D1. Informed Consent and Informed Choice

Chapter Objectives
The relationships between health professionals and patients are changing in all societies to give more voice to patients. The same is true in other social relationships between those in power and consumers or citizens. This chapter aims to:
1. Introduce the concept of informed consent.
2. Introduce informed choice.
3. Discuss the transitions in decision-making that are being undergone in different societies.

D1.1. Informed Consent
An animal surgeon could treat a dog with a tumour on its leg without the dog's agreement. However, people are different, humans have been given special rights to protect them against others. People have life values that are important to them that doctors should not ignore. There is no reason to treat patients as uneducated, and who are unable to understand. A good doctor can explain the situation to the patient. For every procedure the patient should be offered an explanation of the problem and possible solutions, and then their consent asked. This is called informed consent.

The doctrine of informed consent, simply stated, is that before a patient is asked to consent to any treatment or procedure that has risks, alternatives, or low success rates, the patient must be provided with certain information. This information includes at least the following, which must of course, be presented in language the patient can understand:
1. A description of the recommended treatment or procedure(s)
2. A description of the risks and benefits of the recommended procedure, with special emphasis on risks of death or serious bodily disability
3. A description of the alternatives, including other treatments or procedures, together with the risks and benefits of these alternatives
4. The likely results of no treatment
5. The probability of success, and what the physician means by success
6. The major problems anticipated in recuperation, and the time period during which the patient will not be able to resume his or her normal activities
7. Any other information generally provided to patients in this situation by other qualified physicians

Many people would like to accept this responsibility. There are a few who may not, but this should be an exception rather than the rule, and is no reason not to apply the rule of informed consent. Even if someone does not think informed consent is necessary and says to a dentist or doctor you should do what you think is best, it still does not mean the health care professional should not talk to the patient about it.

In modern medicine there are often many alternative therapies, which present the doctor with such dilemmas. The patient may not realize there is such a variety of choices,
but the doctor is still obliged to attempt to explain something of these techniques to form in their own mind which therapy is most suitable respecting this individual's life values. There are also scientific studies to show that effective doctor-patient communication has a positive influence on health outcomes.

From the patient side, responsibility may be a burden, but we need to take it otherwise autonomy and democracy will break down. We should make decisions even if they are a bit complicated. Health care workers need to make patients make decisions, we must find the best way to do this. It will involve some time, which is a limiting factor in many healthcare systems. Health care workers should have good counseling skills. Health care workers should be decision facilitators, the patients should make the decisions. Some health care professionals may also consider that the family knows the patient better than they, and share the responsibility of consultation with family members, so-called “familial autonomy”. There are some families in all societies who function as one, and other families which function as relationships between individuals.

D1.2. Transitions from Paternalism to Informed Choice

While medical ethics was developed in ancient times, as seen in the survival of the Hippocratic Oath of the 3-5th century BC, it did not mention consent. The traditional model until the 1950s in mainstream medicine in most countries was called paternalism, which means the doctor behaved like a father to a child. The figure below shows three different models of the relationship between doctor and patient.

<table>
<thead>
<tr>
<th>Level of Participants in Relationships</th>
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<tr>
<td>e.g. Visit to a doctor to seek treatment</td>
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<tr>
<td>Doctor        Patient</td>
</tr>
<tr>
<td>Patient       Doctor</td>
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<tr>
<td>Paternalism   Informed Consent</td>
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<tr>
<td>e.g. Visit to a supermarket to buy food</td>
</tr>
<tr>
<td>Shop          Consumer</td>
</tr>
<tr>
<td>Consumer      Shop</td>
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<tr>
<td>Paternalism   Informed Consent</td>
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Compared to a few years before the modern response is to reject “paternalism” and over-dominant health care professionals who make decisions for patient's treatment without adequate respect for their voices and values. In the past many more health care professionals, and especially physicians, thought it was not in a patient’s best interest to be told. Whether past doctors were less or more competent to explain and counsel the patient is unknown – though if we could compare the times for average consultations between patient and physician it would give us some part of the indication. It remains a challenge.
D2. Telling the Truth about Terminal Cancer

Chapter objectives
Most people want to know if they have terminal cancer, but many people are not willing to tell family members the bad news. The attitudes towards truth-telling are changing in every society even now, as they have over the past few decades.

This chapter aims to:
1. Describe a typical case of a terminal cancer patient.
2. Explain ways people come to know about their illness.
3. Apply ethical principles to answer the question of whether people have a right to know the truth or not.

D2.1. A Case of Terminal Cancer

Recently, cancer has been the leading cause of death in many developed countries. In cases of terminal cancer, both family and health professionals are faced with the problem of whether or not to tell the truth about the gravity of the situation to the patient. In clinical practice, the question goes beyond “whether” but also includes “when”, “how” and “how much” to tell patients about their diagnosis, treatment choices and possible prognosis. These questions have troubled doctors especially when they try to apply the principle of “doing good” to their patients.

Most people agree that terminal patients have a right to be well informed about their situation. Moreover, most agree that these patients have the autonomy to make decisions for themselves about medical treatment and other issues involving the end-of-life. Nevertheless, a value commitment toward openness has not been achieved in the general population. The most common reason for not telling the truth is the intention to protect dying persons from being harmed by knowing. But in order to address the real interests of terminally-ill cancer patients, we need to clarify various issues and to find a balance between “doing good” and “do no harm”.

The Case of Mr. G

Mr. G, a mentally competent 70 year-old man, was diagnosed with invasive bilateral lung cancer with pleural effusion and bony metastasis a few days after he was sent to the hospital. The doctor gave the diagnosis and explained Mr. G's situation to his family. According to the doctor, Mr. G had about six to twelve months more left to live. Since Mr. G was already in the late stages of his cancer, the doctor did not recommend surgery. Due to the request of the family, the doctor prescribed chemotherapy even though it had very little chance of succeeding. Furthermore, due to the insistence of the family, Mr. G was kept unaware of his condition. Mr. G was a little bit nervous about his condition, while everyone in contact with him was warned not to tell him the truth and to avoid any conversation concerning his condition.......

Collaborating author: Dena Hsing-Chen Hsin, Taiwan

Q1: How would you feel if you were Mr. G?

D2.2. Awareness of dying

In the hospital, we can see four different levels of awareness as first described by Glaser and Strauss (1965), by which patients with life-threatening illness perceive their situation.

Closed awareness – nurses, doctors and family try to hide the truth and engage in conversations that avoid disclosure. They keep conversations to the minimum and steer away from talking about the future, especially when the patient is in the very advanced stages of cancer. Nevertheless, the patient may become suspicious or even become fully aware of the situation at a latter stage.

Suspicion awareness – a situation where the patient begins to suspect the seriousness of his or her condition. The patient may attempt to confirm his suspicion by direct or indirect measures, such as sneaking a look at medical records, or making direct requests from hospital staff or family. Such behavior thus makes families and hospital staff adopt different strategies in response. As a result, relationships among the patient, the staff and the family become strained.

Mutual pretence – this happens at a later stage when everyone (staff, families, even the patient), knows that the patient is dying, but chooses to pretend that the patient is going to be all right. The dramas between them could last for a long time; as a consequence the patient will die without ever knowing the truth from family or medical staff, although they may have full awareness of their condition.

Open awareness – this results from when staff, families and patient know and choose to acknowledge in their actions that the patient is dying. This situation is by no means an easy one; however, it is an essential requisite to achieve the patient's 'appropriate dying' expectation especially when their expectation is ambiguous and uncertain.

Looking at the four levels of awareness in a dying patient gives us much insight on how people communicate and interact with the dying. In Mr. G’s case, the hospital staff followed the request of the family to hide the truth from him. He may constantly stay in closed awareness before he dies. But more likely, he would move to either suspicion awareness or to full open awareness of his diagnosis at the latter stage. The question of whether he should have been told or not and the question of how he faces his growing awareness of his approaching death are just some of the ethical and social issues that can be seen in this case.

Q2. Would you like to know if you had terminal cancer? Would you tell your mother or father if they had terminal cancer?
D2.3. What will happen if we continuously withhold the truth?

Let’s look at Mr. G again….

First, to be deceived into believing that he is all right, Mr. G will never have a chance to make choices about his medical treatment and care. Second, with limited conversation and interaction, Mr. G may feel that he is being isolated or even being abandoned. He may have sensed his physical decline and felt distress but could not share his fears and anxieties with others. Third, it will be impossible for him to accomplish what he wants before he dies. Finally, there will be a serious breach of trust, which challenges the relationship between health care professionals and patients. Mr. G will probably either be suspicious or fully aware that people "lied" to him. He may choose to pretend he does not know just to go along with what his family wishes. He may feel more distressed from the “kind intentions” of his family than if he had been told the truth in the first place.

Q3. How would you feel if you found out on the last day of your life that your family had not been telling the truth to you about your disease?

Q4. How would you spend the last week of your life on earth? What would you do? Where would you go? Who would you see?

D2.4. The Pros and Cons - consequences of awareness

According to research, compared with people in “closed awareness”, people dying in a stage of “full awareness” are more able to plan their dying process. Thus they and their family are more satisfied with their choice of the nature and place of death. Those who know are less likely to die alone and are more likely to die in their own homes surrounded by family.

Pros: If death is certain in the near future, quality of life (QOL) should be the most important concern for the dying. Awareness of dying enables the patient to plan and to fix his affairs during the last stages of his life. It also offers an opportunity for him to control the manner and timing of his death. Fully informed, Mr. G can make his own choices about how he wants to be treated or cared for and who should administer the treatment or care. He may decide that chemotherapy is futile and he may also decide to refuse aggressive or life sustaining therapy. Instead, he may opt for palliative therapies to maintain the quality of his life and die in dignity. Mr. G can also try his best to accomplish his remaining goals in life. To avoid legal complications, he can also make arrangements on what to do at the end of his life as well as what happens to his body after death.

Cons: It is possible that telling the truth will destroy hope and lead to irreversible depression. After being told the truth, Mr. G may experience “shock”, “denial”, “anger”, “bargaining” or “depression”. He may probably need a lot of guidance, support and companionship before he can reach the stage of “acceptance”. He might have serious issues with the fact that his family insisted on not taking the risk of telling the truth at the beginning if told mid-way through the disease.

