minor, we must examine carefully if the procedure will benefit the child or adolescent. At times people, including minors, feel repulsed by their physical appearance, and cosmetic procedures can benefit them greatly, especially if the potential damage and risk of injury are not great.

The patient in this case is 17 years old and there is little doubt that he is mature enough to understand the procedures which are being offered to him and to weigh the consequences of such a treatment. The views of the patient are extremely important in this case. (There is no description of the consultation with him or of his role in the decision to proceed with the mastectomy; however, it is difficult to believe that it was performed against his wishes).

When dealing with a teenaged minor, we should engage the patient and try to understand the importance he/she assigns to the condition, according to his/her values and feelings. If a minor is old enough to be aware of their condition, and desires the procedure because the condition intrudes on his/her daily life, and prevents him/her from sharing activities and experiences with peers it would be ethical to perform the cosmetic procedure.

CASE STUDY 10

Selective treatment

B was 24 weeks and three days pregnant with twins when she discovered that the twins had ‘twin-twin transfusion’ syndrome. In layman’s terms, the twins share the same placenta, blood is transfused from one to the other, and one fetus has more fluid in the embryonic membrane than the other. One twin has polyhydramnios syndrome, i.e., too much amniotic fluid inside the membrane enveloping the fetus, while the other, described as a ‘stuck’-twin, has severe oligohydramnios, i.e., the presence of less than the normal amount of amniotic fluid.

Dr. F explained that the literature shows that when one such twin dies, there is a 30% to 70% chance of perinatal death of the co-twin. However, when feticide is performed successfully, no co-twin fetal deaths have been reported. Therefore, Dr. F recommended selective feticide of the stuck twin. If the condition of the ‘stuck’-twin were to deteriorate, any delay in carrying out the operation could increase the chances of perinatal death of the co-twin up to 70%.

Dr. F said that if left untreated, the chances of perinatal mortality, i.e., death occurring shortly before or after birth, are nearly 100%. The stark fact was that the chances that the ‘stuck’-twin would die were higher than the chances the fetus would be born alive, and there was nothing the doctor could do to improve the situation. There was a slight chance of the ‘stuck’-twin being born alive, though with severe physical and mental handicaps.

It should be noted that according to local law, abortion is a criminal offense except in the case of a medically terminated pregnancy sanctioned by two medical practitioners in good faith and for the purpose of saving the life of the woman. This is not the case here.

→ Should the doctors perform selective feticide of the 'stuck'-twin to ensure the safe birth of the co-twin?

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 If selective feticide is not performed, the chances that both twins will die are high. Therefore, the doctors must try to save one of them.

NO Abortion is not allowed in this case. Furthermore, the medical staff should not make the decision of which life is worth living or not. Since the 'stuck'-twin has a chance to live, even if a poor chance, the medical staff should give it that chance.

Notes about the case study

Court decision

This case came before the Court of the country. The court concluded that the likelihood is that, on balance, the chance of death is higher than the chance the fetus will be born alive. Unless the abortion is carried out, the chance of death of the co-twin is about 30% to 70%, whereas there is no reported medical evidence of fetal death of the co-twin if feticide is performed successfully.

If the babies are delivered now, the chance of mortality goes up to 90%. If nothing is done, when the mother goes into labor and again at delivery, the chance of fetal mortality is also 90%.

B and her husband agreed to the recommended operation. It is in the best interests of the parents and the co-twin that the operation be performed as quickly as possible.

Dealing with fetuses brings up the question of their status. Some people do not regard the fetus as a person whereas others do. For the former group it might be perfectly ethical to proceed with the selective termination, because the fetus is not a 'person' and has no dignity. For those who do regard the fetus as a person, we can say that by not doing the procedure, we are undermining the strong-fetus' right to live in dignity, for it will almost surely bring about his death. The other fetus cannot claim that right since he will, most probably, die either before labor or shortly thereafter.

The ability to live a normal life is an option only for the strong-fetus, but this option is threatened as long as the 'stuck'-fetus is with him. Moreover, withholding the procedure will cause death to both or will, much less likely, bring them both living with a poor quality of life. Either we deny the strong-fetus' right to live with dignity or the 'stuck'-fetus' right to live at all. It is a question of who's right is greater. Since the stronger twin stands to lose the weightier and statistically probable right, the decision to commit feticide, and ensure the 'stuck'-twin's death, is justified. In other words, the comparison of potential harm and benefit for each twin clearly justifies this discrimination.

Another distinction we have to deal with is the distinction between killing and letting die. While some see the difference between the two, some do not. People who do not see any difference between the two will disapprove of the termination of one fetus. However, people who believe there is a difference between them will approve the feticide, in the sense that the physician is merely letting the stuck-fetus die.

CASE STUDY 11

Selective treatment

J and M are 1-month-old conjoined twins. Each has her own brain, heart, lungs and other vital organs, as well as arms and legs. They are joined at the lower abdomen.

Even taking the surgical complexities into account, the twins can be separated but the operation will kill the weaker twin. M's lungs and heart are not sufficiently strong to oxygenate her blood and pump it through her body. Had she been born a singleton, she would not have been viable. Resuscitation would have been abandoned, and she would have died shortly after her birth. She is alive only because a common artery enables her sister, who is stronger, to pump life-sustaining oxygenated blood for both of them.

Separation would require clamping and then severing that common artery. Within minutes of so doing, M will die. Yet if the operation does not take place, both twins will die within three to six months, or perhaps a little longer, because J's heart will eventually fail.

The parents cannot bring themselves to consent to the operation. In their eyes, the twins are equal, and they cannot agree to kill one, even to save the other. As devout Roman Catholics they sincerely believe that it is God's will that their children are afflicted as they are, and they must be left in God's hands.

The doctors are convinced they can carry out the operation, which will give J a worthwhile life. In general terms, J will live a normal or fairly normal life; contrary to M, her life expectancy is normal.

→ Should the hospital separate the twins with the knowledge that the operation will cause Mary's death?

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 hospital should perform the operation because if the twins are not separated, they both will die within a few months. However, if the operation takes place, J will enjoy a normal life. Therefore, the benefit that J may gain from the separation justifies the harm that will certainly be caused to M, even if that harm is M's death.

NO It is neither ethical nor moral to perform an operation when the result is the certain death of another patient. It is not the hospital's right or authority to determine what life can be taken and what life preserved.

Notes about the case study

Court decision

The above mentioned case was heard at the Court of Appeals of the country. The court concluded that the operation would give J the prospect of a relatively normal life. The operation will shorten M's life, but in any case, she is doomed to die. J has a full claim to the dignity of independence, which is her entitlement as a human being. M is 'designated for death' because her capacity to live her life is fatally compromised, regardless of whether the procedure is performed. J's prospects for a full life are counterbalanced by the acceleration of certain death for M. The balance weighs heavily in J's favor.

It is impossible to ignore the manner in which each child is individually able to exercise her right to life. M may have a right to life, but she has little right to be alive. She is alive because, and only because, to put

it bluntly, though nonetheless accurately, she is sucking the lifeblood out of J. She will survive only so long as J survives. J will not survive long because her constitution will not be able to cope. M's parasitic life will be the cause of J's ceasing to live.

It is in the best interest of the twins to give the chance of life to the child whose actual bodily condition is capable of using this chance to her advantage, even if it must be at the cost of sacrificing the life which is so abnormally supported. In balancing the interests of M against those of J, and J's interests against those of M, the least detrimental choice is to permit the operation to be performed.

In this case, the purpose of the operation would be to separate the twins in order to give J reasonably good prospects for a long and relatively normal life. M's death would not be the purpose of the operation, although it would be an inevitable consequence. The operation would give her, even in death, bodily integrity as a human being. She would die not because she was intentionally killed, but because her own body could not sustain her life.

The obligation to act on behalf of two parties, when benefiting one of them is harming the other, presents one of the most difficult ethical dilemmas, and the physician must weigh the harm against the benefit. In cases of conjoint twins, we can express the dilemma as follows: Refusing to separate the twins undermines J's right to live in dignity, for it will bring about her premature death. M cannot claim the right to live in dignity beyond the death of J. J does not need to claim the right to be enabled to live as long as M, for in that sense her life is not threatened. To live after M's death is a possibility for her, but it is one which is threatened as long as she is conjoined with her sister. Thus, she does have a right to claim that life. It is impossible to satisfy the rights of both twins to live the lives which are possible for them. Thus, one of those rights has to be foregone. Choosing to forgo separating the twins denies J's right. Separating them denies M's right. It is therefore a question of deciding which right can be considered greater. Clearly J stands to lose the more weighty right, and the decision to separate the twins can be properly justified whereas non-intervention cannot.

It is the total dependence of M on J which enables this discrimination. If the children had been born separately to different parents and one had a poorer chance of survival than the other, it would not be morally acceptable to choose between them as persons being worthy of treatment to extend their respective lives.

Discussion Selective treatment

This case brings to focus some of the important and notable principles in Bioethics: The first is the Doctrine of Double Effect. Here, an intervention intended to benefit also has unfortunate well-known side effects. As achieving these side-effects is not the purpose of the intervention, the element of benefit justifies the intervention. (This doctrine is usually applied to end of life treatments such as the administration of diomorphine to terminal cancer sufferers to relieve agonies with the possible consequence of suppression of respiration and foreshortening of life).

Its application to this case is of course complicated by the fact that two patients are involved with the benefit of one set against the demise of the other. Nevertheless, the issue of the proper intention of the intervention, to save J's life, even with the knowledge of the inevitable side-effect of denying M the continued support of J and thus hastening her death, has some purchase. The alternative, of course, fails to save either of the lives.

Another issue is the discussion of the distinction between killing and letting die. Whilst some claim that there is no such distinction, others claim that there is a difference in many situations. The latter group would see M's death as imminent in any case, noting that removing her sister's life support would allow her to die while allowing J to live. If the distinction between killing and letting die is denied, then not intervening will have the effect of killing J by allowing her to die unnecessarily.

CASE STUDY 12

Selective treatment

K is a 29-year-old woman. She suffers from a rare congenital disorder known as partial trisomy 8. This disorder has resulted in a mild intellectual disability, developmental delays, and certain physical characteristics unique to partial trisomy 8.

Because of her intellectual disability, K does not understand abstract thinking, the value of money, or the consequences of her actions. She has little or no fear of anyone, and no concept of danger. She becomes frustrated when people try to support her, and is prone to become angry and distressed. She is vulnerable to exploitation by others due to her mental slowness and trusting nature.

K lives in a supportive living arrangement at a boarding hostel with 40 other people. Since April 1991, K has received regular contraceptive injections. However, she discontinued the injections in 2001, and she is not willing to reinstate them due to her desire to conceive. Consequently, K became pregnant, and is now in her 14th week.

K accepts her pregnancy and maintains it is a ‘dream come true.’ She stresses that she is unwilling to agree to terminate the pregnancy or to give the baby up for adoption. She also claims that she will continue having babies if this baby is taken from her.

Dr. S, the psychiatrist, says K will have great difficulty looking after and properly caring for a baby, particularly if the baby suffers from the same genetic disorder as she does. He believes she will have no major psychological problems in going through a pregnancy, provided she lives in a supportive environment. However, in his opinion she will not be able to look after her baby after it is born.

An abortion would also cause major stress for K. However, Dr. S believes that the risk of harm to K resulting from terminating the

pregnancy is much less than the harm that might result if the child were born and then separated from her.

► Is abortion and sterilization the proper solution in K's case?

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.

NO Abortion and sterilization might be beneficial to K's family, the medical staff and society at large, but it might cause harm to K's desires and her wish to become a mother. The pregnancy will cause no harm to K. Therefore there is no reason to deprive her of the right to become a mother or to prevent the fetus from being born.

NO Sterilization is irreversible and therefore cannot be the least extreme solution. There must be another less drastic solution.

YES As Dr. S indicated, the risk of harm to K resulting from termination of pregnancy would be much less than the harm that might result if the child were to be born and then separated from her. To prevent this dilemma from recurring, sterilization must be carried out.

Notes about the case study

Court decision

This case came before the High Court of the country. This was an appeal to the decision of the Family Court, which had ruled it was in K's best interest that the pregnancy be terminated, and that termination was the least restrictive intervention possible considering the degree of K's incapacity. With respect to sterilization, the judge noted that K had been unwilling to cooperate with contraceptive injections. He also

noted it would be undesirable to subject K to further litigation were she to become pregnant again in the future, and that sterilization was the least restrictive intervention possible under the circumstances.

The High Court concluded that in the case of sterilization of a woman, the decision should take the following into consideration: the woman's understanding and preferences when they are known; the degree of impairment; the prospects of any improvement in her condition due to medical advances or the passage of time; whether conception is likely; the harm that will befall her if she is not sterilized, and if she is; the existence of alternatives for preventing conception, and whether they have been exhausted or eliminated; whether it is necessary to act now; her ability to care for a child; and whether the proponents of sterilization are acting in good faith and in her best interests rather than their own interests or for the convenience of the public. The High Court remitted the case to the Family Court for rehearing.

Discussion Selective treatment

The major issues in this case concern the rights of people with disabilities on the one hand and the assessment of competence on the other. The assumption made throughout the situation is that K is not competent to make a decision about the termination of her pregnancy. We are told that she does not understand abstract thinking, although no examples are given. Also, we are told K does not understand the consequences of her actions.