Some people believe requests for euthanasia (See Chapter D3) and the desire to die sooner are associated with awareness of the truth. In reality, those dying patients who are
aware of their condition are more likely to choose hospice care and are less likely to ask for euthanasia. The desire for death is mostly related to the levels of suffering and dependency experienced by the dying patient. These can be addressed and managed properly by modern palliative medicine like hospice care. If we believe that open discussion and rational decision making are key factors in achieving benefit from telling the truth; discussing the possibility of euthanasia should never be regarded as a negative effect of telling the truth.

D2.5. To Know or not to Know- Prevalence of dying awareness

Nowadays, more people have an open attitude towards life and death. The preference for open awareness of dying is being established in modern medical settings and among the general population. The rationale is that when a patient is aware of impending death, then he becomes free and exerts his right to autonomy to be able to decide what he wants from medical care and what to do with the rest of his remaining life.

However, this attitude of “open awareness” towards death varies in different areas and different situations. In many traditional oriental cultures, more people say that they prefer to stay unaware. In these countries, the family traditionally plays a more primary role in making medical choices for terminally ill patients. They feel more secure to give the right of decision making to a traditional source of authority like doctors or families. This attitude is different from modern western approaches where individual liberty is valued. This means that patients have a right to make choices about their medical treatment or care.

There is also a difference when we try to look at how people from different social classes engage in planning for their death. Physical realities are other important variables, and people with a condition of medical uncertainty or tending to have mental disturbance should consider very carefully disclosure of the "truth". In a medical situation such as this, the “truth” is often a percentage risk, which most people cannot fully calculate. We then have to realistically admit that it is not always possible for individuals to become aware that they are soon expected to die.

Even when the prevailing attitude valued by most contemporary societies is to be honest to patients, “open awareness” of dying is still hard to achieve in practice. However, in order to respect the principle of autonomy, both family and health professionals would need to agree that the patient both has a right not to know and a right to know about the truth of his own condition. This is not an easy dilemma to resolve and requires careful consideration.

D2.6. End-of-life medicine and truth telling

To accomplish the goal of a more peaceful end-of-life, modern palliative medicine has established the hospice model where the medical team shifts the goal of medical management of terminal patients from combating the disease to controlling symptoms, and improving QOL. In a hospice, while the patient may be dying they are always important and they will never be abandoned by the health care staff and their families. However, it in the patients’ best interests that they know they are dying in order to receive hospice care. Openness, honesty and hope are necessary to be able to have a peaceful dying process. Thus a prior commitment to openness and honesty is essential for nurses and doctors to offer hopeful palliative care. The biggest challenge for nurses and doctors facing palliative care is how to break the bad news
and at the same time not leave the patient in despair. The health professional’s communication skills and interaction with the dying patient then becomes crucial in carrying out the doctrine of truth telling.

We should not have any doubts about the justification of telling the truth to terminal patients. Telling the truth is also in line with a holistic and humanistic viewpoint that values the individual’s right to know. Not telling the truth not only brings sorrow and regret, but it also does not respect the principle of autonomy. However, we should be careful about how we tell the truth. Carelessly done, it could cause more damage. This goes against the principles of “do-no-harm” and “doing good”. Effective communication, sufficient support systems and good relationships among the dying, the family and health care providers are needed if we are to progress as a society that values truth telling as a necessary element for a good dying process.

Questions

Q5. Try to write a living will or advance directive (a document which says how you would like to be treated when dying).

Q6. Do you think you can make plans to negotiate your dying process only if you are fully informed of your terminal condition?

Q7. After reading the above chapter, can you discuss the benefits versus the risks of disclosure?

Q8. Does attitude towards telling the truth about terminal illnesses depend on culture? How about in your culture?

Q9. Is there such a thing as “good dying process” and “peaceful death”? How would you describe it? Is it something that individuals should strive for? How should society deal with this?

Q10. Should there be a consensus towards truth telling? Should there be universal standards (applicable to all countries) for truth telling? Who should decide these standards? Who could administer it?

Q12. What is death with dignity? Why is that valued in present society?
D2.7. An Introduction to Hospice Care

Hospice is a concept of care designed to provide comfort and support to patients and their families when a life-limiting illness no longer responds to cure-oriented treatments. The first Hospice began in the early 1960's when a British physician, Dr. Cicely Saunders, created St. Christopher's Hospice near London. With special emphasis on pain management and other symptom control, hospice care can reach the goal of peaceful end of life by offering comfort and dignity to the dying patient.

Hospice care is usually provided by a team of specially trained professionals like nurses, doctors, social workers, dieticians and religious priests or counselors. Volunteers and family members are also very important in hospice care. Everyone works together as a team to provide physical, emotional, psychological and spiritual care to the dying patients and their families. Since hospice focuses on caring, not curing, hospice care services are usually provided in the patient's home or care facilities other than the acute hospital setting. One consequence of hospice care is a reduction in health care costs.

In general, a patient can only enter a hospice program if he is certified by a physician to have a limited life expectancy, usually six months or less. However, to respect the patient's autonomy, health care professionals will need to agree with the patient’s desire for a resumption of traditional care at any stage in time. Furthermore, an individual's needs must be continually assessed and treatment options should be explored and evaluated in the context of the individual's values and symptoms.

With all these descriptions of the palliative medicine model of hospice, we may come to realize that the basis of hospice and palliative care is the belief that each of us has the right to die pain-free and with dignity, and that our families will receive the necessary support to allow us to do so. In accordance with this, it is obvious that to offer ideal hospice care without a prior commitment to openness and honesty is not possible.

What can hospice care provide?

- Management of the patient's pain and symptoms
- Assistance in the emotional, psychosocial and spiritual aspects of dying
- Provision of needed drugs, medical supplies, and equipment
- Coaching the family on how to care for the patient
- Special services like speech and physical therapy when needed
- Short-term in-patient care when pain or symptoms become too difficult to manage at home, or when caregivers need time-off
- Counseling and care to surviving family and friends
D3. Euthanasia

Chapter objectives
Euthanasia literally means 'good death' and generally aims to hasten the death of people who suffer severely without any hope of recovery.
This chapter aims to introduce:
1. The development of policy in the Netherlands, which was the first country in the modern world to make euthanasia not a crime.
2. The conditions under which assisting the death of a terminally ill patient may be ethical, as many countries face this policy question.

D3.1. What is euthanasia?

Another word for euthanasia is mercy killing. Euthanasia has been a very controversial subject at periods over the past 3,000 years. Some people regard it as a morally objectionable form of killing. In some forms of Buddhism, euthanasia is rejected because ending life is thought to be wrong at any time. Many Christians oppose euthanasia because the Bible regards human life as sacred and as belonging to God. According to this view, euthanasia is wrong, as it is not up to humans to decide over life and death. But different people interpret their religious traditions in different ways.

The act of euthanasia is today understood as termination of life on request. But it has not always been a voluntary choice. The decision to terminate life has been misused during human history, especially between 1933 and 1945 during the German Nazi regime in Europe. This criminal regime murdered millions of people because they were disabled, ill, old, or of different ethnic group. Murders committed for these reasons were also called “euthanasia”. The Nazi regime excused their criminal deeds as termination of worthless lives. Such an excuse is against the humane nature of love and compassion. The crimes committed in the past are one of the reasons why euthanasia, also understood as termination of life on request, is a criminal act in almost all States of the world. The Netherlands has made euthanasia legal, though it is still controversial there, and in this chapter some of those debates will be used to explain euthanasia.

Q1. Do acceptable forms of killing humans exist?
D3.2. The legal development of euthanasia in the Netherlands

Though the practice of euthanasia is much older, the Dutch euthanasia law has a history of legal development and contention since the 19th century. The euthanasia law in the Netherlands must be seen in its historical background of attempts at protecting physicians that act in the spirit of the law and in the interests of the patient.

Before 1990, physicians risked prosecution, but then the Royal Dutch Medical Association and the Ministry of Justice agreed upon the procedure of notification. This meant that prosecution became unlikely if a physician followed the guidelines set out in the non-prosecution agreement between the physician and the patient.

Q2. Where is the Netherlands? What religion do people there have?

D3.3. The concept of euthanasia

According to the authoritative 1991 study in the Remmelink report, euthanasia is defined in the Netherlands as follows: 'deliberately terminating the life of another person at his or her request'. It differs from other categories used in Dutch health care institutions:

- **Assisted suicide** is defined as 'deliberately assisting a person in a life-terminating act at his or her explicit request'. It is different from voluntary euthanasia which does not support every purpose in the act of self-destruction;

- A **life-terminating act without an explicit request** is defined as 'deliberately terminating the life of a person without his or her explicit request'. It is different from voluntary euthanasia in that it is not based on a well-considered, persistent and explicit request from the patient;

- **Active euthanasia without an explicit request from the patient** differs from voluntary euthanasia as it is not based on a well-considered, persistent and explicit request from the patient;

- **Indirect euthanasia** is known as 'Death resulting from the administration of opiates and other painkillers in large doses';

- **Passive euthanasia** or abstention is defined as 'Death resulting from the withholding or withdrawal of potentially life prolonging treatment'.

In the official definition, the termination of life at the request of the patient is central to the decision to terminate life in the case of voluntary euthanasia. The above definitions are similar to those used internationally in bioethics.

D3.4. The decriminalisation of euthanasia

In the Netherlands voluntary euthanasia has been decriminalised. The decriminalisation of euthanasia made the Netherlands the first country in the world to formally sanction "mercy killing".

In the new law euthanasia is administered only to patients who are in a state of continuous, unbearable and incurable suffering. There are other requirements as well:

- A second opinion from an external physician;
- The patient must be judged to be of sound mind; and,
- A request to die must be made voluntarily, independently and persistently.

The patient must be terminally ill with physical suffering. However, the physicians are not supposed to suggest it as an option. Both an oral and written request legitimise the physician to accede to the request, however, the physician is not obliged to do so. He or she may only accede to the request while taking into account the due care-requirements mentioned in the bill. In each case the doctor must be convinced that the patient is facing interminable and
unendurable suffering. If he or she believes that this is not so, the physician may not accede to the request for euthanasia, no matter what the declaration of will states.

It is important to note that euthanasia and assisted suicide continue to be criminal offences, but are decriminalised in certain circumstances. The Dutch Penal Code (in Articles 293 and 294) now includes that provision. It stipulates that the termination of life on request and assistance with suicide are not treated as criminal offences when carried out by a physician and if criteria of due care are observed. Therefore the view that euthanasia and assisted suicide are no longer punishable does not reflect the substance of the bill correctly.

**Q3. What is the meaning of decriminalisation? Is euthanasia in the Netherlands legalised?**

**Q4. Under what conditions is euthanasia practised in the Netherlands?**

**Q5. What are the legal requirements?**

D3.5. Activity: Three Case-studies
The following discussion of court cases illustrates the centrality of the meaning of the defence of necessity in the developments that led to the decriminalisation of euthanasia in certain cases. Read the three cases below and think of arguments for and against the view that the physician acted rightly.

**Q6. How are the cases different from one another?**

**Q7. Do you agree that 'defence of necessity' applies?**

1. **The case of Geertruida Postma**
   
   In 1971, Dr Geertruida Postma injected her mother with morphine and curare, resulting in the patient's death. On a number of occasions the patient had asked her daughter to end her life. She had suffered a brain haemorrhage after which she could hardly speak, hear, and sit up.

   Dr Postma was charged under Article 293 of the Dutch Penal Code. In 1973, the Leeuwarden criminal court found Dr Postma guilty but only ordered a one-week suspended sentence and one year's probation. The court indicated that the physician could administer pain-relieving drugs leading to the death of the patient in certain circumstances, provided the goal of treatment was the relief of physical or psychological pain arising from an incurable terminal illness. In this case, however, Dr Postma's primary goal was to cause the death of the patient.

   In the same year, the Royal Dutch Medical Association (KNMG) issued a statement supporting the retention of Article 293 but arguing that the administration of pain relieving drugs and the withholding or withdrawal or futile treatment could be justified even if death resulted.
2. The case of Mrs Schoonheim

The 1984 Alkmaar ruling by the Dutch Supreme Court concerns Mrs Schoonheim, a 95-year old, bedridden patient, who had been unable to eat or drink and had temporarily lost consciousness shortly before her death. The patient requested euthanasia from her doctor, who consulted with another physician who agreed that the patient was unlikely to regain her health.

The point here is that the patient was suffering from a chronic and not a terminal illness. The doctor in charge was convicted by a lower court and the Court of Appeals of an offence under Article 293 of the Dutch Penal Code, although no punishment was imposed. On appeal, the Supreme Court overturned the conviction, holding that the doctor was entitled to succeed in the defence of necessity under Article 40. The Court decided that the doctor had properly resolved the conflict of interests involved.

3. The Chabot case

The so-called Chabot case led to a breakthrough in relation to the defence of necessity. A fifty-year old patient, Mrs Netty Boomsma, had a long history of depression, a violent marriage and her two sons had died, one by suicide and one of cancer. Her suffering was mainly psychological. Upon the death of the second son she decided to commit suicide and approached the Dutch Federation for Voluntary Euthanasia, who referred her to Dr Boudewijn Chabot. Dr Chabot diagnosed her as suffering from severe and intractable mental suffering. He consulted a number of his colleagues, though none of them examined Mrs Boomsma in person. In September 1991, Dr Chabot assisted Mrs Boomsma to commit suicide by prescribing a lethal dose of drugs. He reported her death to the public coroner.

Dr Chabot was prosecuted under Article 294 of the Dutch Penal Code. He sought to invoke the defence of necessity. Importantly, the Supreme Court held that there was no reason in principle why the defence of necessity could not apply where the cause of a patient's suffering is psychological. However, the court held that for the defence to apply the patient must be examined by an independent medical expert. Dr Chabot had sought medical opinions from seven colleagues but none had actually seen Mrs Boomsma. Accordingly, the defence of necessity failed. In June 1994, Dr Chabot was found guilty of an offence under Article 294. The Supreme Court declined to impose a penalty, although in February 1995 Dr Chabot received a reprimand from a Medical Disciplinary Tribunal.
D3.6. Social and political issues concerning euthanasia

A wide range of critical views have been and are still expressed against euthanasia and assisted suicide. Euthanasia is applied only when we can speak of unbearable and hopeless suffering. Is a death wish voluntary under circumstances of unbearable and hopeless suffering?

Some critics argue that instead of killing the patient, the patient should be made to feel better. Requests for euthanasia may be a result of depression and confusion, a feeling of worthlessness, or due to persuasion of interested parties with ulterior motives. Prompted by the Chabot case, a group of Dutch authors wrote a pamphlet named *Scared to Death by Life*. The authors argued that human freedom is regulated not only by rational thought, but also by emotions and unconscious motives. The authors doubt that the physician-patient relationship is always characterised by free and rational decision-making in end-of-life matters.

One must take into account the patient's feelings of guilt, anger and inadequacy, and the possible motives of the physician, such as hunger for power, and rescue fantasies. Moreover, social determinants such as prevailing regulations, the public debate and the availability of palliative care in hospitals and homes for the elderly, also put to question the meaning of 'voluntary' in end-of-life decision-making.

According to critics of euthanasia legislation, euthanasia and assisted suicide are not about giving rights to the person who dies but about changing public policy so that doctors or others can directly and intentionally end or participate in ending another person's life. Opponents fear that an increasingly lenient legal definition of mercy killing could make euthanasia commonplace, and render it inappropriate to deny euthanasia of babies or the mentally incapacitated.

The notion that the decriminalisation of euthanasia leads to more acts of life termination must be dealt with seriously. Examples of such practices include the administration of lethal drugs to shorten the life of persons unable to request it, and the assistance with suicide in the cases of psychiatric patients and elderly persons who currently are not suffering at all but who do not wish to continue living. This so-called slippery-slope effect is feared to lower the threshold at which human life is valued, and to make it easier for physicians and society at large to give up the life of the patient. This fear alone, it could be argued, even if not grounded on facts, may cause grave harm to the mental well being of the Dutch elderly and society as a whole. Nevertheless, the opposite argument, that an increased openness and awareness about euthanasia and practices of life-termination could give an enhanced sense of control-over-life to the fearful, would imply an increase in the sense of well-being of society as a whole.

**Q8. Should euthanasia and assisted suicide be regarded as a private or as a public matter?**

**Q9. Do you think that the slippery-slope effect applies to the Netherlands? Would it apply in your country?**
D4. Brain Death

Chapter objectives
Modern life sustaining technology sometimes leaves persons in the state of brain death, which required societies to reconsider the definition of death and ways to diagnose it.
This chapter aims to introduce:
1. What is brain death?
2. How the diagnosis of brain death is understood by different members of a family.
3. Use of role play to illustrate the difficulty to understand technical medical information by the public.

D4.1. Read the following story and consider how you would feel if you were Roya.

It was 4:30 pm on Saturday, the 7th of August. It was a very hot day. Roya was the only one at home. Her parents were at their neighbor's (Mr. Maleki) home to visit the wife who was suffering from heart disease.

The phone rang...
"Is this Mr. Abai`s home?"
"Yes."
"May I talk to your father or mother please? I am calling from the Central hospital"
"Sorry they are out."
"Would you please give me his mobile phone number?"
"Ok, just a moment."

It was late at night but her parents and her brother had still not come home yet. It was the first time that Roya was home alone. She was about to call her father when the door bell rang. Excitedly she rushed to the door. Her father was alone and looked very upset. She had never seen her father like that before.

"Why are you alone, daddy? Where's mom? Where's Ali?"
"What happened?"
"They are at the hospital," he replied trembling with tears in his eyes.
"Why are both of them at the hospital?"

Roya knew that her brother Ali had gone cycling with his friends this morning. But why were they at the hospital? Shouldn't they be at home by this time? Roya was getting more nervous.
as these thoughts ran through her mind. Anxiously, she was conscious of every change of emotion going through her father's face. Why? Why? Why? Over and over, she asked herself...trying to make sense of her father's somber mood. In a soft, trembling voice, her father almost whispered...

"Ali had an accident. Your mom's looking after him."

At that moment, it was as if Roya's entire world had gone to pieces.

"Dear child, don't cry....there is nothing that we can do."

After what seemed like centuries of pain and sorrow....exhausted, with no tears left to cry, Roya went to bed.

Dawn of another day
A letter

Roya dearest,
I have gone to the hospital. Don't worry. I'll be back by noon

Love, Dad

Roya waited and waited and waited.

The door
Father
"Dad, dad, dad....", Roya rushed into her father's arms.
"Roya, my sweet child."

And they stayed that way for a moment, silent and calm before the storm...
"Ali's still sleeping. Nothing has changed. My beautiful boy, unconscious, lies on that white bed..."
"Unconscious?"...a word she had never heard before.
"I want to see Ali. Please take me with you! Please!"

At the Intensive Care Unit
Her mom
A crying stranger, looking through the window... a far-cry from the happy, smiling mom that she knew.....through that thin piece of glass...her brother.

Ali?
"My brother?"... surrounded by strange instruments, a tiny tube in his nose, a thick one in his mouth and other things attached to his head and body. That mass of humanity that was Ali was silent and still as a log.

"No.no. no....that's not my brother. Ali... !!!", hysterically Roya started shrieking, sobbing...pounding her little fists on the glass. Suddenly, like a rabid dog, she turned to her father..." What happened to him? What did they do to my brother?", she shouted as she started hitting herself...to take away pain by giving pain.

Blankness

The waiting room
A man in white

"Mr. and Mrs. Abai. I am sorry to tell you. But we have been observing your son's critical condition since last night. We did whatever we could do to save his life. And I am very sorry to say that your son is in a state of brain death."

Brain dead, brain dead, brain dead... words floating in her shocked mind.

"Is there any hope for my son's recovery?"

Recovery, recovery, recovery...

They stared at the doctor's face, looking for a glimmer of hope.

"Unfortunately, there is nothing we can do. There is no treatment for brain death.", offering no hope, the doctor could only lower his face and stare at the floor.

Hearing these words Mrs. Abai cried in pain

Lost in a haze, Roya asked,

"What does brain death mean? My brother, Ali, when is he coming home?"

They stopped and looked at her.

The man in white

"Ali had an accident when he was coming back home yesterday. He crashed into a cement block and suffered from severe head injury and trauma."

"But my brother wears a helmet..."

"According to his friends, Ali wasn't wearing one at that time. His helmet was in his bicycle bag."

"My child, calm down... Nurse, nurse, Please take Roya to the canteen and get her some ice cream."

Three adults

"It has been 24 hours since his accident. He is still under observation. And we will do whatever we can. But all the medical tests show that his cortex and brain stem cells have no activity. Although his heart is functioning, he is completely dependent on a ventilator for breathing"

"We do not understand," Mr. Abai replied.