It is clear that K understands the consequences of having sexual intercourse without contraceptives – which is why she does not wish to use contraceptives. In addition, most new parents have little idea of many of the consequences of having children, but they are not subjected to a compulsory course in these matters before they are allowed to become parents. Moreover, she understands the idea of adoption, which she resolutely refuses to accept for her child. She is also capable of planning her next moves if her child is taken from her.

Given all of this, it seems that the major reason for the proposal to terminate the pregnancy is to stop K from becoming a mother for the

sake of her child. But K is already enabled to live in a hostel environment with support. Parenting might well be possible with support: also, people with major physical disabilities certainly have this opportunity. If it turns out, as is by no means certain, that K does not turn out to be a good mother, even with support, then there are social provisions to protect the welfare of the child. This is true of all people who turn out to be extremely bad parents. In these cases, the child's interests are seen to trump the interests of the parents.

This situation is even more critical since we are dealing with an irreversible medical procedure. When an option is being considered to execute a procedure like this, which may have significant consequences on the patient's life, the reasons and the aims for carrying out such a procedure must be carefully considered; an in-depth examination should clarify whether the good of the patient and not that of the family, as well as medical or other considerations, have been taken into account.

Furthermore, one of our goals, as a society, is to integrate people with disabilities into what might be considered normal life. The disability movement constantly makes the point that a person with disabilities is not a disabled person. From this point of view, we should do whatever we can in order to help people with disabilities to live a normal life. This attitude arises from the principle of dignity, which gives every human being the right to make decisions according to their beliefs.

CASE STUDY 13

Selective treatment

M, a 31-year-old man, suffers from an intellectual disability. His IQ is about 35, and he cannot cope in any environment without a great deal of assistance. He is not able to speak, although he can utter a few garbled words. Recently, M was transferred from the hospital to home care.

M constantly vomits his food and regurgitates it into his mouth. As a consequence, many of his teeth have rotted from stomach acids, his throat and esophagus are chronically inflamed, and he weighs only around 45 kilograms, 20 kilograms below the normal weight for his height. Above all, the greatest concern is that his blood chemistry has become irregular to the point that he needs rehydration and adjustment of his iron balance. His vomiting is threatening his life. X-rays and gastroscopy indicate there is no apparent physical or anatomical reason for the vomiting or regurgitation.

M was referred to Dr. X, a behavioral analyst. In Dr. X's view, three basic types of treatment were possible: satiation, which allows a person to eat as much as he likes; differential reinforcement, in which a person is given something he likes more than he likes regurgitation and vomiting as a reward for not regurgitating or vomiting; and aversion stimulus, in which punishments are imposed for regurgitation and vomiting. The first two methods, satiation and differential reinforcement, failed in M's case and his vomiting returned to its previous state. Further assessments were carried out, but they all failed.

Then, Dr. X recommended treating M's regurgitation and vomiting through the use of electric shock as an aversive stimulus 'as a last resort and only if necessary'. Note that the proposed type of electric shock bears no similarity to psychiatric electro-convulsive therapy, which involves passing an electric current through the brain. In M's case, an electrode connected by wires to a device would be attached

to the fleshy part of one of M's forearms. The device would be activated by remote control to deliver twenty pulses over one third of a second. The pulses would be localized, and no pain would be felt anywhere else in M's body.

The proposed device would be made by a local company that manufactures electric fences and cattle prodders. The device is not yet in the developmental stage, and has yet to undergo clinical trials.

→ Should the medical staff use the proposed electric shock treatment?

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 After all possible treatments failed, electric shock is the most beneficial solution to M's medical condition. M's situation is life-threatening; therefore, any attempt to save his life should be considered.

NO The use of a controversial treatment such as electric shock not only might harm the patient, but might also affect public sentiment. Even if the treatment were useful for M, the pulses would cause him unjustified pain. Therefore, the electric shock treatment should not be an appropriate alternative to other medical measures.

NO The electric shock treatment has not yet been tested, and its side effects are not known. Unquestionably, this suggested course of treatment should be rejected.

Notes about the case study

Court decision

This case came before the District Court. The court concluded that the question of using aversion stimuli with mentally disabled people, even those suffering from a disorder of life-threatening severity, has raised considerable controversy internationally. Electric shock is the most controversial type of aversion stimulus. There is a danger that the issue will be looked at too emotionally and will be influenced by the politics of a particular viewpoint.

Because the proposed treatment is so controversial and by no means standard, the Court must be cautious and must scrutinize all aspects of the treatment with particular care.

With respect to the shock treatment in this case, the proposed device is only in the developmental stage and has not yet been tested clinically. M is not normal physically, in that his body weight is greatly below normal, and the physical effects of the treatment on him cannot be accurately forecast. It cannot be said with any certainty that the proposed treatment will succeed in modifying M's behavior.

The fact that M's behavior is life-threatening is accepted, although the evidence does not establish the immediacy of the threat. There is no suggestion that without the treatment his death might result in a matter of days or hours. The proposed intervention in M's case is serious. The risk to M's health, if the shock treatment is not authorized, must be balanced against the pain of this intervention and the other available positive interventions. It is not yet proven that the shock treatment is the least restrictive intervention possible considering M's present environment and the degree of his disability. Further positive interventions (some of which may have been tried before in hospital) are possible in the new environment in which M has now been placed. Hence, it would not be appropriate for the Court to sanction the use of electric shock therapy.

Discussion Selective treatment

The major focus of ethical problems in this case exists in issues surrounding the introduction of innovative therapies. All such therapies should be submitted to an ethical committee for consideration of the issue of consent of the patient and possible harms above all else. No promises of benefit can be made at this stage, as the intervention is experimental.

Aversion therapy by definition is unpleasant. This is because it employs means which are less pleasant to the patient than the chosen behaviors which are to be corrected. In recalcitrant cases one might expect the unpleasantness to be more significant. But how unpleasant can they become without being ethically unacceptable? The patient certainly suffers from the application of electric shocks. There is huge discussion about the acceptability of imposing such a degree of suffering on the subject. The line between acceptable treatment and torture becomes pretty narrow here. When we are dealing with psychiatric patients whose behaviors are symptoms of their illness, this kind of treatment should not fit at all.

However, one might think that in extreme cases, where all other possibilities were tried and the patient's only options are to get the innovative treatment, to die or to suffer more than he suffers now, then the treatment will be appropriate.

The research question of when the suffering involved in aversion therapy is justified by its efficacy is an interesting one. This is especially problematic as people's levels of tolerance of pain vary. However, since we do not have any data on this subject, it is difficult to imagine an ethics committee permitting the use of this therapy on psychiatric patients.

CASE STUDY 14

Selective treatment

Recently developed medical treatments

G, a 36-year-old woman, was diagnosed in October 1995 with a tumor on her left brain ventricle. She consulted Dr. JK, a neurosurgeon, who in November 1995 performed a craniotomy (open brain surgery) to remove the tumor. Subsequent tests revealed that the tumor was a neurocytoma, a cancer of the nerve cells with a benign histology.

G was referred to Dr. KTH, a radiation oncologist, for post-operative radiotherapy to eradicate any remnants of the tumor and to prevent its recurrence. Nevertheless, a MRI scan carried out by radiologist Dr. ET in February 1996 revealed a small nodule suspended from the roof of the left ventricle of her brain. Dr. ET advised a ‘wait and see’ approach as it was uncertain whether the nodule was scar tissue or a tumor. Dr. JK, however, disagreed and thought it was likely to be a tumor. Dr. JK advised G to undergo X-Knife radio-surgery treatment.

G sought a second opinion from Dr. HKP, another neurosurgeon in private practice, who likewise concluded that the nodule was a tumor. Dr. JK, Dr. KTH and Dr. HKP claimed they had discussed the risks of radio-surgery with G before she made up her mind to undergo the treatment on 31 January 1997.

In 1997, radio-surgery was a relatively new treatment in the country. It involved generating X-ray photon beams by a linear accelerator, to be delivered through a collimator in a single high dose of irradiation to the desired area of the brain. The radio-surgery, however, led to the very serious side effect of radio-necrosis, in which healthy tissue dies in the aftermath of irradiation. G eventually underwent a second craniotomy in March 1998 to remove the dead tissue and halt the radio-necrosis. The operation was successful, but the resulting disabilities were permanent. She remained crippled with severe dysphasia and right-

sided hemi-paresis. She was unable to write, and could only move in a wheelchair with assistance. She also suffered from amnesia, was prone to depression, and was afflicted with aphasia.

→ Should the physicians have treated G with X-Knife radio-surgery?

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 Every treatment has side effects and risks. In this case, the treatment did succeed and therefore was beneficial to G.

NO The treatment was harmful and left G with severe disabilities. Therefore, the physician should not have treated her with such aggressive treatment.

Notes about the case study

Court decision

This case came before the Court of Appeal of the country which dealt with the question of whether the doctors were negligent in their diagnosis, treatment, and advice. The doctors were found negligent by the trial court. The Court of Appeal allowed the doctors' appeal, finding that the doctors were not negligent in their diagnosis, treatment, or advice relating to G's case.

Discussion Recently developed medical treatments

When offering a particular course of therapy to a patient, the physician's primary and overriding criterion must be the patient's welfare. The doctor must suggest the treatment that s/he believes will most benefit the patient — and certainly not a treatment that s/he knows

a priori will damage the patient. The importance of maximizing benefit while reducing risk is expressed in Article 4 of the *Universal Declaration on Bioethics and Human Rights*:

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

However, it must be understood that medicine is not an exact science, and in many cases the effect of treatment on the patient cannot be predicted. This is especially true of new treatment modalities: Even if new methods have passed all stages of clinical trial, they still are not widespread and there is not yet enough data on all possible reactions and complications. In addition, there are well-known treatments that still have a high risk of negative outcomes. For example, even though surgery is an invasive procedure that always carries some risk, surgeons are not considered negligent each time a surgery does not have the desired result, because the effects of surgery cannot be predicted with perfect accuracy.

Therefore, it is important to involve the patient in choosing a course of therapy, because the patient will ultimately bear any consequences of treatment, as stated in Article 5 of the *Universal Declaration of 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. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

The physician behaves ethically when s/he: considers the patient's benefit in recommending a therapeutic course, indicates if a treatment is relatively new, and discusses all other available options with the patient.

CASE STUDY 15

Selective treatment

Dr. G qualified as a physician in 1974 and trained as a general practitioner. After working in a practice in a metropolitan centre that served a number of drug-addicted patients, Dr. G started his own private clinic in 1991. The clinic was described as a drug and alcohol dependency clinic.

Dr. G prescribed controlled drugs to drug-addicted patients. These drugs included injectable methadone (an opiate, used as a heroin substitute, usually prescribed in the form of an oral mixture), dexedrine (dexamphetamine sulphate, a stimulant drug and the only amphetamine available as a pharmaceutical product), various benzodiazepines, in particular rohypnol (a highly addictive benzodiazepine not available as a government funded drug), and injectable diazepam (usually prescribed in tablet form).

Some patients became dependent on drugs such as dexamphetamine, which they had not taken regularly before.

Dr. G believed that prescribing these substances was clinically appropriate for intractable and damaged addicts. In no case was harm caused to a patient, and there was no reliable evidence of significant diversion of prescribed drugs. There was clear benefit both to the patients and the public, including long-term treatment of drug addicts with 7.5% detoxification success and a low mortality rate. Patients also benefitted from being treated at a clinic and not having recourse to street drugs.

→ Should Dr. G treat his addicted patients with addictive drugs?

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 treatment was successful among Dr. G's patients, who were treated in a clinic and did not have recourse to street drugs.

NO By treating addicted patients with addictive drugs, Dr. G did not help his patients change their habits.

Notes about the case study

Court decision

This case came before the Privy Council of the country. Dr. G submitted an appeal against the Professional Conduct Committee of the General Medical Council for erasing his name from the register for irresponsible and/or inappropriate prescribing of controlled drugs. It was noted that although this was the ultimate sanction, it was not excessive, disproportionate, inappropriate, or unnecessary to the public interest.

The evidence and the conclusions of the Committee indicated a very serious state of affairs. Their Lordships were unable to accept the argument that the patients did not suffer harm. No attempt was made to stabilize the patients with oral preparations and no attempt to engage the patients other than by maintenance prescriptions. Hence, inevitable harm was caused to such patients.

Proceedings under Section 36(1) of the Medical Act are designed to ensure the protection of the public, the maintenance of public confidence in the profession, and the maintenance of appropriate standards in the medical profession. The circumstances of the present case indicate the importance of maintaining public confidence in medical practitioners working in this difficult area with particularly vulnerable patients. Their Lordships bear in mind that the Committee specifically found:

The Committee heard evidence that your policy of giving patients what they asked for may have been accompanied by social and health benefits and that it helped to shield some from impure

street drugs. They concluded however that the risks to your patients and the public as a whole far outweighed any benefits.