"Just tell us... is he alive? Will he be able to move? ... to talk? Will he be able to have a normal life?"

"Unfortunately, there is no treatment for brain death. And we can do nothing to bring your son back."

"Is my son the first one to suffer from this condition? Please do something, anything..."

"I'm afraid that your son is neither the first or last person to become brain dead. I'm sorry we can do nothing. There is nothing else we can do."

"Nothing."

"Yes, nothing. I'm sorry to bring this up during your time of sorrow, but we have to ask you to make an important decision about your son. We can not do this by ourselves"

"What kind of question is that?" Mr. Abai barked angrily.

"I am a teacher and what I know is how to teach Mathematics, you are a doctor you should know and decide!"

"I understand Mr. Abai", replied the Doctor.

"You and your wife are in a very shocked and emotional state. I know it is not easy to make a decision at this time. Please read this so that you can understand better what I am trying to tell you."
A pamphlet…

"What is Brain Death?" The Anatomy of the Brain

The brain consists of two parts: the higher brain and the lower brain. The higher brain includes two hemispheres and the Cerebral Cortex. It is responsible for several higher functions, including intellectual function, speech and emotion. The lower brain includes the Brain Stem, which is the final pathway between cerebral structures and the spinal cord. It is responsible for a variety of automatic functions, such as control of respiration, heart rate and temperature.

A moment that seemed like eternity

"I'm sorry, I can't read this just now. What does it mean?", a distraught Mr. Abai said.

"In your son's current state, unfortunately, his brain cells, cortex as well as brain stem, are dead and have no function. Therefore, as you can see, he can neither move nor talk. Even his respiration is dependent on the ventilator. If we turn the ventilator off his heart will stop too."

"Do you mean he is dead now? But his heart is pumping and his body is warm!"

"That is what I was trying to say, you should decide because there are a variety of opinions and each country has its own regulations to deal with brain dead patients."

"You told us that my son is not the first brain dead patient here. What happened to the others?"

It was a very difficult situation. The kind of situation where there were no clear, cut answers. The kind of situation that called for a change of scene, some fresh air to breathe...a stagnant silence followed.

In the end, they could only stare at each other...

In a different place but not a different time

Roya, desperately hanging on to her innocence, painting images of her brother...

"Ali is the smartest and best brother in the whole, entire world. He attends university, you know. He is so kind. He helps me with my mathematics problems."

Reality

Questions

Q1. Describe how Ali's father, mother, and sister (Roya) reacted to Ali's accident. How would you respond?

Q2. Brain death is one of the ways to recognize death. In most countries people would just be told Ali was dead. Is brain death a confusing term?

Q3. How well did the doctor explain Ali's medical condition?

Q4. Each person may think they are doing the best in the situation, but they may not be. Ali's father tried to protect Roya, but where would you want to go if your family member was taken to hospital? How does culture affect this?
D4.2. What is brain death?

Brain death is defined as the irreversible loss of all functions of the brain. Although diagnosis of this condition varies country to country in general it can be determined in several ways. First - no electrical activity in the brain; this is determined by an EEG. Second - no blood flow to the brain; this is determined by blood flow studies. Third - absence of function of all parts of the brain - as determined by clinical assessment (no movement, no response to stimulation, no breathing, no brain reflexes.)

The criteria may be legally applied in some conditions, with exclusions for persons who are very young, in drug overdose, or whose bodies are very cold, because of the reliability of the criteria. There are also other conditions, like locked in syndrome, persistent vegetative state or coma which is distinct from brain death, because the persons in those states are alive. Sometimes writers and the media get confused.

There are several ways in which a person can become brain dead, these include:
- Anoxia caused by drowning, respiratory diseases, or drug overdose.
- Ischemia - Blockage of an artery leading to the brain or in the brain, heart attack (stoppage of the heart for a period of time), bleeding in the brain.
- Intra-cranial hematoma - caused by a head injury (a blow to the head) or a ruptured aneurism.
- A gunshot wound to the head - causes destruction of brain tissue and swelling of the brain.
- Intra-cranial Aneurysm - the ballooning of a blood vessel supplying the brain - can cut off blood supply or rupture.
- Brain tumors - can destroy brain tissue and increase pressure within the brain.

When any of the above occur, they cause swelling of the brain. Because the brain is enclosed in the skull, it does not have room to swell, thus pressure within the skull increases (this is "intra-cranial pressure"). This can stop blood flow to the brain, killing brain cells and causes herniation of the brain (pushing the brain outside of its normal space). When brain cells die, they do not grow back, thus any damage caused is permanent and irreversible.

A persons' heart can still be beating because of the ventilator and medications helping to keep the blood pressure normal. In most countries of the world a person who is declared brain dead is legally dead. Japan is one exception, and leaves the decision up to the person's prior expression on the organ donor card, with their family's agreement.

Q1. If you could transplant brains between two bodies would you call that a brain transplant or a body transplant? In other words, does your personality rest inside your brain or in your body?

Q2. Discuss the function of the brain and central nervous system. Look at a picture of the brain, and identify the different regions along with their functions.
D4.3. Death definition and brain death diagnosis

In many countries death is defined as the irreversible cessation of circulatory and respiratory functions or the irreversible cessation of all functions of the “entire brain, including the brain stem”. Brain death is defined as the irreversible cessation of the whole brain functions. In India (The Transplantation of Human Organ Act 1994) the law recognizes “brain stem” death as human death and it is defined based on irreversible cessation of brain stem functions. Japanese law introduces two alternative definitions for human death and gives opportunity to the individuals to choose the definition of death either traditional definition or brain-based definition based on their own views.

In many countries the law requires establishment of a “Brain death determination committee” to confirm the diagnosis of brain death. The members of the diagnosis committee should not be a member of transplant team.

**Picture of the human brain**

Q1. Consider your own understanding of "Life" and "Death", and discuss these in small groups.
D5. Organ Donation

Chapter objectives

The transplant of tissues and organs between persons has developed since the 1960s, and in many countries organ donation is a question asked routinely when individuals apply for a driver's license.

This chapter aims to introduce:

1. The types of laws used to regulate organ donation.
2. The ethical issues associated with organ transplants.
3. The type of counseling given to the donors' family regarding organ donation from a brain dead body.
4. Use the role play to illustrate the dilemmas surrounding a heart transplant, and ask whether recipients should be able to know the donors' family.

D5.1. A Review of Organ Transplantation Laws

Legal tools are a necessity in organ procurement to allow transplant surgeons to remove organs from potential donors. Uses of new life-saving technologies vary across cultural and socioeconomic backgrounds. Therefore a variety of capacities exist in terms of expertise, legislation, access to sophisticated transplant facilities and the economic affordability of organ replacement therapy.

In Asia different cultural and religious backgrounds which influence social acceptance of transplant technology draw a different picture. In some countries the organ transplantation law did not increase the organ retrieval rate but actually decreased the number of transplantation cases. For example, in Korea before the enforcement of the current law (Organ Transplantation Law 2000), 162 cases were diagnosed as brain dead in the year before, but only 43 cases were diagnosed in 2003.

Unlike most Western countries, in many Asian countries there is an age limitation for organ donation after death. For example while organ removal is prohibited from children under fifteen years old in Japan, this age is sixteen years old in Korea. In India, Turkey, Saudi Arabia and the Philippines the ages are eighteen years old and in Singapore is twenty one years old. Although there is an age limitation for organ removal from children, in order to save other children lives who need to receive an organ, in many countries (except Japan) the law allows parents to get permission for organ donation based on the best interest of their beloved ones.

Q1. What do you think about children who need to receive an organ, while the law prohibits organ removal from children even based on their parent’s consent?

Collaborating author: Alireza Bagheri, Iran/Japan
Q2. In your country what is the minimum age that people can donate their organs?

D5.2. The issue of consent

In some countries regulations for organ transplants are different. Donor consent has been recognized as a necessary for organ donation in all these laws. In many countries if there is no document to show deceased willingness for organ donation, the family can permit organ removal based on their beloved one’s interest. Donor card and living will are documents to show donor’s willingness for donation. Individual who wants to be an organ donor after her/his death can sign such document.

In Singapore (Human Organ Transplant Act, 1987/2004) an opting out system has been applied which means the designated officer (a medical practitioner) of a hospital may authorize, in writing, the removal of any organ from the body of a person who has died in the hospital for the purpose of the transplantation except from an individual who has during his lifetime registered his objection to the removal of the organ from his body after his death. In other words an individual who won’t be a donor after his death should fill out an objection form. (Singaporean Muslims are exempted from opting out system).

In Japan a donor card signed by individual as well as her/his family has validity for organ removal (a double signed card), and individuals can choose “not to donate” at the back of the donor card. In other countries although the attempt should be made to obtain the family agreement, donor consent alone is legally enough. In Iran (Organ Transplantation Act, 2000) oral consent confirmed by one of the family member in writing is accepted. In Turkey also oral consent is accepted.

D5.3. Surrogate decision making

In Asian countries, family surrogate decision making by the family when an individual has not left any document, either willingness for organ donation after death or any objection, has been recognized. The Japanese organ transplantation law (The Law Concerning Human Organ Transplants, 1997) is an exception to this. In other words Japanese parents can not be as surrogate decision maker for their children in case of organ donation. In some countries like, the Philippines, India, and Saudi Arabia in case of unclaimed body after forty eight hours failing to locate a family member, surrogate decision making has extended to the official authority.

It should be noted that in organ transplantation laws in many countries, it is not clear that within a family, who has authority to give permission for organ donation.

D5.4. Organ removal from living donors

In some countries living donation can be performed only if the recipient is a near relative. In Singapore as for living organ donation, written authorization of the transplant ethics committee of the hospital and donor consent in writing for the removal of the specified organ from his body are necessary.

In Saudi Arabia (Regulations of organ transplantation, 1994), and Malaysia, living organ donation is limited to genetically relatives. While in Malaysia, organ donation to spouse is accepted, in Saudi Arabia, before performing living related transplantation the relationships between donor and recipient should be attested by an official organization.
In some countries if recipient is not a near relative, human organ can be removed and transplanted with the prior approval of the authorization committee.

In Iran in order to prevent organ trade, in case of living donation, donor and recipient should be compatriot. In case of living donation in Turkey, (Turkish Organ and Tissue Transplantation, 1979) doctors are obliged to inform the donor’s spouse as well. In many countries if donor and recipient are not relatives their name should not be disclosed.

Only in the Philippines (Organ Donation Act of 1991), there is an international sharing of human organs and tissues. Sharing of human organs or tissues shall be made only through exchange programs duly approved by the Department of Health, provided, that foreign organ or tissue bank storage facilities and similar establishments grant reciprocal rights to their Philippine counterparts to draw organs or tissues at any time.

In some countries there is a guideline to select the recipients. For instance in Singapore there is a priority setting for selection of the proposed recipients which a person who has not registered any objection for organ donation with respect to that organ, shall have priority over a person who has registered an objection.

Q3. Did anyone you know ever receive a blood transfusion, or donate blood? (Blood is a renewable organ, which makes it different to many organs).

D5.5. Incentives for organ donation

In Japan there was an initiative by a leading transplant surgeon as “Thank you fund” to provide payment to the families of organ donors. This initiative has been criticized by other doctors and no longer practiced.

In Iran a non governmental organization (NGO) is responsible to present a certain amount of money as a social gift to the kidney donors.

In Singapore an organ donor has priority to receive an organ if s/he becomes a case in need for an organ. It can be consider an indirect incentive for organ donation.

Q4. Do you think that organ donors should be rewarded?

Q5. Do you think organ transplant recipients should be able to thank the donor's family? Can you think of any problems of doing so?

D5.6. Read the following story and consider how you would feel if you were in the Abai family or the Maleki family?

It was Sunday afternoon, the 8th of August. Mr. Maleki was at the pharmacy to purchase some drugs for his wife who was suffering from severe heart disease.

His mobile phone rang,
"Mr. Maleki, I am Jahed the coordinator from Teheran University hospital."
"Hello Jahed."
"I just want to make sure that you are in the city, because there is a possibility for your wife to receive a new heart. There is a matching donor, whose heart, the Organ Procurement Committee has decided to allocate to your wife from among the patients on the Waiting List. Fortunately all medical tests and HLA Typing also matched."
"Thank you so much Jahed", Mr. Maleki said, with tears of happiness, "But what shall we do?"
"Just be available and I will call you when the final decision is made. Please do not tell Mrs. Maleki because it is not sure yet and I do not want her to be told until we are sure. We are just in the process of getting consent from the patient’s family. I think your wife should come to the hospital tomorrow. I will call you again tonight."
"Thank you so much. I look forward to your call. Bye."
"Good-bye, Mr. Maleki."

Mr. Maleki came back home very happy but was not able to say why. His wife and his daughter were upset.
"What happened?", he asked, "Is something wrong?"
His daughter replied:
"Ali Abai, Roya's brother, had an accident. When I called Roya to go out together she refused and told me that Ali's condition was very bad and the doctor said that his brain cells have no function."
"What does it mean? Okay I will go to Mr. Abai's home", Mr. Maleki said.

At the Abai family home.
"Hi Roya, is your father home?"
"Hi Mr. Maleki", she replied with a low voice. "Come in, please, he is talking on the phone in another room."
"Welcome Mr. Maleki", Mr. Abai said with a very sad voice.
"Hello Mr. Abai. I was very sad to hear that Ali had an accident. Is he better now? We are very sorry that it happened…"
"Thanks, he is at the hospital and doctors have little hope for his recovery." He cried. "I just was talking to my cousin who is a doctor and he also confirmed what Ali's doctor has told us."
"I am very sorry, I don’t know what to say: it is a very hard situation. We pray for his recovery. If there’s any thing that I can do, please let me know."
"Please just pray for him."

Monday morning. 7:30.
Mr. Maleki asked his wife to get ready to go to the hospital.
"But did you forget? On Wednesday we have an appointment with my doctor not today."
"I got a call last night from the hospital. Your doctor asked us to go today."
"Did they say for what?"
"Let’s go. We’ll find out when we get there", Mr. Maleki said.
At 8:30 when they were leaving their house, they saw Mr. Abai and Roya who were also going somewhere and they greeted each other from their cars.

Central Hospital: The Abai family:
After visiting Ali, Mr. and Mrs. Abai, were guided into another room.
**A man came in and introduced himself as the** organ procurement coordinator.
"Thank you for coming, I am Jahed. I am very sorry about what happened to your dear son. We know how you must feel now and I hope you will allow me to talk more about his condition."
The Abai's could only nod to say yes.
"I think his doctor has already informed you that after the accident his brain lost its function and his breathing is now controlled by a **respirator**, a machine. In such circumstances a patient is in a brain dead state. Unfortunately, we can do nothing now and he will never recover. But there is something which I have to share with you. And forgive me to talk about it
in this very hard situation which you are in. There is a possibility of saving other lives by
donating some organs from Ali to transplant to some patients and to give them a chance to stay
alive."

Mr. and Mrs. Abai were quiet and listened.
"In our country according to the law for organ removal from these cases, a **Donor Card** or a
**patient's prior declaration to organ donation** is needed. As you have written in this form,
there is no written paper to show Ali's agreement or disagreement. The law does allow the
family to make a decision on behalf of their beloved ones based on his or her best interest.
Indeed, the family is the closest and the one guaranteed to be the **surrogate decision maker** in
this very important matter."

For Mr. And Mrs. Abai it was very hard even to hear such things and they felt they needed to
get fresh air. They asked to go out for a while.

Mr. Abai asked his wife with tearful eyes about her opinion. Mrs. Abai started,
"How can we, How,…it is Ali there, quite and silent, our dear son, only 23 years…"
"Do you remember", Mr. Abai said, "in a new year show on TV there was a program about the
patients who were on the waiting list for organ transplantation?"
"Yes", - she said after a while, - "but why are you asking about that?"
"Do you remember what Ali said after the show?"
"No. What kind of question you are asking!"
"I remember Ali was very impressed by the show and said: "It is so nice to be able to save
other lives..."
"Yes", she said after a while and cried…
They came in the room again.
"Jahed, we remember that Ali once said after seeing a television program that "It would be so
nice to be able to save other lives."
"Are you sure?", Jahed, the coordinator, said.
"Do you think that if Ali was able to talk, he would agree?", Mr. Abai asked.
"If you agree to organ removal, the surgeons can save some other lives and it is a great act of
love."

It was a very tough decision. They looked at each other and at papers given by the coordinator.
Being there was only increasing their suffering.
"What do you think?", Mr. Abai asked his wife.
"I hope Ali’s soul will be happy with this." Bursting to tears she left the room.

Mr. Abai signed the forms and went after his wife.

_Tehran University Hospital: The Maleki family_
Mr. and Mrs. Maleki were waiting to see Jahed, the **organ procurement coordinator**. A nurse
came and asked them to go to the doctor's room.
"I just got a call from the **Organ procurement unit** that they have allocated a heart to you.
Congratulations!" Her doctor said with smile.
"Thank you very much doctor", Mr. and Mrs. Maleki both replied.
"No you should thank the donor! You should be admitted right now for a **pre operation check
up**. I think we'll receive the heart tonight and schedule your operation for early tomorrow
morning."

It was late at night when Jahed came to see Mrs. Maleki in the hospital,
"The heart has been transferred to our hospital now."
He asked Mr. Maleki to sign some forms and wished them good luck.

**Tuesday night, Tehran University Hospital Intensive care unit:**
Mr. Maleki and his daughters and son were looking at Mrs. Maleki through a glass window. They were crying but all very happy. The doctor came in and said:
"Fortunately a very critical hour has passed and she is conscious now and we are very hopeful for her recovery."
"We do not know how to thank you doctor", Mr. Maleki and his children said.
"Don't mention it, as I said, the real thanks must be to the donor", the doctor replied.
"How can we thank the donor's family", Mr. Maleki asked.
"According to the regulation you cannot have contact."

**Two Weeks later:**
For the past three days Mrs. Maleki had been at home after being discharged from the hospital. She was still in her recovery period, with a little pain, but very hopeful and appreciates having a second chance for life, gifted to her by a heart donation from a brain dead patient. They were expecting the visit of Jahed the coordinator at 4 pm, coming to check Mrs. Maleki's condition. This morning, Mr. Abai also called them to say they will come around 5:00 pm to visit Mrs. Maleki.

At 4:00 o’clock, the phone rang and Jahed apologized for his delay and said he will reach there in an hour. At 5:00 Mr. Abai and his family came. Although after Ali's death, they felt much sorrow in their heart but they tried to show their happiness for her successful treatment by having a smile on their faces.
"Come in please, welcome", - Mr. Maleki said as he opened the door.
"Good afternoon Mr. Maleki".
"Thank you for your coming. What nice flowers", Mrs. Maleki said.

After a while Mrs. Maleki was talking about her operation and how painful the day after the surgery was. The door bell rang as Jahed arrived.

"Welcome Jahed, Welcome."

Mr. Maleki was about to introduce Mr. Jahed to his guests, but realized that the Abai’s and Jahed were very surprised to meet there. They seemed know each other from before. It was all quiet for a moment, it seemed as though time had stopped. The children were confused by the gazes that were exchange between their parents.
"Hello Jahed", Mr. Abai said.
"Hello Mr. Abai, Hello Mrs. Abai, it is nice to see you here, I did not know that you know Mr. Maleki."
"We have been family friends for a long time."
"That is nice, you are already familiar with each other, but how?" Mr. Maleki said.
"Yes …" Mr. Abai said. His way of looking at Jahed asked the question. Jahed, felt at a lost but telling the truth was inevitable.
"Yes Mr. Abai, Yes", Jahed said with helplessness.
Mrs. Abai was not able to control herself and burst to tears. Jahed knew that excitement was not good for Mrs. Maleki's health, then, by pointing with his eyes they all went into another room to talk.

After a few minutes, Mrs. Abai came in with smile and she put her ear on the chest of Mrs. Maleki, and said, from now when I miss my son I will come here to hear the sound of Ali's heart in your chest.

**Q6. What question did Mr. Abai ask through his look at Jahed?**
D6. Brain Death and Organ Transplant Drama

This drama is developed from the two chapters in the Bioethics Textbook on brain death and organ transplants, and includes the roles of the key actors and actresses. There is a power point file that can be downloaded from the website to show the main scenes. It is also possible as a student project to make their own role play for any of the bioethics cases, and their own power point presentations or posters, etc.