Discussion Treatment of drug addicts

At times, some patients in a delicate, sensitive condition cannot rationally choose the appropriate treatment for themselves. The doctor's role is to objectively diagnose their condition and to discern the proper course of treatment for them, such that both the patient and society benefit. The welfare of the patient is foremost in determining therapeutic benefit, but others affected by the illness and its treatment are also considered, as described in Article 4 of the *Universal Declaration on Bioethics and Human Rights*:

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

There are treatment modalities that seem to be damaging the patient, yet the doctor (and perhaps even the patient) perceives the treatment as beneficial and benign. When a physician believes that an unconventional therapy is appropriate, the opinion of an ethics committee should be sought. The committee can air all sides and critique the doctor's position in relation to other medical opinions. In examining the case in an objective, professional manner, the committee should consider the welfare of the patient and of the public, and reach a considered conclusion.

CASE STUDY 16

Research – Unwitting patient participation

Shortly after JM learned he had hairy-cell leukemia, he underwent treatment for the disease at the University Medical Center

Dr. G, the physician who diagnosed the disease, was aware that certain blood products and blood components were of great value in a number of commercial and scientific efforts and that access to a patient whose blood contained these substances could offer competitive, commercial, and scientific advantages.

Dr. G recommended that JM's spleen be removed, informing JM that his life was in danger and that the proposed splenectomy operation was necessary to slow down the progress of the disease. Based upon Dr. G's representations, JM signed a written consent form authorizing the splenectomy.

Prior to the operation, Dr. G and Dr. Q made a decision to obtain portions of JM'S spleen following its removal and made arrangements to take these portions to a separate research unit. These research activities were not intended to have any impact upon JM's medical care. However, neither Dr. G nor Dr. Q informed JM of their plans to conduct this research or requested his permission. JM's spleen was removed.

After the surgery, JM returned to the University Medical Center several times at Dr. G's direction. On each of these visits, Dr. G took additional samples of blood, blood serum, skin, bone marrow aspirate, and sperm.

Dr. G established a cell line from JM's T-lymphocytes. On March 20, 1984, a patent was issued for this cell line, naming Dr. G and Dr. Q as the inventors.

It is important to note that research on human cells plays a critical role in medical research. Researchers are increasingly able to isolate naturally occurring and medically useful biological substances and to produce useful quantities of such substances through genetic engineering. These efforts are beginning to bear fruit. Products developed through biotechnology to treat several dreadful diseases have already been approved for marketing.

→ **Should Dr. G, as M's physician, be involved in medical research that was not known to JM and that had no therapeutic value for JM?**

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.

NO Dr. G's interest in JM's cells may affect his professional judgment, leading him to recommend treatments that are not therapeutic to the patient. Therefore, as long as Dr. G did not obtain JM's consent to the research, he should not have conducted it.

YES Medical research should not be prohibited in such cases because progress in medicine depends upon such research studies. Nevertheless, the research must begin from the position that a physician will never harm his patient. It is highly likely that JM or any other patient would not choose to participate in such research and would seek treatment in another hospital, thus damaging medical progress from which society can potentially benefit.

Notes about the case study

Court decision

This case came before the Supreme Court of the country. The court concluded that no law prohibits a physician from conducting research in his area of practice. Progress in medicine often depends upon physicians, such as those practicing at the university hospital where JM received treatment, who conduct research at the same time as caring for their patients.

Yet a physician who treats a patient in whom he also has a research interest has potentially conflicting loyalties. This is because medical treatment decisions are made on the basis of proportionality, weighing the benefits to the patient against the risks to the patient.

A physician who adds his own research interests to this balance may be tempted to order a scientifically useful procedure or test that offers marginal, or no, benefits to the patient. The possibility that an interest extraneous to the patient's health has affected the physician's judgment is something that a reasonable patient would want to know in deciding whether to consent to a proposed course of treatment. It is material to the patient's decision and, thus, a prerequisite to informed consent.

The Court acknowledges that there are competing considerations. To require disclosure of research and economic interests may corrupt the patient's own judgment by distracting him from the requirements of his health. However, this state's law does not grant physicians unlimited discretion to decide what to disclose. Instead, it is the prerogative of the patient to determine for themselves the direction in which they believe their interests lie.

A physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment. A physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty.

Discussion Unwitting patient participation

Scientific research is of untold importance to the further progress and development of medicine. Medical research is the engine of medicine, and because of it we are able to treat diseases which a few years ago were untreatable.

However, medical research must meet ethical criteria, and a patient who joins a clinical research cohort must do so freely, with informed consent, as specified in Article 6(2) of the *Universal Declaration of Bioethics and Human Rights*:

Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice...

This consent must be based on a complete understanding of the connotations of participating in the research project, after being presented with all relevant information.

It is very important to pay attention to issues of consent with regard to the use of tissue obtained in the course of surgical treatment for any purpose other than the care of the patient whose tissue is involved.

The consent to remove the spleen from this patient did not cover its subsequent use by the surgeon for research purposes. Specifically, the production of a cell line had not been covered by the consent to remove the spleen.

In the past, clinicians used to store body parts for purposes of research and teaching without the permission of the patients (or families). However, today we consider such behavior unethical, as such, collection is regarded as an affront to the dignity of the patients and a source of considerable distress to the relatives of the patients concerned. Most Human Tissue Acts in developed countries now ban the collection or use of patient tissue for any purpose other

than that connected with the purpose for which it was removed from the patient.

It should be emphasized that researchers must ensure the patient's safety, such that the study is terminated if the experimental therapy worsens the subject's condition or does not alleviate his/her symptoms.

There is also ethical concern about the blurring of the lines between medical decisions made for the sake of the patient and medical decisions made with other objectives in mind. One might think that we should separate the research and the treatment of patients so that physicians who treat patients will not do research. On the other hand, we all understand the importance of research, and the decision to prevent clinicians from researching in their area of practice seems to be an over-reaction to this possibility. Such clinicians might be among the most able researchers given their familiarity with the field of practice. A lesser restriction, namely that they not be allowed to carry out research on tissues removed from their own patients, would serve the same purpose and avoid the loss of the research expertise of the relevant doctors.

CASE STUDY 17

Use of new medicaments or procedures – Well advised use of new drugs

The HIV/AIDS epidemic is a major public health problem in a particular country, where it has been described as ‘an incomprehensible calamity’. The epidemic has claimed millions of lives, inflicted pain and grief, caused fear and uncertainty and threatened the economy. One of the most common ways HIV is transmitted to children is from mother to child at and around the time of birth. The government has estimated that 70,000 children have been infected in this manner every year since 1998.

The Medicines Control Council has registered Drug N for use in reducing the risk of mother-to-child HIV transmission. This means that Drug N has been found suitable for this purpose, and that it is safe, of acceptable quality, and therapeutically effective.

In July 2000, the manufacturers of Drug N offered to make the drug available to the government free of charge for a period of five years, in order to reduce the risk of mother-to-child HIV transmission.

Although Drug N is known to be adequate in reducing the risk of transmitting HIV/AIDS, the government has decided to make Drug N available only at a limited number of pilot sites, two per province. The drug is also available in the private sector. The result is that although the drug has been offered to the government for free, doctors in the public sector who do not work at one of those pilot sites are unable to prescribe it to their patients.

It should be noted that Drug N is a potent drug and its potential hazards are unknown.

→ **Is the government entitled to refuse to make Drug N available to pregnant women with HIV who are treated in the public health sector and who seek to prevent or reduce the risk of transmitting HIV to their infants?**

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 government is entitled to refuse any kind of treatment whose hazards are not yet known. The treatment might cause more damage than benefit.

NO Drug N is a registered drug and is known for its adequacy in reducing and preventing the transmission of HIV/AIDS from mothers to their newborns. The drug must be made available to the public sector to reduce the transmission of the disease.

Notes about the case study

Court decision

This case came before the Constitutional Court of the country. The court ordered the government to remove the restrictions on the distribution of Drug N without delay. Drug N must be made available to reduce the risk of mother-to-child transmission of HIV at public hospitals and clinics that are not research and training sites. Indeed, the use of Drug N must be permitted and facilitated to reduce the risk of mother-to-child transmission of HIV. It must be made available for this purpose at hospitals and clinics when the attending medical practitioner, acting in consultation with the medical superintendent of the facility concerned, determines such treatment is medically indicated, including appropriate testing and counseling of the mother concerned.

The court does not underestimate the nature and extent of the problem facing the government in its fight to combat HIV/AIDS and, in

particular, to reduce the transmission of HIV from mother to child. The court also understands the need to exercise caution when dealing with a potent and relatively unknown drug. The nature of the problem however is such that it demands urgent attention. Drug N is a potentially lifesaving drug. Its safety and efficacy have been established. The operational challenges for the best possible use of Drug N on a comprehensive scale need to be assessed to reduce the risk of mother-to-child HIV transmission. Additionally, issues relevant to the safety and efficacy of and resistance to the use of Drug N need to be monitored. In the meantime, loss of life must be prevented wherever possible.

Discussion Well advised use of new drugs

National governments must protect and advance the health of their populations, as stated in Article 14 (1) of the *Universal Declaration of Bioethics and Human Rights*:

The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.

If a treatment is available for a widespread disease, use of that treatment should be encouraged in the affected regions, while taking into account the projected benefits and risks of using the medication. When the medicine involved has been tested for safety and efficacy, it can be used more widely. If the medicine is still experimental and relatively untested, its use should be more limited, and closely monitored.

In balancing the need to provide treatment that may benefit citizens with the obligation to protect them from potential harm, government must examine the projected benefits, weigh them against the potential damage and compare the likely effects of treatment vs. non-treatment.

In our case, it is not clear enough whether the drug is safe, tested and ‘registered’ or whether it is a ‘relatively unknown drug’. The restricted availability could be due to the claim that its potency and potential hazards are unknown. If so, then it should only be used where there is adequate professional expertise to monitor its use and deal with adverse events. Such a policy would be ethical.

However, it is doubtful whether such expertise would be so exactly dispersed as being available in two pilot sites in each province.

If the drug is safe, of acceptable quality and therapeutically effective, then it is difficult to think of an ethical justification for its restricted use. All licensed drugs are at risk of causing serious long term harm. There are many famous cases of the withdrawal of very widely used drugs because of their proven hazards appearing long after release. This is why all drug use needs to be monitored and adverse events reported. In this respect, Drug N is no different from all other licensed medicines.



CASE STUDY 18

Use of new medicaments or procedures – Experimental vs evidence-based medicine

RM has lung cancer. He was admitted to the local Medical Center, where he underwent extensive treatment for his cancer but the treatment was ineffectual in arresting or curing the disease. His condition has steadily deteriorated, and the medical staff can do nothing to help him. Death is inevitable.

Desperately hoping to survive, RM consulted a doctor who is engaged in cancer research and has developed a new substance known as X. This doctor believes the new substance is safe and effective in treating cancer and might be helpful to RM. He agreed to treat RM with the substance.

Two years prior to RM's request to be treated with X, a Ministry of Health committee examined the substance for purposes of human research. The committee did not authorize use of the substance on human beings due to a lack of sufficient data from laboratory and animal trials, which are required before approving the use of an experimental drug on human beings.

The committee for clinical trials also stated that it cannot be reasonably determined whether the use of this substance offers any hopes of saving lives, restoring health, or relieving suffering. Moreover, the risks in its use cannot be assessed.

Use of this substance has not been authorized, and the Director General of the Ministry of Health is not prepared to authorize it. It should be noted that RM's physicians are opposed to using this substance and are not willing to treat RM with it in the hospital or at any other venue.

→ Should the use of this substance be allowed for RM?

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 Conventional treatments have been unsuccessful, and there is no other known cure that can relieve his suffering. Therefore, he should not be deprived of the use of a drug that offers him any hope of survival, even if it is an experimental drug. Considering RM's terminal condition, the benefits of using the experimental drug are greater than the anticipated harm.

NO The substance is an experimental drug that has not been authorized for research purposes or for treating patients. Its side effects are not known; therefore, the use of the drug must be prohibited.

Notes about the case study

Court decision

This case came before the Supreme Court of the country. The court dismissed RM's request to allow him to use the experimental substance. The court determined that each year thousands of drugs that researchers believe can save lives are tested, but only a few of them are approved for human research. Animal trials that carefully assess the inherent risks compared to the anticipated benefits are required before authorizing a drug for human experimentation.

In the meantime, the disease continues to claim its victims, with many patients in RM's desperate situation, seeking approval for treatment with one experimental drug or another. Nevertheless, approving such requests might lead to a slippery slope that would undermine the Ministry of Health's authority in supervising the use of drugs and protecting even those who are deathly ill against dangerous and inefficient drugs.

Allowing the use of untested drugs might also cause harm to patients. Their eagerness and their excessive and ill-founded hopes placed in an untested drug might lead them to abandon conventional treatments that might cure or relieve their suffering.

Allowing the substance to be used might also lead to taking advantage of critically ill patients and their families, who are willing to sacrifice everything to find a cure for the patient. Nevertheless, one judge commented that if she had been free to rule based solely on her own inclinations, she would have authorized RM's request.

Discussion Experimental vs evidence-based medicine

Severely ill patients who have exhausted recognized therapeutic alternatives often find themselves turning to substances and treatments that have not cleared basic scientific screening for safety and effectiveness. Doctors are obligated not to expose patients to treatments that have the potential to cause harm, as explained in Article 4 of the Universal Declaration on Bioethics and Human Rights:

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Even when medical science does not provide a therapeutic option, the patient cannot be given treatment when its safety has not been proven, and when expected benefits are not at all clear. Such treatment could expose the patient to significant injury.