Cast: Narrator, Doctor 1, Doctor 2, Man in white, Roya, Father (Mr. Abai), Mrs. Abai, Jahed, Mr. Maleki, Mrs. Maleki, Ali (who is brain dead), Mr. Maleki’s daughter

Narrator: It was 4:30 pm on Saturday, the 7th of August. It was a very hot day. Roya was the only one at home. Her parents were at their neighbor's (Mr. Maleki) home to visit the wife who was suffering from heart disease.

The phone rang...

Doctor: "Is this Mr. Abai's home?"
Roya: "Yes."
Doctor: "May I talk to your father or mother please? I am calling from the Central hospital"
Roya: "Sorry they are out."
Doctor: "Would you please give me his mobile phone number?"
Roya: "Ok, just a moment."

Narrator: It was late at night but her parents and her brother had still not come home yet. It was the first time that Roya was home alone. She was about to call her father when

The door bell rang...

Father: "They are at the hospital" he replied trembling with tears in his eyes.
Roya: "Why are both of them at the hospital?"

Father: "Ali had an accident. Your mom's looking after him."
"Dear child, don't cry....there is nothing that we can do."

Narrator: Dawn of another day. A letter was left, "Roya dearest, I have gone to the hospital. Don't worry. I'll be back by noon. Love, Dad". Roya waited and waited and waited.

Roya: "Dad, dad, dad....".
Father: "Roya, my sweet child."
"Ali's still sleeping. Nothing has changed. My beautiful boy, unconscious, lying on that white bed..."
Roya: "Unconscious?"---.
"I want to see Ali. Please take me with you! Please!"

Narrator: At the Intensive Care Unit.
Roya: "No. no. no. no. that's not my brother. Ali…!!!"

"What happened to him? What did they do to my brother?"

Narrator: The waiting room.

Doctor: "Mr. and Mrs. Abai. I am sorry to tell you. But we have been observing your son's critical condition since last night. We did whatever we could do to save his life. And I am very sorry to say that your son is in a state of brain death."

Father: "Is there any hope for my son's recovery?"

Doctor: "Unfortunately, there is nothing we can do. There is no treatment for brain death."

Roya: "What does brain death mean? My brother, Ali, when is he coming home?"

Man in white: "Ali had an accident when he was coming back home yesterday. He crashed into a cement block and suffered from severe head injury and trauma."

Roya: "But my brother wears a helmet..."

Man in white: "According to his friends, Ali wasn't wearing one at that time. His helmet was in his bicycle bag."

"My child, calm down... Nurse, nurse, Please take Roya to the canteen and get her some ice cream."

Doctor: "It has been 24 hours since his accident. He is still under observation. And we will do whatever we can. But all the medical tests show that his cortex and brain stem cells have no activity. Although his heart is functioning, he is completely dependent on a ventilator for breathing."

Father: "We do not understand"

"Just tell us ...is he alive? Will he be able to move? … to talk? Will he be able to have a normal life?"

Doctor: "Unfortunately, there is no treatment for brain death. And we can do nothing to bring your son back."

Father: "Is my son the first one to suffer from this condition? Please do something, anything..."

Doctor: "I'm afraid that your son is neither the first or last person to become brain dead. I'm sorry we can do nothing. There is nothing else we can do. "Nothing."

"Yes, nothing. I'm sorry to bring this up during your time of sorrow, but we have to ask you to make an important decision about your son. We can not do this by ourselves"

Father: "What kind of question is that?" "I am a teacher and what I know is how to teach Mathematics, you are a doctor you should know and decide!"

Doctor: "I understand Mr. Abai". "You and your wife are in a very shocked and emotional state. I know it is not easy to make a decision at this time. Please read this so that you can understand better what I am trying to tell you."

Narrator: A moment that seemed like eternity.

Father: "I'm sorry, I can't read this just now. What does it mean?"

Doctor: "In your son's current state, unfortunately, his brain cells, cortex as well as brain stem, are dead and have no function. Therefore, as you can see, he can neither move nor talk. Even his respiration is dependent on the ventilator. If we turn the ventilator off his heart will stop too."

Father: "Do you mean he is dead now? But his heart is pumping and his body is warm!"

Doctor: "That is what I was trying to say, you should decide because there are a variety of opinions and each country has its own regulations to deal with brain dead patients."

Father: "You told us that my son is not the first brain dead patient here. What happened to the others?"
Narrator: It was a very difficult situation. The kind of situation where there were no clear, cut answers. The kind of situation that called for a change of scene, some fresh air to breathe...

Roya: "Ali is the smartest and best brother in the whole, entire world. He attends university, you know. He is so kind. He helps me with my mathematics problems."

Narrator: It was Sunday afternoon, the 8th of August. Mr. Maleki was at the pharmacy to purchase some drugs for his wife who was suffering from severe heart disease.

Jahed: "Mr. Maleki, I am Jahed the coordinator from Teheran University hospital."
Mr. Maleki: "Hello Jahed."
Jahed: "I just want to make sure that you are in the city, because there is a possibility for your wife to receive a new heart. There is a matching donor, whose heart, the Organ Procurement Committee has decided to allocate to your wife from among the patients on the Waiting List. Fortunately all medical tests and HLA Typing also matched."
Mr. Maleki: "Thank you so much Jahed", "But what shall we do?"
Jahed: "Just be available and I will call you when the final decision is made. Please do not tell Mrs. Maleki because it is not sure yet and I do not want her to be told until we are sure. We are just in the process of getting consent from the patient's family. I think your wife should come to the hospital tomorrow. I will call you again tonight."
Mr Maleki: "Thank you so much. I look forward to your call. Bye."
Jahed: "Good-bye, Mr. Maleki."

Narrator: Mr. Maleki came back home very happy but was not able to say why. His wife and his daughter were upset.

Mr. Maleki: "What happened?" "Is something wrong?"
Mr. Maleki's daughter: "Ali Abai, Roya's brother, had an accident. When I called Roya to go out together she refused and told me that Ali's condition was very bad and the doctor said that his brain cells have no function."
Mr. Maleki: "What does it mean? Okay I will go to Mr. Abai's home."

Mr. Maleki: "Hi Roya, is your father home?"
Roya: "Hi Mr. Maleki". "Come in, please, he is talking on the phone in another room."
Mr. Abai: "Welcome Mr. Maleki."
Mr. Maleki: "Hello Mr. Abai. I was very sad to hear that Ali had an accident. Is he better now? We are very sorry that it happened...."
Mr. Abai: "Thanks, he is at the hospital and doctors have little hope for his recovery."
"I just was talking to my cousin who is a doctor and he also confirmed what Ali's doctor has told us."
Mr. Maleki: "I am very sorry, I don't know what to say: it is a very hard situation. We pray for his recovery. If there's anything that I can do, please let me know."
Mr. Abai: "Please just pray for him."

Narrator: Monday morning, 7:30.
Mr. Maleki asked his wife to get ready to go to the hospital.
Ms Maleki: "But did you forget? On Wednesday we have an appointment with my doctor not today."
Mr. Maleki: "I got a call last night from the hospital. Your doctor asked us to go today."
Ms. Maleki: "Did they say for what?"
Mr. Maleki: "Let's go. We'll find out when we get there."

Narrator: At 8:30 when they were leaving their house, they saw Mr. Abai and Roya who were also going somewhere and they greeted each other from their cars.

Jahed: "Thank you for coming; I am Jahed, the organ procurement coordinator. I am very sorry about what happened to your dear son. We know how you must feel now and I hope you will allow me to talk more about his condition."

"I think his doctor has already informed you that after the accident his brain lost its function and his breathing is now controlled by a respirator, a machine. In such circumstances a patient is in a brain dead state. Unfortunately, we can do nothing now and he will never recover. But there is something which I have to share with you. And forgive me to talk about it in this very hard situation which you are in. There is a possibility of saving other lives by donating some organs from Ali to transplant to some patients and to give them a chance to stay alive."

"In our country according to the law for organ removal from these cases, a Donor Card or a patient's prior declaration to organ donation is needed. As you have written in this form, there is no written paper to show Ali's agreement or disagreement. The law does allow the family to make a decision on behalf of their beloved ones based on his or her best interest. Indeed, the family is the closest and the one guaranteed to be the surrogate decision maker in this very important matter."

Narrator: It was very hard even to hear such things and they felt they needed to get fresh air. Mr. and Mrs. Abai asked to go out for a while.

Mr. Abai: What do you think?
Mrs. Abai: "How can we, How...it is Ali there, quite and silent, our dear son, only 23 years..."
Mr. Abai: "Do you remember, in a new year show on TV there was a program about the patients who were on the waiting list for organ transplantation?"
Mrs. Abai: "Yes", - "but why are you asking about that?"
Mr. Abai: "Do you remember what Ali said after the show?"
Mrs. Abai: "No. What kind of question you are asking!"
Mr. Abai: "I remember Ali was very impressed by the show and said: "It is so nice to be able to save other lives..."
Mrs. Abai: "Yes"...

Narrator: They came in the room again.
Mr. Abai: "Jahed, we remember that Ali once said after seeing a television program that "It would be so nice to be able to save other lives."
Jahed: "Are you sure?" "Do you think that if Ali was able to talk, he would agree?" "If you agree to organ removal, the surgeons can save some other lives and it is a great act of love."

Mr. Abai: "What do you think?".
Mrs. Abai: "I hope Ali's soul will be happy with this."
Doctor 2: "I just got a call from the **Organ procurement unit** that they have allocated a heart to you. Congratulations!".

**Mr. and Mrs. Maleki**: "Thank you very much doctor".

**Doctor 2**: "No you should thank the donor! You should be admitted right now for a **pre operation check up**. I think we'll receive the heart tonight and schedule your operation for early tomorrow morning."

**Narrator**: It was late at night when Jahed came to see Mrs. Maleki in the hospital,

**Jahed**: "The heart is transferred to our hospital now."

"Good luck!"

**Doctor 2**: "Fortunately a very critical hour has passed and she is conscious now and we are very hopeful for her recovery."

**Mr. Maleki and his children**: "We do not know how to thank you doctor".

**Doctor 2**: "Don't mention it, as I said, the real thanks must be to the donor"

**Mr. Maleki**: "How can we thank the donor's family".

**Doctor 2**: "According to the regulation you cannot have contact."

* * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * *

**Narrator**: For the past three days, Mrs. Maleki had been discharged from the hospital. She is still in her recovery period, with a little pain, but very hopeful and appreciates having a second chance for life, gifted to her by a heart donation from a brain dead patient. They were expecting the visit of Jahed the coordinator at 4 pm, coming to check Mrs. Maleki's condition.