It is important to note that patients who have lost hope in the conventional treatments offered them are often in a delicate state, and often will do anything to obtain treatment. These patients must be approached with understanding and great sympathy. In extreme or unusual cases, it is possible to weigh the use of a treatment of unproven safety and efficacy, but such action must be taken in accord with local laws and with the explicit permission of the patient.

CASE STUDY 19

Use of new medicaments or procedures

Mrs. CS, a 78-year-old widow, has terminal cancer. She was admitted to the hospital, where she has undergone extensive treatments for her cancer. She was treated with extensive chemotherapy and all of the technological means that offer the best hopes for recovery. The treatments however were not effective in curing or even arresting her cancer. Her condition has steadily deteriorated and her prognosis is poor; death is imminent.

Because conventional treatment has not been successful, Mrs. CS wishes to use an alternative drug in an effort to cure or arrest the course of her cancer. This drug is a chemical compound extracted from the kernels of apricots that over the years has been recommended for the treatment of cancer.

The drug is not generally recognized by qualified experts as a safe and effective cancer drug, but various proponents of the drug have claimed that it can cure or control the spread of cancer, or at least can mitigate the symptoms of the disease without curing it.

This drug has not been approved by the Food and Drug Administration or the National Cancer Society. It has not been proven as an accepted method for the treatment of cancer. Hence, the hospital in which Mrs. CS is being treated, exercising its best medical judgment, refuses to allow Mrs. CS or any other hospitalized patient therein to be treated with the alternative drug.

→ **Should Mrs. CS be permitted to take a drug whose use is not sanctioned by the hospital where she is a patient?**

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.

NO By allowing the use of the alternative drug, a relatively nontoxic but unproven cancer treatment, the hospital might encourage public reliance on a ‘false hope’. Such a false hope might lead cancer victims to delay or forego diagnosis and treatment generally recognized by the medical profession as beneficial and effective.

YES Mrs. CS availed herself of all the options offered by ‘orthodox’ treatments without any success. Therefore, Mrs. CS has now turned to an alternative drug as her last hope, the only alternative left after undergoing the most effective treatments currently offered by the medical profession. Accordingly, the public harm in denying an unsuccessful chemotherapy patient an opportunity to take an alternative drug is considerably reduced.

NO The hospital might lose its accreditation if it were to permit the use of unregistered medications. In exercising its duty of care to its patients and in its best medical judgment, the hospital cannot condone the use of this drug, especially since the treatment has not been supported by the Federal Drug Administration or the National Cancer Association.

Notes about the case study

Court decision

The above mentioned case was heard by the Superior Court of the state. The court concluded that a patient’s right to choose or reject a cancer treatment, based on the advice of a licensed medical doctor, whether or not approved by the State or hospital, could not be more fundamental in nature.

By refusing to grant the instant injunction, the court would effectively undermine this very independent choice, which is a fundamental basis for the right to privacy.

Doubtless, the hospital desires to protect the public and in so doing protect its own good name. However, the constitutions of the country and of this state are irrevocably committed to the principle that individuals must be given the maximum latitude in determining their own destiny. In addition, when a person is terminally ill with cancer and unresponsive to other treatments, the alleged public harm in the administration of an alternative therapy is considerably reduced.

To deny a person their last opportunity to make a choice as to how to combat a disease that has ravaged their body would be to exhibit a lack of understanding of the meaning of an individual's rights in our free society.

The situation of seriously ill patients who do not respond to conventional treatment is very difficult. Physicians, who wish to do their best for their patients, search for new ways to relieve the patient's problem.

One of the options in such cases is to refer the patient for a treatment which is not registered or which is not defined as conventional treatment. Countries usually do not allow the possibility of using medications which are not proven as effective and not harmful as it must be remembered that we are seeking to benefit the patient.

Therefore, the clinicians have to be sure that the substance is not toxic, especially when many natural remedies have not been subjected to standard evaluations of toxicity.

In this case, however, there is no description of the information shared with the patient about the hopelessness of her condition and the availability of palliative treatments. Often such patients are not so much afraid of dying as of the manner of dying. Huge advances in palliative care offer great reassurance to these patients and the risky and vain pursuit of curative therapies is avoided.

CASE STUDY 20

Use of new medicaments or procedures – Non evidence-based treatment

JS is an 18-year-old boy and JA is a 16-year-old girl. Both suffer from variant Creutzfeldt-Jakob disease (vCJD). Although JS and JA are from separate and unrelated families, each has been afflicted by this appalling and fatal disease and each is at a similar stage in the disease.

Each one of them has changed from a normal, energetic teenager into a helpless invalid who lies in bed and whose ability to enjoy life is severely limited. JS and JA are cared for in their respective homes. Their families are extraordinarily dedicated and are providing their children with a high standard of care.

For each patient, the experts are in agreement about the state of the disease and its inevitable outcome in the absence of any new treatment. There is no cure, and to date no recognized effective drugs have been able to prolong life or arrest the continuing neurological deterioration. Both JS and JA are bound to die. Once the symptoms appear, the average patient lives for 14 months. Fifteen months have passed since JS began to show symptoms, while JA's symptoms appeared three years ago. The fact that both young people are still alive is a tribute to the outstanding care they receive at home.

The proposed treatment for both patients is identical and known as P. This treatment is new and so far has not been tested on human beings. Both families are very well informed about the disease and the proposed treatment, including its risks and possible benefits. Both families are strong advocates of the proposed treatment.

The risks posed by P infusions are dose-dependent. At high doses, P is toxic, and a balance must be achieved between effectiveness and potential toxicity. With the cautious dosage suggested in the trial protocol,

the risk does not appear great, though the effects upon humans are of course unknown. The benefits to be gained from P infusion are less tangible and more difficult to assess. There might not be any obvious benefit or any benefit at all. At best, there might be some improvement. Another possibility is that the otherwise inevitable deterioration of the nerve cells would be arrested. The third possibility would be prolonging the life of the patient in his or her present state.

Indisputably, neither JS nor JA is competent to make decisions about this proposed treatment.

→ Should JA and JS be treated with the proposed experimental treatment?

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 Under the circumstances, with no known cure for this fatal disease, no one should deprive these children of their only chance for a treatment that might relieve their suffering. The benefits they might gain overcome the risks of the proposed treatment.

NO The proposed treatment has been never tried on human beings. Use of the proposed treatment should be forbidden, especially in this case, wherein both JA and JS are not competent to decide whether they would like to receive this treatment.

Notes about the case study

Court decision

This case came before the High Court of the country. The court concluded that where there is no alternative treatment available and the disease is progressive and fatal, it is reasonable to consider an experimental

treatment with unknown benefits and risks, if there are no significant risks of increasing the patient's suffering and there is some chance of benefitting the patient. A patient who is not able to consent to pioneering treatment ought not to be deprived of the chance for such treatment in circumstances where he would have been likely to consent, had he been competent.

If there is a possibility of continuation of a life which has value to the patient and if the patient is bound to die sooner rather than later without the treatment, then these two young people have very little to lose in going ahead with the treatment. The treatment poses a reasonable risk to take on their behalf. These patients have a real interest in how they live the rest of their lives as well as how they die.

After balancing all of the relevant considerations, it is in the best interests of JS and of JA that this treatment be carried out and that they undergo surgical and other ancillary treatment to enable this to happen. Although administering this treatment cannot be run as a research project, it would provide an opportunity to learn, for the first time, the possible effect of PPS on patients with vCJD.

Discussion Treatment which is not evidence-based medicine

The first point of inquiry in this case relates to the problem that the patient cannot give his consent to experimental treatment. This situation occurs on a regular basis in emergency rooms and intensive care units. The ethical stance is that if there is uncertainty due to the incompetence of the patient, then clinicians should err on the side of life in proceeding with the intervention in order to respect the best interests of the patient.

Usually, when performing a medical intervention which is not evidence-based medicine, such as when all the various stages of the research of the proposed treatment have not yet been completed, efforts should be made to act in the patient's interest, while assessing the anticipated benefit from the proposed treatment.

In principle, patients who are in a difficult stage of a disease should be given treatments with recognized results, treatments which have passed clinical trials and whose efficacy is known. Such is even more so the case when the patients are unable to give informed consent to the proposed research treatment.

At the same time, we are endeavoring to increase the benefits from the treatment to these patients and to reduce the potential harm. Therefore, it is only natural that the medical team will lean towards giving the treatment with which they are familiar.

However, in certain circumstances, there might be allowances for giving unrecognized treatments. In such cases where: there is no option other than that which is currently in research phase, there is a likelihood that the patient will benefit from the treatment and when it is possible to ascertain (through close monitoring or in other ways) that severe harm will not be caused to the patient from the treatment, then treatment which is not evidence based medicine can be administered.

Moreover, protections offered to the patients in these situations should be the presence of a sound experimental protocol which has been reviewed by an independent ethics committee. Here the risk/benefit balance is canvassed as well as it can be. Though minimal risk should be the standard in clinical research, what counts as minimal risk varies from case to case. This case constitutes one of the extreme poles of the spectrum, where death or serious impairment is inevitable without the application of the experimental therapy. The side-effects of the therapy would have to be very serious indeed to constitute a greater risk than the outcomes of non-intervention. The calculated risk should therefore be minimal. At the other extreme, where healthy volunteers are participating in a drug trial, minimal risk would be calculated in comparison with the kinds of risks which we all take in everyday life, such as crossing a busy street.

CASE STUDY 21

Transplantations – Bone marrow donation from a minor

AB is a 3-year-old girl with an incurable disease known as Gaucher's disease. This genetic disease results from an inborn enzyme deficiency. The symptoms in this patient include severe anemia and an enlarged liver and spleen, putting pressure on the lungs and causing breathing difficulties and a tendency to develop pneumonia. AB's deteriorating medical condition was temporally relieved after a splenectomy performed two months ago. Nevertheless, AB's condition continues to deteriorate day by day as her liver enlarges. Currently AB's disabilities are affecting her mobility, causing her difficulty in standing and walking. Her condition is expected to deteriorate rapidly in the next few weeks.

The only treatment likely to restore the missing enzyme and cure AB is a bone marrow transplant from a matching donor. If AB does not receive a bone marrow transplant, the disease will lead to her death within a short time. AB's brother died of this disease at the age of one. CD, AB's 8-year-old sister, was tested and found to be a tissue match for AB. There does not appear to be any other matching donor for AB. The risks to the donor are minimal. The only risk is from the anesthesia. Removing the bone marrow from CD's body is a simple procedure, involving extracting an amount of bone marrow equal in volume to a unit of blood.

Dr. S, a child psychiatrist, believes that extracting bone marrow from CD might be traumatic. He also believes she will be more traumatized if she must live with the feeling that she did not do everything she could have to save her sister's life. This trauma will increase as she enters adolescence. Dr. S believes that it is in CD's best emotional interests to donate bone marrow and recommends proceeding with the transplant.

Should a bone marrow transplant from CD to her sister be allowed?

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 procedure has no inherent risks except the risk of the anesthesia. The harm to her sister AB, certain death, exceeds the risk of extracting the bone marrow.

YES Dr. S believes that the future emotional harm to CD, due to the fact she did not save her sister when she could have justifies the bone marrow donation.

NO CD is a minor, and she should not be exposed to even the slightest harm by extracting bone marrow from her body.

Notes about the case study

Court decision

This case came before the District Court of the country. The court approved the bone marrow donation from the minor CD to benefit her sister, AB. After considering the risks and the slight potential damage to CD, the court concluded that it is in CD's best interests to donate the bone marrow. CD's mental well-being is of no less important than her material welfare.

Discussion Bone marrow donation from a minor

In administering medical care, we consider the welfare of the patient, and of others directly connected to the patient who will be affected by the treatment process. Article 4 of the Universal Declaration on Bioethics and Human Rights directs us to strive to maximize benefit while minimizing damage. Not just for the patient, but for all those affected:

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

When a minor is considered as an organ donor, we must determine the effects of donating versus not donating, on the child's life. When the impact of not donating is severe, causing the child physical injury or mental distress, and when the donation procedure incurs little significant damage (bone marrow is easier to donate than a kidney, for example), it would be ethical to request the child to be a donor. Conversely, when donation involves significant negative effects, is invasive, or carries long-term risks, and when the donation itself will benefit the donor less directly, it would not be ethical to use the minor as a donor.

When a minor must be used as a donor, effort must be made to explain, as much as possible, the meaning of donation and the procedures the child will undergo, as stated at the end of 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. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

In addition, it is important that decisions of this nature must involve entities that are not connected with the patient in need of the donation, to ensure that the decision is based on the welfare of the child-donor.

CASE STUDY 22

Transplantations – Kidney donation by a mentally impaired patient

H is a 39-year-old male who has been deemed legally incompetent. At the age of one, he was diagnosed with mild to moderate mental retardation. As a child, his motor development was very slow. He spent most of his life in institutions for the mentally retarded. When he turned 26, he returned home, where he has been taken care of devotedly by his father ever since.

H has limited social understanding and poor judgment of everyday situations. His ability to learn is limited, and his personality is quite infantile. He loses control very easily, despite his attempts to restrain his impulsiveness.

Thanks to the devoted care of his father, H has been able to fit into the community. He holds down a job, and his outward appearance is neat and clean.

H's mother is a 62-year-old survivor of wartime atrocities. She is mentally ill and does not take any part in H's care. Her relationship to him is one of rejection.

H's father is 65 years old. For the past three years, he has been undergoing dialysis for end-stage renal insufficiency by hooking up to a dialysis machine at home every 8 hours. To improve the quality of his life, the father needs a kidney transplant, which will extend his life expectancy by five years at the most.

H was tested and was found to be a 50% match with his father for kidney transplantation. H's two older sisters were not tested.

→ **Should a kidney donation from H to his father be allowed even though H is incompetent to agree to such a donation?**

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 devoted treatment provided by H's father contributes to H's well-being and comfort. Any worsening in H's father's health will directly harm H, because the father will no longer be able to take care of his son. Furthermore, any improvement in the father's condition, as expected from the kidney transplant, will help H by enabling his father to continue taking care of him. Therefore, it will be to H's benefit to donate his kidney to his father.

NO The kidney donation might harm H due to the risks inherent to the procedure and the potential danger in losing a kidney. Moreover, in the best case scenario, the kidney transplant will extend the father's life for only five years. Hence, the operation is not justified, and another alternative should be considered.

Notes about the case study

Court decision

This case came before the Supreme Court of the country. The court concluded that a kidney transplant at age 65 is very rare. The odds of the transplant's success cannot be predicted, and in the best case scenario the father's life expectancy will be extended for only five years. Recovery from the operation will take approximately two months, and only afterwards will H get the attention he needs from his father.

In considering the balance between the benefits accruing to H and the potential harm to him as a result of the kidney donation, the conclusion is that the kidney donation should be prohibited. There is no doubt that the care H receives from his family, and primarily from his

father, is exceptional, devoted, and worthy of admiration. Clearly it is in H's best interest to stay at home and not be institutionalized. Nevertheless, H does not have the capacity to understand what he will experience if a kidney is removed from his body. The father is not in a critical condition that prevents him from caring for his son unless he has a kidney transplant.

The potential benefit to H from donating a kidney is not sufficient to justify the removal of a kidney from someone who is incapable of understanding what is being done to him and incompetent to give his consent to the procedure.

Discussion Kidney donation by a mentally impaired patient

In medical care, we aspire to maximize the benefits of treatment while minimizing damage, not just for the patient, but for those in the patient's circle who will be directly affected by treatment. This is stated in Article 4 of the *Universal Declaration on Bioethics and Human Rights*:

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.'

There are cases in which a handicapped or mentally impaired person is benefitted by medical care given to another, usually a relative or guardian who cares for them. Therefore, the disabled person has an interest in the medical care of his/her guardian.

In these cases, when we estimate the potential benefits and damages of the guardian's treatment, we should take into account as well the potential benefit and injury to the disabled dependent.

However, when we contemplate letting the impaired person donate a kidney, we must consider several important points.

First, organ donation impacts the donor's entire life. When we ask a mentally impaired person, who cannot understand the implications and consequences of organ donation, to donate a kidney, we must make certain that the procedure will yield major benefits for the donor. Those benefits must be substantial enough to counter the significant risks and damage incurred by organ donation.

Second, we must explore the possibility of achieving the same benefit in another way, for example, seeking another, unimpaired donor. If such a possibility exists, efforts should be made to find such a donor, who should be preferred over the impaired person.

In any event, it is important to involve an ethics committee or other jurisdictional body in the decision process, and not leave the decision to the patient in need of the donated organ. This is especially true if the patient is also the impaired person's guardian, which would make it difficult for the guardian to clearly evaluate the disabled ward's best interests, without considering the guardian's own medical needs.

CASE STUDY 23

Transplantations

Mr. S, a 54-year-old man, and Mrs. S, a 52-year-old-woman, are the parents of two sons, J and T.

T is a 28-year-old man. He is married; an employee of the PS Railroad and a part-time student at the University of C. T suffers from chronic glomerulus nephritis, a fatal kidney disease. He is now being kept alive by frequent dialysis treatments on an artificial kidney, a procedure that cannot be continued much longer.

J is 27 years old. He has been declared legally incompetent, and through proper legal proceedings, has been committed to a state institution (a combined hospital and school) for the feebleminded. He has an I.Q. of around 35, approximately corresponding to the mental age of six. He is further handicapped by a speech defect, which makes it difficult for him to communicate with those who are not well acquainted with him.

Doctors determined that T would have to have a kidney transplant in order to survive. The new kidney could come either from a cadaver, if and when one became available, or from a live donor if a compatible donor could be found. T's entire family was tested, including his mother, his father, and a number of other relatives. None of these family members were medically acceptable as live donors due to incompatible blood type or tissue type. As a last resort, J was tested and found to be highly compatible.

A psychiatrist who examined J stated that he believed T's death would have an extremely traumatic effect upon J. T is J's role model and is vital to J's continued improvement at the hospital and in school.

→ **Should J, an incompetent young man, be allowed to donate a kidney to his brother, to replace his brother's diseased kidney and save his brother's life? Should the operation be allowed to take place?**

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 Under these particular circumstances, not only would the surgery be beneficial to T, it would also be beneficial to J. J is highly emotionally and psychologically dependent upon T, and his well-being would be jeopardized more severely by the loss of his brother than by the removal of a kidney.

NO It is well known that less compatible donors are available and that a kidney from a cadaver could be used, even if the odds of such an operation succeeding are not as great as with a kidney donated by the fully compatible donor brother. Considering the fact that J is incompetent, this alternative must be the only course of treatment.

Notes about the case study

Court decision

This case was held at the Court of Appeals of the state. The majority opinion concluded that J, a mentally defective person, has emotions and reactions on a scale comparable to those of a normal person. He identifies with his brother T; T is his role model and his tie with his family. T's life is vital to J's continued improvement at the hospital and school. T's visits are very important to J. J is aware he can play a vital role in resolving T's health problem. The Department of Mental Health must take all possible steps to prevent any guilty feelings J would have if T were to die, because such feelings might harm his improvement. The operative procedure, in this instance, is in J's best interests. Losing

his kidney is to his benefit when weighed against the harm that might occur if his brother were to die.

To the contrary, the minority opinion held that the incompetent brother has the mental abilities of a six-year-old child. It is commonly and undisputedly known that the loss of a close relative or a friend does not have a major impact on a six-year-old child. Opinions concerning psychological trauma are at best highly nebulous. Furthermore, there are no guarantees that the transplant will succeed, since the body frequently rejects transplanted organs. The life of the incompetent person is not in danger, but the advocated surgical procedure constitutes some risk. The evidence shows that less compatible donors are available and that a cadaver kidney could be used, even though the odds of such an operation succeeding are not as great as in the case of a fully compatible donor brother.

Discussion Transplantations

When we examine the harm and benefits to be gained by carrying out a specific medical procedure on a patient, we must weigh not only the harm and benefits to be gained by the patient while performing the specific procedure, but also the all-inclusive harm and benefits. This means that even by giving up the kidney, the patient can gain more benefits than harm.

One of the most important issues in cases like this is the consent of the donor. In cases of the incompetence of potential donors of tissues, two kinds of approximations to consent can be ethically justified.

First is the use of substituted judgment, where consent is fashioned out of the established values and preferences of the donor which, at the time of donation, they are unable to express.

Second is the construction of a hypothetical consent by means of envisaging the future life of the donor (especially if that donor is a child) and imagining the most likely attitudes of that mature person to that act of donation. If it is most likely to be positive (maybe as a result of saving the life of a sibling), then a hypothetical consent can be arrived at.

If it is likely to be negative (maybe in light of possible risks to the donor's health which have or might have been realized), then no such hypothetical consent can be forthcoming.

Neither of these approaches fits the current case precisely due to the feeble-mindedness of the potential donor. On one hand, the values and preferences of the kind needed are not so easily evidenced, since J is incompetent and never has been in a position where he could express his wishes, beliefs, etc. On the other hand, the normal intellectual and emotional maturation of the donor cannot be envisaged.

However, there is something of value to be found in each of the approaches.

In the first approach, value can be found with respect to the knowledge of past relationships between the donor and the recipient.

In the second, value can be found in the likely persistence of those relationships, since T is a role model for J and his death might have a traumatic effect on J. In both instances, the traumatic effect of T's death should not be disregarded.

CASE STUDY 24

Reproduction

X1 and X2 married in 1994. In 2000, X2 had a hysterectomy and pelvic lymphadenectomy to treat her cervical cancer. During the surgery, X2's ovaries were moved outside her pelvis and preserved to prevent them from being damaged by the radiation therapy she would receive after the operation.

In 2003, X1 and X2 decided to attempt a surrogate birth arrangement with the help of A, a woman living in a foreign country. X1 and X2 travelled to that country and in 2003, eggs removed from X2's ovaries were artificially inseminated with X1's sperm at the C Center. On a subsequent day in 2003, two of the fertilized eggs obtained through this procedure were transplanted into A's uterus.

In November 2003, A gave birth to twins, henceforth the Children, at D Center, located in the foreign country.

X1 and X2 started to take care of the Children immediately after their birth. The government of the foreign country issued birth certificates for the Children, identifying X1 as their father and X2 as their mother, effective December 31, 2003.

In January 2004, X1 and X2 returned to their home country with the Children.

On May 28, 2004, they were notified of a disposition to refuse to accept the birth notifications on the grounds that the fact of delivery of the Children by X2 cannot be found, and therefore a legitimate parent-child relationship cannot be determined between X2 and the Children. Since the provisions of the Civil Code concerning a legal mother-child relationship can be construed to mean that a woman who has delivered a child shall be the mother of the child, X2 cannot be legally regarded as the parent of the Children.

It should be noted that the current legal system in this country has not yet established legislation for surrogate birth.

▶ Should the children be recognized as the biological children of X2?

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 X2 is the biological mother of the children. Even though they were not delivered by her, they were fertilized from her own eggs. Society must recognize the benefits of advanced technology.

NO As long as a society does not legally recognize this advanced technology, its use must be forbidden in order to avoid unnecessary damage, as in this case where the children could not be recognized as the biological children of X2 in their home country and are not recognized as the children of the surrogate mother in the foreign country.

Notes about the case study

Court decision

This case came before the Supreme Court of the country. The court concluded that since surrogate birth, which was not anticipated under the Civil Code, actually occurs and is expected to continue to occur in the future, it is necessary to begin discussing how to treat surrogate birth under the existing legal system.

This issue should be considered in terms of both the legal system for medical services and the legal system for parent-child relationships. It should focus on various possible problems, such as potential medical problems, problems that might arise between the parties concerned, and problems involving the welfare of the unborn child.

It should also take into consideration that women sincerely desire to have children genetically related to them, as well as the sense of ethics generally accepted in society regarding a woman's decision to ask another woman to deliver her child. In this regard, legislative measures should be taken promptly.

In this case, due consideration should be given to the desire of X1 and X2 to take care of the Children as their own children. To fulfill this desire, a legal parent-child relationship should be established between them. There is enough room, even under the existing Civil Code, to establish a special adoption between X1 and X2 and the Children.

Discussion **Reproduction**

Along with the rapid progress in medicine, various new technologies are being developed and put into practice. Such advances in technology have made it possible for men and women, married or not, who are otherwise incapable of having their own children, to fulfill their wish for children. However, this has also caused various unanticipated legal problems.

The issue of surrogacy under dispute in this case is among those included in these problems. Since these problems, with respect to the law of personal status arising as a result of advances in technology, were not anticipated when the Civil Code was enacted, it is no wonder that the Civil Code does not have any provisions addressing these problems.

It is not appropriate to immediately deny a legal parent-child relationship only because it is not provided for in the Civil Code. It is the duty of the court to examine the contents of the legal relationship in dispute and to acknowledge the relationship if it is acceptable, based on the construction of the existing Civil Code.

In order to ensure that many people will be able to enjoy the benefits of the progress in medicine without any worries, efforts should be made to establish a consensus in society and take legislative measures based on such consensus.

Advances in medical technology require that societies examine the proper and effective use of these technologies and its consequences.

The technology of surrogate pregnancy is helping people fulfill their desire to be parents. The fact that technology already makes this possible requires society to deal with the legal and ethical aspects of the procedure, to protect the rights of all those involved—parents, surrogate, and especially the child—and to act for the welfare of them all.

Countries must give voice to the principle of maximizing the benefit of medical treatment, in legal and other spheres, to aid in implementing the *Universal Declaration of Bioethics and Human Rights* and to further benefit patients.

Surrogacy arrangements have several ethical problems; most of them centre around the issue of who is the mother of the child born by such arrangements. The law of many countries declares the woman who gestates and delivers the child to be the legal mother of the child. Thus, a woman who is unable to carry a child but whose ova are used in creating the embryo implanted in the womb of a surrogate finds herself in a precarious position. The child, whom she considers to be her own biological child, has another woman as his legal mother. No contracts can be drawn up, in most countries, to oblige the legal mother to pass the child to her biological mother, nor to oblige the commissioning mother to accept the child when it is delivered.

The former situation can occur when the surrogate has bonded with the child through gestation and delivery and cannot face losing it, while the latter situation can occur when the child is born with serious health problems or handicaps. Either of these situations is disastrous for the women involved.