This morning, Mr. Abai also called them to say they will come around 5:00 pm to visit Mrs. Maleki.

At 4:00 o'clock, the phone rang and Jahed apologized for his delay and said he will reach there in an hour. At 5:00 Mr. Abai and his family came. Although after Ali's death, they felt much sorrow in their heart but they tried to show their happiness for her successful treatment by having a smile on their faces.

**Mr. Maleki**: "Come in please, welcome".

**Mr. Abai**: "Good afternoon Mr. Maleki".

**Mrs. Maleki**: "Thank you for your coming. What nice flowers".

**Narrator**: After a while Mrs. Maleki was talking about her operation and how painful the day after the surgery was. The doorbell rang.

**Mr. Maleki**: "Welcome Jahed, Welcome."

**Mr. Abai**: "Hello Jahed".

**Jahed**: "Hello Mr. Abai, Hello Mrs. Abai, it is nice to see you here, I did not know that you know Mr. Maleki."

**Mr. Abai**: "We have been family friends for a long time."

**Mr. Maleki**: "That is nice, you are already familiar with each other, but how?".

**Narrator**: They all looked at each other and asked the question...

**Mr. Abai**: "Yes …"

**Jahed**: "Yes Mr. Abai, Yes".

**Mrs. Abai**: From now when I miss my son I will come here to hear the sound of Ali's heart in your chest.

D7. The Heart Transplant

My name is Tom. Now, I am 12 years old and am a 6th grade pupil of an elementary school in New York City, USA. Last year at this time I was in poor health and had a weak body. I had been a very fragile boy since birth because I had a heart valve disease. So I could not do any exercises in the school. Dr. Smith, my family doctor, thought that I would not be able to grow up to be a man because I would die soon.

One day Dr. Smith said, "Tom, I have very good news for your health. The surgeon at the City Hospital told me that your health will become good by a heart transplant if we can get a donor for you."

A few weeks later, Dr. Smith called my parents and said to them to bring me to the hospital as soon as possible. We went to the hospital with my parents by a taxi. Dr. Smith said very seriously to me, "Tom, we found a donor for you at last." After listening to the possible benefits and risks, considering that I might soon die and had always been sick, we all thought I should have the operation. With my parent's consent, I underwent the heart transplant operation by the surgeon. My postoperative recovery was good and speedy.

Today, I am in good health and I enjoy jogging for 3 miles, every morning.

Q1. Do you think that heart transplants are useful for medical treatment?
   A: Yes or No.
   Why?

Q2. Do you think that the transplanted heart in Tom's body is in good health?
   A: Yes or No.
   Why?

Q3. Do you think that the transplanted heart is beating faster when Tom has been jogging for 3 miles?
   A: Yes or No.

Q4. Do you think that you would like to donate your heart if you suddenly die, or receive a new heart if it will save your life?
   A: Yes or No.
   Why?

_____________________________

Collaborating author: Mitsuo Saitoh, Japan
D8. SARS (Severe Acute Respiratory Syndrome)

SARS (Severe Acute Respiratory Syndrome) will go into the medical records as the first new panic disease that has swept international society in the 21st century. Although the number of persons who died from the disease is currently less than a thousand (see the www.who.org website), it affected the lives of millions of persons in 2003. The focus on SARS was so high in the media that news of SARS overshadowed the outbreak of another panic disease, Ebola virus, that killed more than 100 persons in March 2003 in Congo. SARS is the latest of more than 35 new or reemerged infectious diseases over the last 30 years. The difference was that most people in the world, especially in safe and secure social settings felt protected from Ebola virus of Africa, and even the global pandemic of HIV seems distant from most people who donned masks to avoid SARS. SARS infected and killed young and old, healthy and unhealthy, making everyone seem vulnerable.

In Beijing, Toronto, Taiwan, and some other places, hospitals were sealed as an emergency. Patients and staff were all locked up inside the hospital building to isolate them from outside, to stop the spread of the disease. The quarantine orders were announced without little warning and preparation, which caused a massive panic. Similar quarantine emergencies used to be common with diseases like tuberculosis and smallpox in the past. They are a public health measure to protect society from infectious diseases. Those health care workers who were placed in working quarantine experienced fear, depression, anxiety, anger and frustration. During the international battle against SARS one of the features was the high proportion of frontline health care workers who were infected and who died. According to the data compiled from the WHO until the 7 August 2003, 20% of all persons affected with SARS were health care workers (1725/8422). In the early stages of the outbreak, they had all unknowingly treated patients with SARS. Even for the latter stages in the outbreak in the first half of 2003, there were several who became ill with SARS in spite of "full" precautions.

Q1. Did you wear a mask during the SARS panic in early 2003?
Q2. How did you feel when someone coughed a lot?
Q3. Each person infected with SARS was a victim of another, but do you think people regarded each person as being dangerous and somehow bad?
Q4. Every person of any profession has their personal role in a family to be a father, mother, spouse, and child, in addition to their professional roles. Should we respect the health worker’s autonomy to take a break from intensive work to fight SARS? Do you expect health care workers to die for protecting the public health?
D9. AIDS and Ethics

Chapter objectives
AIDS is killing millions of persons every year, and has reduced the average life expectancy of persons in many African countries by decades. As a sexually transmitted disease it has raised many ethical issues. This chapter aims to:
1. Introduce ways to get HIV and AIDS.
2. Consider the global burden of AIDS.
3. Consider ethical issues of AIDS including discrimination and fear of persons with HIV.

D9.1. What is HIV/AIDS?
HIV is an abbreviation for Human Immunodeficiency Virus. AIDS is caused by getting infected with this virus. When the virus enters the human body, it attacks the immune system. The human immune system protects the body from foreign matters like viruses and bacteria. When the immunity gets very weak, the body cannot fight against even minor infections. Therefore, a sequence of diseases becomes apparent. This stage is called “AIDS (Acquired Immune Deficiency Syndrome)”. There is no one single disease called AIDS. AIDS is the condition in which the body is attacked by multiple diseases due to low immunity.

Collaborating author: Fumi Maekawa, Japan

At the moment, there is no fundamental cure for AIDS. During all the above period until death, the virus can be spread to other persons. Therefore, it is important to prevent HIV infection.

**Q1. What is the difference between HIV and AIDS?**

**Q2. What are three ways to get infected by HIV?**

**D9.2. How do you get infected?**

There are only three ways to get infected by the virus

1. Sexual intercourse
2. Blood serum contact e.g. blood transfusion, sharing needles by drug users
3. From mother to fetus (vertical transmission)

This means that in daily life, if you avoid unsafe sex, there is very little chance to get infected by the virus, unless you are infected by blood.

*AIDS is a dangerous disease, but it can be prevented!*

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**The World Situation (Dec. 2002)**

**Estimated number of persons infected with HIV/AIDS**

- Total: 42 million
- Adults: 92%
- Children under 15: 8%

**Estimated number of deaths due to HIV/AIDS during 2002**

- Total: 3.1 million
- Adults: 80%
- Children under 15: 20%
Activity 1 – Fill in the missing cells

Write the corresponding letter next to the five items to complete the table.

_ 29,400,000
_ East Asia & Pacific
_ 1,500,000
_ Australia & New Zealand
_ 700,000

<table>
<thead>
<tr>
<th>Country</th>
<th>HIV infected persons</th>
<th>Newly infected persons per year</th>
<th>Deaths per year</th>
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</thead>
<tbody>
<tr>
<td>North Africa &amp; Middle East</td>
<td>550,000</td>
<td>83,000</td>
<td>37,000</td>
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<tr>
<td>Sub-Saharan Africa</td>
<td>A</td>
<td>3,500,000</td>
<td>2,400,000</td>
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<tr>
<td>Western Europe</td>
<td>570,000</td>
<td>30,000</td>
<td>8,000</td>
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<tr>
<td>Eastern Europe &amp; Central Asia</td>
<td>1,200,000</td>
<td>250,000</td>
<td>25,000</td>
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<tr>
<td>B</td>
<td>1,200,000</td>
<td>270,000</td>
<td>45,000</td>
</tr>
<tr>
<td>South &amp; South-East Asia</td>
<td>6,000,000</td>
<td>C</td>
<td>440,000</td>
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<tr>
<td>D</td>
<td>15,000</td>
<td>500</td>
<td>&lt;100</td>
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<tr>
<td>North America</td>
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<td>45,000</td>
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</tr>
<tr>
<td>Caribbean</td>
<td>440,000</td>
<td>60,000</td>
<td>42,000</td>
</tr>
<tr>
<td>Latin America</td>
<td>E</td>
<td>150,000</td>
<td>60,000</td>
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</table>

The data table is based on the WHO and UNAIDS research on AIDS epidemic update. Accurate statistics are difficult concerning HIV/AIDS, just like other data for any disease. The study on distribution and collecting information about a specific disease is called “epidemiology”. This study is more difficult for HIV/AIDS because of the long incubation period. Many cases may not be detected unless an individual voluntarily takes blood tests. In poorer countries, it is even more difficult just to take the test.

The outbreak of AIDS is most serious in countries inside sub-Saharan Africa, where the average life span of the persons in the country decreased because of such deaths. Still “evidence from Ethiopia and South Africa shows that prevention work is beginning to pay off for young women, with HIV prevalence rates dropping among pregnant teenagers (UNAIDS epidemic update 2002)” which shows that learning about HIV/AIDS decreases the chance of getting infected by it.

Q3. When do you go to the hospital? Do you go there by yourself? Write down how you felt when you went to the hospital, or when you were sick.
D9.3. Ethical concerns of AIDS

What is different about AIDS from other diseases?

When the first AIDS case was reported in the early 1980s, the news terrified many people. Various prejudices caused difficult situations for patients. There were rumors that homosexuals were spreading a fatal disease. Incorrect information increased inequality. Some patients were refused by hospitals, many lost their jobs, and friends rejected each other.

This phenomenon is not only seen in the case of HIV/AIDS. The society tends to discriminate patients with infectious disease. A recent example would be SARS. In China where the outbreak was most serious, many people were isolated. In the past, persons having diseases such as Cholera, Leprosy, and Tuberculosis were isolated from society. Many, died in despair. Why were they discriminated? Why did they have to live such a harsh life?