There is no simple solution to the ethical impasse reached when either of these situations occurs. This emphasizes the importance of preparations women should make before going into such a process. Without careful counseling, there is a greater likelihood that unwise commitments will be made and that some women will face potential negative outcomes unprepared.

CASE STUDY 25

Reproduction

Mr. and Mrs. H have five children. Their fourth child, a son named Z, was born with a genetic disease, a blood disorder known as beta thalassaemia major. By the time he was 2 and a half-years-old, his condition had worsened considerably, to the point where he had to take a daily cocktail of drugs and be hospitalized for regular blood transfusions to remain alive. His life expectancy is uncertain.

Z's condition might be cured by a transplant of stem cells from someone with matching tissue. The stem cells could be supplied from blood taken from the umbilical cord of a newborn child or from bone marrow. The most likely source of matching tissue would be a sibling.

Statistically, Mrs. H has one chance in four of producing a child with matching tissue, even though the odds are somewhat greater that such a child would not have beta thalassaemia major. None of Z's three elder siblings have tissue that matches his.

Mrs. H resolved to have another child in the hope its tissue would match Z's. She conceived, but prenatal testing showed the child would have beta thalassaemia major, so she underwent an abortion. She conceived again, and a healthy son was born, but unfortunately his tissue did not match that of Z.

At this point Mrs. H met Dr. F, managing and scientific Director of the largest provider of in vitro fertilization (IVF) services in the country. Dr. F told Mrs. H about a cutting-edge procedure developed overseas. This procedure might be able to solve her problem and provide healthy embryos whose tissue matches Z's.

Should the use of this technology be allowed just to produce a healthy child with matching tissue to cure its sibling with a genetic disorder?

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.

NO The use of such technology might harm public policy. Today this technology may be used to cure a genetic disorder, but tomorrow it might be used to help engineer a child who is more beautiful, more intelligent, and so on. Therefore, the benefit to Z in producing a sibling with matching tissue does not justify the possible harm in approving the use of such technology.

YES As a society, we cannot ignore the benefits we can derive from advanced technologies. If there is a solution that can cure a genetic disorder, we cannot deprive the family of the opportunity to help one of its members. As a society, we should encourage the use of such technologies to cure other diseases that are incurable today. In addition, the use of the technology for immoral purposes could be barred by legislation.

NO Putting all other considerations aside, the potential mental harm caused to a child from knowing he was brought into the world only to cure his brother should prohibit the use of such technology.

YES Mental harm to the child is not a reasonable consideration, since without this procedure this child would not be alive.

Notes about the case study

Court decision

This case came before the Supreme Court of the country. The aforementioned dilemmas were not the issue in this case. The dilemma in this case was the interpretation of an act allowing the use of IVF

technology in certain cases. In this country, IVF treatment can only be carried out under license.

For some years, such licenses had been given out for screening for genetic diseases as part of IVF treatment. Tissue typing had never, however, been carried out as part of such treatment, and Dr. F believed this procedure required express authorization under license. After careful consideration of the implications, his institution applied for a ruling as to whether an IVF clinic could properly apply for a license to administer treatment that included tissue typing.

Mr. and Mrs. H then made two attempts to produce a child by IVF treatment involving Pre-implantation Genetic Diagnosis (PGD) and tissue typing. Those two attempts failed. Mr. and Mrs. H were barred from further attempts. They petitioned to the Court of Appeals, which held that further IVF was allowed.

In situations where we use technologies and scientific knowledge to advance health, not only the patient's well-being must be considered, but also that of other patients, even future ones, when applying the new technology and examining the benefits and the harm which could be caused to them. When applying such technologies, we must examine not only their potential medical-health benefits and harm, but also possible mental, familial and social benefits and harm.

In the situation of survivor siblings, two main arguments are cited:

First, there is the slippery slope argument which claims that it is an empirical fact that doing X today will lead to doing Y tomorrow, where there is no conceptual link between X and Y. Such claims call for evidential support, which we do not have in this case. Further, some such possibilities can be envisaged and the practice can be successfully regulated to avoid such extensions. In this situation, we can let people use the benefits of technological advancement, while the society does its duty and creates boundaries on the use of such technologies.

Second, there is the suggestion that knowing that one's life began with the purpose of helping a sibling is potentially harmful. Most things have the potential for harm and benefit; this knowledge is among them. The

savior sibling might well become particularly attached to the brother he saved, or proud of the fact that he was the means of making every effort, though unsuccessful, to save a sibling's life. We cannot know certainly which will occur. However, the chances are that the beneficial result will occur rather than the harmful one.

We must remember that the new child is certainly wanted. Probably a large proportion of the population of the world is made up of people who were not wanted or whose births were not planned at all. One might suggest that being wanted for such a high purpose, as in this case, is better than not being wanted at all.

In the case of savior siblings, we must look carefully at the ways in which the child is to be exploited. There is all of the difference in the world between wishing to collect compatible stem cells from the umbilical cord of the savior sibling, on the one hand, and in employing him simply as a reservoir of tissues and organs to be plundered if and when required by the sibling, on the other. The health of the savior sibling is not threatened by the collection of umbilical cord cells at all, as they are not part of his anatomy. Individual justifications would be called for, with the interests of the savior sibling being uppermost, in the event of any further demand for donations.

In addition, we must take into account all of the systems and examine the influence of the technology on society as a whole. The danger inherent in technologies such as these is that they may drag us down the slippery slope of utilizing them for non-medical/health purposes. Therefore, the physicians and decision-makers in the health system must be particularly stringent in using such technologies, ensuring that they are used only for their true purpose.

CASE STUDY 26

Information – Obligation towards third parties

In March 1987, Mrs. M was diagnosed with medullary thyroid carcinoma, a genetically transferable disease.

Her physicians did not inform her or her children of the possibility they may have inherited this genetic condition and therefore, may be at risk of developing the lethal disease. Needless to say, Mrs. M's physicians also did not tell her or her children they should be tested for medullary thyroid carcinoma.

Since they were ignorant of the potential impact of their mother's disease, Mrs. M's children did not undergo any testing.

Three years later, Mrs. M's adult daughter (Mrs. H) learned that she also had medullary thyroid carcinoma.

It is likely that had she been tested when her mother was diagnosed, she would have taken preventative action and her condition, more likely than not, would have been curable.

Mrs. H suffers from advanced medullary thyroid carcinoma and its various debilitating effects.

→ **Does a physician have a duty of care to warn a patient's children of the genetically transferable nature of the condition for which the patient is being treated?**

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 When information can be beneficial to third parties and the physician knows of the existence of those third parties, the physician's obligation extends to those third parties even at the price of disclosing confidential medical information. The prevailing standard of care was obviously developed for the benefit of the patient's children who fall within the sphere of foreseeable risk, as well as for the patient. Therefore, the physician has a duty of care with respect to Mrs. M's children.

NO Mrs. M's physicians had a duty of care to warn Mrs. M of the genetically transferable nature of her disease and to explain to her the importance of testing her children for medullary thyroid carcinoma. That duty does not extend to warning Mrs. M's children. Moreover, requiring a physician to seek out and warn various members of a patient's family would often be difficult or impractical and would place a heavy burden upon the physician.

Notes about the case study

Court decision

The case came before the Supreme Court of the country. The Court concluded that when the prevailing standard of care creates a duty that is obviously for the benefit of certain identified third parties and the physician knows of the existence of those third parties, the physician's duty extends to those third parties as well.

However, this warning should be addressed to the patient. The physician is not required to personally warn the patient's children about the disease. Moreover, in most instances, a physician is prohibited from disclosing a patient's medical condition to others, except with the patient's permission. Thus, in any circumstances in which a physician has a duty to provide a warning regarding a genetically transferable disease, that duty will be satisfied by warning the patient.

In this case, the physician failed in his duty to warn his patient that a lethal disease, for which he was treating her, was genetically transferable and that the patient's children were at risk of developing the disease. The court reversed the dismissal of Mr. H's negligence claim and remanded for further proceedings.

Discussion Obligation towards third parties

A physician's obligation to his patient is the foundation of the medical profession. A physician must act in the best interests of his patient at all times. The recognition of the patient's rights to his own body increases the physician's obligation to tell the patient about his medical condition and its ramifications. In addition, the physician has an obligation not to disclose confidential information relating to his patient to third parties, whether they are family members or other third parties.

Nevertheless, the right to confidentiality of medical data is not absolute. Doctors are freed from this duty in certain circumstances. Notably these include the control of infectious diseases such as diphtheria, and other possible threats to public health such as the diagnosis of epilepsy in a public service vehicle driver. In these cases, doctors have an obligation to inform the relevant authorities when personal privacy should be sacrificed for the sake of public wellbeing.

Sometimes the threat posed by clinical information about a patient is posed only to one person. However, extremely serious threats, even to one person, do justify disclosure of patient's health information.

The fact that many could make use of the medical information for their own good is part of the basic right to extract health advantages from the scientific information and is part of the physician's obligation to act in advancing the public's health.

When it is conceivable that the patient will then divulge the important information to third parties, who will use it in order to advance their own health, the physician's obligation to impart to the patient such information in the most comprehensive manner for the benefit of all the potential beneficiaries, is amplified.

Genetic data present peculiar difficulties because, in an important sense, it is not simply personal information, to which privacy usually attaches. Genetic information on treated patients is also information about persons related to them. The question of whether those persons should be informed about genetic test results of their patient's relatives is therefore less clear than in the usual diagnostic situations, where a patient might not want purely personal information to be shared with others.

Two parameters which we can take into consideration are the seriousness and imminence of the threat. Where a threat is of a serious nature, but is not imminent, or where it was imminent, but not serious, then voluntary disclosure by the doctor would be appropriate. Where it is both, serious and imminent, then involuntary disclosure to affected parties would be proper.

In the present case, we might suggest considering it as the latter kind that is, as an early intervention which would have enabled avoidance of a serious and imminent health problem.

Case study 27

Information –

Not disclosing a medical secret to a patient

In late 1984, KP had cardiac surgery, during which he was transfused with cryoprecipitate, a blood component intended to stop his bleeding. It succeeded in stopping the bleeding but unbeknownst to all, it was contaminated with the human immunodeficiency virus (HIV). The gift of life proved fatal to KP, who died of HIV-related pneumonia in 1990.

The blood had been collected in November, 1984 from an unwitting donor, Mr. L. In November, 1985, Mr. L returned to the same center to give blood a second time. By then, the center was able to test blood for HIV. They discovered that Mr. L's blood was contaminated with HIV and so advised him.

In June, 1987, the center traced Mr. L's potentially contaminated 1984 donation to the Hospital where KP had cardiac surgery, and so advised the Hospital. It was not until February 1989 that the Hospital traced the blood to the 1984 transfusion given to Mr. KP.

In April, 1989, the head of the Hospital blood bank telephoned Mr. KP's family doctor, Dr. B, and informed him that Mr. KP's 1984 transfusion may have been contaminated with HIV. By this time, the patient was already suffering from a chronic cardiac condition, and was experiencing anxiety and depression.

Dr. B was concerned about his client's mental health and poor cardiac condition. Operating on the assumption that Mr. KP was not having sexual intercourse with Mrs. KP, he did not inform Mr. KP of the possibility he had been infected with HIV.

In March, 1990, Mr. KP died of pneumonia-related causes. In April, Dr. B learned that Mr. KP had been HIV positive. In September of that same year, Mrs. KP discovered she was HIV positive.

Should Dr. B have informed Mr. KP that he may be HIV positive?

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 Unquestionably, Dr. B must inform Mr. KP that he may have been infected with HIV, regardless of his mental health. The potential harm to Mr. KP as a result of untreated HIV infection is much greater than the potential harm and stress resulting from being informed of his condition.

NO Mr. KP suffered from heart disease, and his cardiac condition was poor. If Dr. B had informed him of the possibility he might be infected with HIV, there is a reasonable chance he would have had a heart attack. Under these circumstances, it is to the benefit of Mr. KP's health not to know about the HIV infection.

Notes about the case study

Court decision

This case came before the Supreme Court of the country. The court concluded that Dr. B's decision to withhold information from Mr. KP fell below the standard of care of a reasonable and prudent family physician with his experience. Even if Dr. B had the right to withhold the information, he also had an obligation to carefully monitor his patient's health, an obligation to which he did not apply his usual skill and competence.

In certain circumstances, a doctor may determine that withholding certain information is in the patient's best interests. Only in certain exceptional circumstances is it permissible to withhold information from a patient. The circumstances of this case do not fall within these exceptional circumstances. It was not 'protective' of Dr. B to withhold the information from Mr. KP, and he had an obligation to disclose that there was prophylactic treatment available.

Dr. B was negligent in withholding from Mr. KP that his 1984 transfusion was potentially contaminated with HIV. Had Mr. KP been given this information, it is likely he would have sought treatment, and his life could have been prolonged by approximately two years. Further, had Mr. KP been told, he would have informed Mrs. KP. The ethical stance is that taken in the judgment, viz., that if there is uncertainty due to the incompetence of the patients, then clinicians should err on the side of life in proceeding with the intervention in order to respect the best interests of the patient.

Mrs. KP probably contracted HIV from her husband during the last year of his life. Had Mr. and Mrs. KP known of the risks, they likely would have taken steps to protect Mrs. KP.

Discussion Not disclosing a medical secret to a patient

A physician is obliged to disclose to his patient all of the data regarding his or her medical condition.

The necessity to disclose the truth to a patient stems from a person's human dignity and the natural autonomy of the patient, but it is also a matter of assessing the benefits or possible harm of such disclosure. The physician should act according to the best interests of his patient. Therefore, patients are just as entitled to refuse to receive information as to refuse treatment.

Furthermore, there are certain cases, and they are exceptions to the rule of revelation, where the physician and the medical staff may withhold information from the patient. Such cases, in many instances, require approval from outside the relationship between the doctor and patient (for example the Ethics Committee etc.). Approval for not passing on information to a patient will be given in such cases as when revealing the medical information could harm the patient and worsen his condition. It should be stressed that the condition and specific character of the patient must be considered, as there are certain situations where not informing patients of a serious illness will benefit them and enable them to live out their lives in comfort. However, there are other cases, when non-revelation and not knowing the details of their illness will

be stressful, and disclosure of the nature of their illness will enable them to live their lives doing what is important to them. Therefore, there is considerable significance in examining the situation and the special personality of the patient.

In some cases, where a patient's health condition constitutes a threat to the health of others, the doctor might be obliged to inform that interested party. The doctor must take into consideration the seriousness and the imminence of the threat. In some countries, doctors have a responsibility to sexual partners, who have the right to know the risks involved in sexual relations with the patient, and to receive advice about protection.

In this case, if the wife would have been told the origin of her husband's infection, the result would have been entirely different.

CASE STUDY 28

Information – Medical confidentiality and its limitations

Mr. X worked as an assistant surgeon in the State Health Service.

Mr. X was directed by the National Government to accompany Mr. Y to the State Hospital for advance medical treatment. Mr. Y was suffering from a condition provisionally diagnosed as aortic aneurism. Mr. Y was scheduled for surgery on May 31, 1995, but it was cancelled due to a blood shortage.

On June 1, 1995, Mr. X and Mr. Y's driver were asked to donate blood for Mr. Y's surgery. Samples of their blood were taken and tested. The results showed that Mr. X was HIV positive. At that time, Mr. X had been unaware of this condition.

In August 1995, Mr. X proposed marriage to Ms. A. His proposal was accepted, and the wedding was scheduled for December 12, 1995. However, after the hospital informed Ms. A's family that Mr. X was HIV positive, the marriage was called off.

Since the marriage had been arranged but was subsequently called off, several people, including members of Mr. X's family and people from his community, became aware of Mr. X's disease. Consequently, Mr. X was severely criticized, ostracized by the community, and forced to leave.

→ **Should the hospital have informed Ms. A's family that Mr. X was HIV positive?**

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.

- NO** The hospital has a duty to maintain confidentiality as a basic principle in ensuring the human right to privacy. Disclosing that Mr. X is HIV positive is a breach of that duty.
- YES** Confidentiality is a basic obligation in the physician-patient relationship but it is not an absolute obligation. One of the exceptions to that obligation is when such disclosure of confidential information will ‘save’ innocent people, such as Ms. A, and spare them of exposure to this dreadful disease.
- NO** In disclosing confidential medical information, the entire medical profession might be harmed by this breaching of the physician-patient relationship. This injury is much greater than any benefits accruing to Ms. A.

Notes about the case study

Court decision

This case came before the Supreme Court of the country. Mr. X claimed damages against the hospital, on the grounds that information which according to medical ethical standards should have remained confidential had been illegally disclosed, and therefore the hospital was liable for damages.

The Supreme Court concluded that the most important aspect of the doctor-patient relationship is the doctor’s duty to maintain confidentiality. A doctor cannot disclose to any other person any information regarding his patient gathered in the course of treatment, nor can he disclose the mode of treatment or the advice given by him to the patient. However, the general rule of confidentiality is not absolute. It contains exceptions which permit disclosure with the consent of, or in the best interests of, the patient, in compliance with a court order or other legally enforceable duty, and in very limited circumstances, where the public interest so requires.

Considering that Mr. X was found to be HIV positive, disclosing this information would not be in violation either of the obligation to maintain confidentiality or of Mr. X's right to privacy, as this disclosure saved Ms. A, whom he was about to marry. Otherwise, if the marriage had taken place and been consummated, she too would have been infected with the dreadful disease.

Discussion Medical confidentiality and its limitations

The meaning of the obligation of medical confidentiality is that a physician must keep all information concerning the medical condition of the patient confidential. This obligation is the foundation of the relationship between doctor and patient, which has existed since the time of Hippocrates. This is what creates the trust and confidence between the patient and the physician—trust and confidence without which proper treatment could not be provided. This obligation is defined in Article 9 of the *Universal Declaration of Bioethics and Human Rights*:

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

In addition, the right to medical confidentiality is not absolute and it could be withdrawn when at variance with other rights. For example: The patient himself has the right to waive confidentiality and reveal the information regarding his medical condition to whom he so chooses. Also, local laws (in various countries) limit this right in certain cases (for example: when someone is unable to drive and the physician is requested to report this to the transport authorities in his country; in New Zealand, sexual partners have the right to know whether you are HIV positive, etc.)

In cases where non-disclosure of the information can harm a third-party, the rights of all parties concerned should be weighed. There should be a consideration of the seriousness and imminence of the

threat. Where a threat is of a serious nature but is not imminent, or where it is imminent, but not serious, then voluntary disclosure by the doctor would be appropriate. Where it is both, serious and imminent then involuntary disclosure to affected parties would be proper.

A patient's positive HIV status is regarded as posing both a serious and imminent threat to the health of his or her sexual partners. Voluntary disclosure is preferred but, as a guarantee of this occurring, joint consultations with the patient and partner are requested. This is, of course, useful only when the patient is frank about the identity of sexual contacts.

We would like to note that there are countries which resolve this issue through a committee which examines the case and makes a decision (whether to disclose to the third party or not) and it is important that the physician is aware of the situation in his country.

CASE STUDY 29

Information – Violation of medical confidentiality

On April 18, 2003, Ms. X got into an argument with her live-in partner, and was stabbed with a knife in the lower right side of her back. She was transferred to the National Hospital. The doctor in charge examined Ms. X and found that the stab wound on the lower right side of her back was about three centimeters long. Moreover, her clothes were extremely bloodstained.

The doctor explained to Ms. X that her urine needed to be tested for blood to determine whether the stab wound had punctured the kidney but she adamantly refused to have a urine test. The doctor finally decided to perform a procedure in which he would anesthetize her and then sew up the wound in order to stop the bleeding. The doctor explained the procedure to Ms. X and told her that a urethral catheter would be inserted in her body. Ms. X received an anesthetic injection without showing resistance.

While Ms. X was under the influence of the anesthetic, the doctor collected a urine sample by inserting a catheter in her body. Although the collected urine sample did not contain blood, the doctor suspected that Ms. X was under the influence of drugs. He therefore conducted a simple drug test, and found a positive reaction for amphetamines.

In the meantime, Ms. X's parents had come to visit her. The doctor explained the extent of her injury to them, and informed them that stimulants had been detected in her urine sample. The doctor further explained to Ms. X's parents that, as a national public officer, he was obligated to notify the police of this fact. The doctor then notified a police officer that stimulants had been detected in Ms. X's urine sample.

Should the doctor have disclosed information about the presence of stimulants in Ms. X's urine sample to her parents and to the police officer?

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.

NO The doctor is obligated to uphold Ms. X's right to medical confidentiality. The fact that he disclosed the information to Ms. X's parents and to the police officer was a breach of that obligation.

YES The doctor should have disclosed the information to the police because the presence of stimulants is a felony and it is in the public interest for the police to be made aware of such cases in order to prevent them in the future. The public interest in the disclosure of this information to the police is greater than Ms. X's right to confidentiality and privacy. However, the doctor should not have disclosed the information to Ms. X's parents.

Notes about the case study

Court decision

This case came before the Supreme Court of the country. The court dealt with the following question: In a case where a police officer seizes a urine sample after being notified by a doctor, who collected the sample from an emergency patient and tested it for drugs for medical purposes, is the process of obtaining said urine sample illegal?

The court added that, given the facts mentioned above, the doctor collected a urine sample from the defendant, an emergency patient, and tested the sample for drugs for the purpose of medical treatment. This suggests that there was medical necessity in such an act. Therefore, even if the doctor cannot be deemed to have obtained consent from the defendant, the doctor's act cannot be regarded as illegal medical practice.

Furthermore, when a doctor notifies the investigating authorities of the fact that the presence of an illegal drug has been detected in a urine sample, collected from a patient in the course of performing necessary medical practices or tests, such an act is permissible as a justifiable act and it is not in breach of the confidentiality obligation.

Discussion Violation of medical confidentiality

Medical confidentiality is an important and valued asset for a patient. Due to the physician's obligation to maintain this confidentiality, the patient feels that he can rely on his doctor and reveal everything about his problem, without fear of his personal and private affairs becoming public knowledge. In addition, because of this medical confidentiality, as the patient reveals all of his problems, the doctor is able to provide the patient with the most beneficial treatment.

Repealing the patient's medical confidence could cause harm and damage on two levels: One, on the private level; the patient is harmed as his disclosure is revealed and he will then avoid taking his physicians into his confidence in the future. Two, on the general level; this would send a message to the public that there are certain cases when it is preferable not to take your physician into your confidence.

Such a message is extremely harmful to the trust which patients put in their physicians. This case is not clear enough as to the question of whether the patient understood the consequences of inserting a urethral catheter. The patient had firmly refused to have a urine test, in full knowledge of the dangers of not checking for the presence of blood in her urine. She should have been reassured that no such test would follow the insertion of the catheter. If the sole purpose of inserting the catheter was to take the urine sample, then this constituted a physical assault.

In our case, we have to note that we do not know the age of the patient. Sharing the information about the positive drug test with the parents might be a serious breach of confidentiality.

As to the information which was told to the police, we have to remember that the doctor has to act, first and foremost, for the benefit of his patient. However, if a doctor acts as an agent of the police and conducts unnecessary tests in the process of clinical care in order to detect criminal activity on the part of the patient, he steps beyond his professional remit as a doctor.

If the police, as part of their inquiries, have good reason to believe that a patient has committed a crime and that her doctor might be in possession of relevant information gathered in the course of *bona fide* medical examination, then they may request that information from the doctor. A doctor should not impede police in the execution of their public duty in these situations by refusing to disclose the data. This is, however, very different from a doctor acting spontaneously with the purpose of fully seeking evidence as a detective in criminal matters. Such extension of activity by doctors would certainly deter some patients from seeking health care when it is needed.

CASE STUDY 30

Information – Confidentiality in AIDS patients

PD went to the Medical Centre with her future husband FH to have pre-marital blood tests to ensure that neither of them carried any sexually transmitted disease. At the time of their joint consultation, PD and FH were not living together, though they engaged in sexual relations and practiced protected sex. FH came to the Centre for testing at PD's request. She was concerned about her future husband's STD status because he came from a country where the prevalence of sexually transmitted diseases was significantly higher than usual.

The doctor was aware of the purpose of the test and of PD's concerns. Yet he did not inform either PD or FH that, in the absence of their consent, he was legally prohibited from disclosing any information concerning the HIV or AIDS status of one partner to the other. They did not discuss how the test results were to be dealt with. PD believed she would have FH's results and he would have hers, but the topic was not specifically raised.

PD and FH each answered intrusive questions about their sexual behavior in the presence of the other.

Both PD and FH gave blood at the joint consultation in the presence of the other, and then left the surgery. The doctor told them to return to his surgery in about a week's time when the pathology tests would be available.

A week later, the doctor received PD's pathology report, which was negative for both hepatitis B and HIV. The following day, he received FH's pathology report, which was positive for hepatitis B and HIV.

PD returned to the Centre sometime between one and two weeks after the initial consultation. The receptionist gave her a copy of the pathology report relating to her. She asked for a copy of FH's pathology report, but was told that it was confidential and could not be given to her. The receptionist did not make any mention that if FH gave his consent, she could be given FH's pathology report.

The doctor informed FH by telephone that he had tested positive, but did not inform PD of FH's results. Furthermore, the doctor did not take any steps to ensure that FH inform PD of his test results. The doctor also did not try to get FH to consent that the clinic or himself disclose this information to PD.

FH misled PD and told her he had tested negative.

A few years later, PD became aware that she was HIV positive.

➔ **Should the doctor, in his position as physician for both PD and FH, have disclosed to PD that FH was HIV positive because of the joint consultation?**

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 knew about the purpose of the test, and he should at least have asked them if they wanted to get the results jointly or separately. Furthermore, at the time of the joint consultation, the doctor asked them each intrusive questions about their individual sexual behavior. In so doing, he gave PD the feeling that she would be given FH's results.

NO Medical confidentiality is a basic principle in medical practice. The doctor is obligated to both of them, and he cannot harm one to fulfill the wish of the other.

Notes about the case study

Court decision

This case came before the Supreme Court which concluded that in the context of a joint consultation, such as the one that occurred here, the doctor owed a duty to both his patients, PD and FH, to address the question of mutual disclosure of results and the possibility of discordant results. He did not do so. In that respect, breach of duty was established.

In the course of the initial joint consultation, had the doctor fulfilled his duty to address the question of mutual disclosure of results and the possibility of discordant results, the probable result is that the doctor would have secured the consent of FH as well as of PD to receiving the results together. It is likely that each would have consented to their respective results being known to the other through the doctor at a further joint consultation. Moreover, under the contingency that FH had refused, PD would likely have terminated her relationship with FH. In either case, PD would have escaped the injury she suffered because FH would not have been in a position to deceive her.

Discussion Confidentiality in AIDS patients

Confidential medical information belongs to the patient, and its protection is one of the fundamentals of the medical profession. The fact that the doctor respects the privacy of the patient's medical information increases the trust between them, contributing to increased effectiveness of medical treatment.

That is the reason why doctors must be careful and very clear when they have the opportunity to counsel couples or individuals. Counseling of patients before they undertake HIV testing is thought to be ethically indicated in order to avoid the kinds of difficulties which occur in this case and to enable informed decisions with respect to other social consequences of a positive result, such as stigmatization, refusal of insurances and mortgages, job discrimination, etc. When such matters

are canvassed in a counseling session, the potential applicant is better placed to decide whether or not to proceed.

When counseling is provided in the kind of situation referred to in this case, the advisability of a joint counseling session is obvious.

In this case, mutual trust would appear to be the foundation of the couple's request for testing in the first place. At a counseling session, the refusal of either party to agree to joint disclosure of the results would have provided the other with some warning of lack of this mutual concern and of possible problems of disclosure on the part of her partner.

We should take into consideration situations in which the patient's right of medical confidentiality conflicts with another person's rights, and refusal to release private information may cause them injury. This is even more complicated when both parties are under the care of the same doctor, who is professionally obligated to both of them; the doctor must consider the great damage that would be caused to one patient if they are not informed of the other patient's medical information. However, one might take the view that the doctor should not have proceeded if the parties could not agree about the manner of the disclosure.

CASE STUDY 31

Information

Mrs. X was carrying a 32-week old fetus. Based on the results of an ultrasound scan, she had been informed that her fetus may have skeletal dysplasia, a condition commonly known as dwarfism. Mrs. X was referred for counseling and a further ultrasound was taken, confirming the diagnosis of skeletal dysplasia.

Mrs. X went to the emergency department of the RW Hospital and requested that her pregnancy be terminated. She then became hysterical and suicidal, demanding termination.

She was referred to a psychiatrist for counseling and assessment. Some days later, the psychiatrist recommended termination of the pregnancy to maintain Mrs. X's psychiatric health and preserve her life.

A number of medical practitioners in the hospital were consulted. They concurred with the psychiatrist's recommendation. In early February 2000, a fetal reduction procedure was performed, and Mrs. X delivered a stillborn female.

In May 2001, a member of the Federal Parliament filed a complaint to the Medical Practitioners Board about the termination. In April 2002, the Board commenced a preliminary investigation into the medical procedure and into the conduct of the medical practitioners involved, including the hospital.

For its investigation, the Board sought documentation from the hospital. Mrs. X informed the hospital that she did not consent to the release of her medical records (held by the hospital) for that purpose.

Should the hospital disclose Mrs. X's medical records to the Board, despite her refusal?

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** It is in the public interest to investigate such cases. An adequate investigation requires all of the relevant information and medical records.
- NO** Disclosing those medical records despite Mrs. X's refusal would be a serious breach of her right to privacy and confidentiality. It is also in the interest of the public not to violate this important and basic principle in medical practice.
- NO** Disclosure of this patient's records to the Board would discourage other women in need of similar critical medical assistance from seeking such assistance, or from speaking frankly to a doctor about their circumstances. At worst, the consequences might be that women in such need would seek other, unsafe, means of terminating their pregnancies.

Notes about the case study

Court decision

This case came before the Court of Appeal of the country. The question in this appeal is whether the RW Hospital may refuse to provide the medical records of a patient to the Medical Practitioners Board ('the Board') on the grounds of public interest immunity. That is, it is in the public interest not to disclose the information. The Hospital claims that for the sake of safeguarding the public interest, all medical records of *'women patients in public hospitals seeking advice and treatment concerning reproductive matters including obstetrics and gynecological care'* should be immune from compulsory disclosure.

The court concluded that the Hospital had failed to establish any basis for its refusal to produce the documents.

Discussion Information

It is a standard requirement of good clinical practice to audit the results of therapeutic interventions. Such an audit almost always has to employ people who were not the practitioners involved in the procedures themselves (for example pathologists, management personnel, etc.). Such persons are committed to the same standards of confidentiality as the treating physicians, but have access to the data on a professional ‘need-to-know’ basis. Such access is not considered to be a breach of medical confidentiality. Inquiries, such as the one involved in this case, are of a similar kind. Here the practice of the clinicians and management is being audited for purposes of the maintenance of professional standards on which the public’s trust in the doctor/patient relationship is based.

The patient’s consent to treatment includes all who are involved in that treatment, including the sharing of her information with other professionals on a ‘need-to-know’ basis, for example, the radiologists, the pathologists, the nurses and so on. Separate consents for their access to the patient’s data are not required. A good case can therefore be made for saying that in cases of inquiries into possible breaches of professional standards in care, the same considerations apply. Moreover, public confidence in the medical profession rests upon confidence in the competence and professional standards of doctors and related professionals, which are taken for granted by patients. If these are not safeguarded by inquiries into possible breaches which require the full disclosure of the facts of the cases in question, then that confidence will be undermined.

CASE STUDY 32

Information – Medical confidentiality of a convict

W was detained as a patient at a secure hospital with no time limit after having shot and killed five people and wounding two others. He was deemed a potential threat to public safety. Ten years after he had first been detained, he applied to a mental health review tribunal to be discharged or transferred to a regional secure unit, with the object of eventual discharge.

His responsible medical officer, who had diagnosed him as suffering from schizophrenia that could be treated by drugs, supported his application, but it was opposed by the Secretary of State. His solicitors instructed a consultant psychiatrist, Dr. E, to examine W and report on his mental condition. Their intention was to use the report to support W's application to the tribunal.

In his report, Dr. E strongly opposed W's transfer and recommended further tests and treatment for W. He drew attention to W's longstanding interest in firearms and explosives. Dr. E sent the report to W's solicitors in the belief that it would be placed before the tribunal, but in view of the contents of the report, W withdrew his application through his solicitors.

When Dr. E learnt that the application had been withdrawn and that neither the tribunal nor the hospital charged with W's clinical management had received a copy of his report, he contacted the medical director of the hospital. After discussing W's case with Dr. E, the medical director agreed that the hospital should receive a copy of the report in the interests of W's further treatment. At Dr. E's prompting, the hospital sent a copy of the report to the Secretary of State, who, in turn, forwarded the report to the tribunal when referring W's case to them for consideration.

→ Should Dr. E have sent a copy of his report to the Secretary of State?

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 In this case the number and nature of the killings carried out by W must inevitably give rise to the gravest concern for public safety. The authorities responsible for W's treatment and management must be entitled to the fullest relevant information concerning his condition, even at the price of violating W's confidentiality.

NO W has a right to confidentiality. This is not merely his right, but rather it is in the broader interest of the public to fulfill this right. Otherwise, the mentally ill will not cooperate with the health authorities.

Notes about the case study

Court decision

This case came before the Court of Appeal, Civil Division. In the matter of the public interest in the duty of confidentiality Dr. E owed to W and in the competing public interest in disclosing the report, the court held that the balance came down decisively in favor of disclosure. The court indicated that the number and nature of the killings committed by W were such that decisions leading directly or indirectly to his release from a secure hospital should not be made, unless the authorities responsible for W were properly able to make an informed judgment that the risk that such killings would be repeated was so small as to be acceptable.

Accordingly, since Dr. E had highly relevant information about W's condition, he had been justified in passing it on to those responsible for making decisions concerning W's future. The suppression of that information would have deprived the hospital and the Secretary of State of details relevant to questions of public safety.

Discussion Medical confidentiality of a convict

The confidentiality of medical information is an integral human right that medical staff has a fundamental obligation to respect. This obligation is expressed in Article 9 of the *Universal Declaration on Bioethics and Human Rights*:

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

Confidentiality not only builds trust between doctor and patient but it also increases therapeutic effectiveness. However, this obligation is not absolute, and sometimes we withdraw it in order to protect the public, even if the ‘public’ is one person.

In order to decide whether the public should be protected from people who could endanger them, we should consider the seriousness and the imminence of the threat. These factors will determine whether or not it is ethical to disclose the information.

Various events might have occurred during the time of a convict’s detention. They might have attended classes on anger management, on dealing with sexual problems, confronting their offenses, and so on. As result of such attention and due to the passing of considerable time, they might well be considered to no longer be a risk to others. To incarcerate them despite such changes would be to not respect them as individuals born free and equal in dignity and rights.

Furthermore, there is great difficulty in making a judgment about the likeliness of the offender not to re-offend. The public also has rights, including the right that their lives and freedoms are not threatened. Therefore, such processes of judgment of the likeliness to re-offend must be thorough and comprehensive. Where expert views are obtained about such matters, no matter in what connection, concealing the information available compromises the comprehensiveness of the

process of assessment. Such concealment is therefore unethical as it, in turn, prejudices the interest of the public to be protected.

We suggest that such a decision and its ethical implications be discussed in a structured committee of several people, who bring differing perspectives to the deliberations.

CASE STUDY 33

Varia – Medical publicity and advertising

The Medical Council in a particular country has established a code of regulations for the practice of medicine, including the maintenance of professional standards among doctors.

The code regulates, inter alia, the ways in which doctors may promote their practice, including publicizing services and fees. The code provides that doctors may communicate certain basic information about their qualifications and about the services and procedures they offer on websites, on service information notices in the office or immediately outside of it, and in doctors' directories. However, the code prohibits the communication of precisely the same information in newspapers, magazines or other print media. The code also limits the number of services doctors can list on a service information notice to five items. Furthermore, the code permits doctors to give public lectures, participate in TV or radio programs, and publish books to inform the public about medical or health developments, but when so doing, doctors *'should ensure that reference is not made to the doctor's experience, skills and reputation, or practice in a manner which can be construed as promotional'*.

Dr. K is the Assistant Medical Superintendent of a Sanatorium and Hospital. He is responsible for publishing information about the hospital's services, in particular, information about treatments and technology available to the public.

Dr. K believes that due to this strict code, the people of his country do not have sufficient information about doctors and their practices to make truly informed choices about which doctor and what medical services to engage. According to Dr. K, the threat of disciplinary proceedings for breach of the code involved in these restrictions constrains doctors from fully informing the public about available services, skills, or technologies.

It is impractical (if not impossible) for a doctor to speak out publicly on medical topics, without reference to his experience and skills in the area under discussion. A doctor's audience will wish to know (and will certainly inquire) about his personal experience on the matter at hand.

→ Is Dr. K correct in his assumptions?

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.

NO The aim of these restrictions is to preserve a high standard of medical practice. Those restrictions are beneficial to the image of the medical profession.

YES The constraints in the code only deprive the public of important information on health issues and medical developments. This might be beneficial to the profession's image, but it is not beneficial to the public, which will remain unaware of new methods of treatment. In balancing between the public interest in knowing more about medical fees and services and the duty of medical practitioners to uphold the dignity of their profession, the public's right to know must be deemed more important than the dignity of the profession, which can be preserved in other ways.

Notes about the case study

Court decision

The case came before the Court of the country. The court concluded that the prohibition in the code was plainly not the minimum interference necessary to ensure maintenance of a level competitive playing field among doctors. Since the Council did not put up any other justification for the restriction under attack, Dr. K's criticism must be upheld

as valid. The court added that there was simply no good reason for interfering with freedom of expression by imposing a limit of five items that could be advertised. Furthermore, it was impossible, in practical terms, for doctors to talk about new medical techniques or procedures without at least indirectly referring to their personal experience, skills, and reputation. Why should the public attach any weight to the information doctors provide, unless their credentials can be verified?

The code constrained the provision to the public of important information about available medical services. It placed doctors at risk of disciplinary proceedings every time they attempted to tell the public about some new technique, procedure, or operation. Doctors inevitably will promote their practice by utilizing this method and consequently, violate the stricture against self-promotion in the code. The result was that doctors would be reluctant to speak out about medical and health developments of legitimate public interest. The restriction against incidental self-promotion in the code operated disproportionately.

Discussion Medical publicity and advertising

The topic of medical publicity and advertising has occupied the Western world in the last few years. As the individual's freedom of occupation takes on the status of a basic right, the door opens further for the individual to advertise their professional services. Partial or total blocks to advertising are enacted in consideration of other important principles, such as: respect for the profession, prevention of internal competition that will hurt younger doctors or limit the field to wealthy doctors only, among other issues.

It should be remembered that any decision to allow or prohibit publication has advantages and disadvantages. For example, if we allow doctors to advertise their services with no limitations, they may publish false claims or incite false hopes; alternately, they may refuse to treat difficult cases of illness that may damage their 'good name' if treatment fails. On the other hand, if we withhold information from the public about the advantages or experience of this or that doctor, it is likely that patients will not know that a certain doctor specializes in the treatment of their problem.

Moreover, practitioners with *bona fide* qualifications to practice should be seen as trustworthy to carry out those services which fall within their areas of competence. Thus while it is proper to advertise the range of competences available to patients, it has been thought to undermine the professionalism of practitioners to claim that they are better qualified than some other licensed practitioner.

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