Reasons to fear?

At present, there is no fundamental cure for AIDS. This means that once you are infected with the virus, it is most likely that you will have to live with it. Still, the AIDS virus is less infectious compared to the influenza virus, for example. The big difference between these two viruses is that a person with influenza has typical symptoms that can be identified both by the persons themselves and by others, where as in the case of HIV, many people may spend years without noticing that they are infected. It may be scary to think that someone around you might have an unnoticed disease.

Reasons to discriminate?

The main route of HIV infection is through sexual intercourse. The virus can be easily spread in society through one infected person having unprotected sex with multiple partners. On the other hand, it can be avoided by not having sex, or by having protected “safe” sex with a specific partner. In many countries, it is a taboo to talk about sex in public. The existences of sex workers are seen as immoral by many, but have been present since ancient history. This issue itself contains many ethical debates. Still, can we leave those who are sick because they were involved with prostitution? Let’s look at some comments that people gave towards AIDS patients, and think whether you can agree or disagree to each of them.

Activity 2. Voices

Read each of the following comments. Which comment do you agree with the most? Which do you disagree with? Why?

I will avoid them. God did not give them a second chance.

I doubt their morality but want to help for their recovery.

I have sympathy for those infected by transfusion or those infected by spouse, but dislike for ones who had bad behavior.

I am plain scared of them.

I feel sorry for the ones who get it from blood. Not so sorry for the gay people.

Depends on how they contract the disease. No sympathy for those who use drugs.

I love everyone!

Q5. Have you seen any movies or TV dramas discussing AIDS? Have you read any books on AIDS? How did you feel before and after watching it?
Activity 3: Role Play

Make a group of 4~5 persons and write a scenario where one person doubts that he/she might be infected with AIDS and then decides to take a blood test. Decide among the group members what role you would like to play.

Use your imagination!

What is the background of the person who wants to take the blood test? Would he/she talk to the family? To a friend? Who are the people surrounding her situation? How would they react?

Think how you would act according to your role.

<table>
<thead>
<tr>
<th>The situation</th>
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<th>Who is involved?</th>
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<tr>
<th>Who are you?</th>
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D10. Ethical Principles for Medical Research Involving Human Subjects

by the World Medical Association Declaration of Helsinki
Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000
Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002
Note of Clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004

A INTRODUCTION

1 The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.

2 It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

3 The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

4 Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

5 In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.

6 The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.

7 In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.

8 Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special
protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.

9 Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10 It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

11 Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.

12 Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

13 The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

14 The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.

15 Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.

16 Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.
Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.

The subjects must be volunteers and informed participants in the research project.

The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.

When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents
obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

27 Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

C ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28 The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

29 The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists. See footnote

30 At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study. See footnote

31 The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

32 In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.
Note: Note of clarification on paragraph 29 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or

- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

Note: Note of clarification on paragraph 30 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

The Declaration of Helsinki (Document 17.C) is an official policy document of the World Medical Association, the global representative body for physicians. It was first adopted in 1964 (Helsinki, Finland) and revised in 1975 (Tokyo, Japan), 1983 (Venice, Italy), 1989 (Hong Kong), 1996 (Somerset-West, South Africa) and 2000 (Edinburgh, Scotland). Note of clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002.

Version of 9.10.2004

Q1. This is a statement accepted by most medical associations in the world to guide ethical conduct of research. Are there any articles you disagree with?

Q2. How would you feel as a research subject? How would you fee as a researcher?
D11. Bird Flu

Bird flu is a frequent virus infection affecting wild birds and domesticated birds caused most commonly by H5N1 virus. The disease is transmitted from farm to farm through contaminated feed, bird cages, clothing (shoes), etc. The virus is destroyed by elevated temperature (70°C) and it does not contaminate the poultry meat, so people can still eat cooked meat. Avian flu viruses do not normally spread to humans. Nevertheless, several cases of human infection with bird virus (A/H5N1) have occurred since 1997 among poultry workers. Up to 2005, there is no evidence of human to human transmission of the infection.

The usual human influenza vaccine protects against the current seasonal influenza strains. Currently, there is no vaccine to protect against the H5N1 virus. According to the pharmaceutical firms, four to six months from the start of pandemic outbreak would be required to produce sufficient quantities of vaccine, although by the end of 2006 there may be large stockpiles in many countries.

The anti viral drugs such as TAMIFLU (Oseltamivir) can help curb the symptoms as well as the development of the disease, and may help prevent it spreading. The usual seasonal vaccine against the current flu virus strains, which, while not protecting from avian flu, should be administered in order to enable, in case of contraction of flu, better narrowing down of the diagnosis.

The following precautions to avoid being contaminated by the avian virus should be applied:

- Avoiding direct contact with birds and poultry or their excretions (industrial farms, markets etc.)
- Making sure that the air conditioning of buildings is regularly serviced;
- Washing hands regularly in particular before handling food;
- Covering one’s mouth when coughing and sneezing;
- Wearing a mask when presenting flu symptoms or when there is a risk of contact with someone who might be infected.

Influenza pandemic is a global outbreak that occurs when a new influenza virus appears in the human population. In case a pandemic starts it is best to stay home for some weeks and avoid contact with others. There is also predicted to be social unrest and panic in those times, which may kill and injure as many people as the disease itself. The World Health Organization (W.H.O.) has regular updates and information.

Q1. Where has the closest case of human avian influenza to you been?
Q2. How many cases have there been of human deaths? What is the mortality rate?
Q3. How many people does human influenza kill every year?
D12. Indigenous Medicines and Access to Health

Chapter Objectives

Many persons in the world do not have adequate access to health services and medicine. Medicine has evolved over human history in every culture, and there are various forms of medicine. This chapter aims to:

1. Explain the differences between traditional and modern medicines.
2. To examine whether traditional medicines can help increase the proportion of persons with access to medicine.

D12.1. Definitions

**Indigenous peoples** maintain cultural and social identities and social, economic, cultural, and political institutions separate from mainstream or dominant societies and cultures and have unique ties to traditional habitats and ancestral territories and natural resources in this environment. In many cases, indigenous peoples live in separated communities or ethnic groupings (Asian Development Bank). However, all people are indigenous to somewhere in the world.

**Traditional medicine** is, according to the definition given by the World Health Organization (WHO), “knowledge based on the theories, beliefs, and experiences indigenous to different cultures either codified in writing or transmitted orally and used in maintenance of health as well as the prevention, diagnosis, improvement, or treatment of physical and mental illness”. Traditional medicine includes diverse health practices and approaches, incorporating plants, animals, and/or mineral based remedies, spiritual therapies, manual techniques, and exercises applied singularly or in combination. Traditional medicine is part of the core of all cultures, since the dawn of humankind.

**Modern medicine** also called 'allopathy,' 'western medicine,' 'conventional medicine,' 'mainstream medicine,' 'orthodox medicine,' or 'cosmopolitan medicine' has a history of several hundred years, since the advent of biological sciences. Last century has brought many achievements in medicine, especially with regard to control of certain infectious diseases, developments in immunology leading to organ transplantations, and most recently the progress in decoding the human genome.

**Q1. Have you ever experienced treatments delivered by someone from the community, without particular training in modern medicine? What do you think about such methods?**

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D12.2. Access to health care

There are many people who do not have access to medicine and health care, even in the economically richest countries of the world. Cultural beliefs and the high cost of modern pharmaceuticals are also barriers to access to western medicine. The WHO acknowledges that 80% of the population, especially in the rural areas of Asia, Africa and Latin America, relies primarily on traditional healers for their health needs.

Statistics show that in Europe, North America and other industrialized regions, over 50% of the population have used (CAM) at least once and empirical evidence proves that traditional medicines are the only source of health care for 80% of the people in the developing countries. However, these methods are largely not recognized by the formal health care systems and usually subordinate to mainstream medicine. Only few countries, like China, Korea, Vietnam, have a fully integrated system, where both medicines are used “like the two wings of a bird”.

In most developing countries, traditional healers by far outnumber the allopathic practitioners. For example, in Uganda there is at least one traditional healer for about 300 people as compared to one Western-trained medical practitioner for every 10,000 people in urban areas and 50,000 people in rural areas, respectively.

Traditional Chinese medicine, acupuncture and moxibustion, meridian therapy, Ayurveda, yoga, Siddha and Unani medicine are formalized diagnostic and therapeutic systems with a history of millennia, recognized mainly in their countries of origin and elsewhere. Other therapies, such as homeopathy, reflexology, aromatherapy, osteopathy, Bach Flower healing, naturopathy (and iridology), hypnosis, medical astrology, pendulum diagnosis, colour therapy, may be relatively new but their principles are founded in laws of nature and extensive clinical experience of dedicated observers.

In palliative medicine, obstetrics, and neonatology, they find also wide acceptance. Therefore they are alternative or complementary (CAM) to mainstream western medicine. In the UK, CAM practitioners currently outnumber general practitioners by 40,000 to 36,000. Alternative health care modalities include reflexology, massage, acupressure, chiropractics, nutritional therapy, and other similar methods.

Q2. Many traditional medicines of vegetable and animal origin are harvested from nature, often from endangered species. How do you think sustainable use of natural products can be insured? If pharmaceutical companies produce new drugs based on traditional knowledge and/or resources coming from indigenous peoples, how should these be rewarded?

Q3. Should the costs of non-conventional methods be covered by health insurance? What about countries where coverage is limited or not existing?

Q4. What should be done to close the gap of suspicion between traditional healers and modern medicine practitioners?
D12.3. Holistic approach to health

A holistic approach to health care is very important to look after the health of each person, family and community, which will help avoid people getting sick. Traditional health systems take into account physical, mental, spiritual, social and ecological dimensions of well-being, fundamentally trying to restore the balance, which by being disturbed is causing the disease. Treatments are designed not only to address the symptoms but to restore the state of equilibrium within oneself and the environment.

Traditional medicine is based on the principle that each individual has his/her own constitution and social circumstances, which result in different reactions to the causes of disease. Different people may receive different treatments even if, according to modern medicine, they suffer from the same illness.

This “holistic” approach of the patient as a unity of mind, body and spirit is one of the reasons traditional medicines are getting increasingly popular in developed countries as well, in spite of the relatively well established conventional health care systems.

Q5. If you or someone near to you gets sick, would you prefer the newest medicine, which maybe still experimental, or some therapy which has been proven effective for generations?

D12.4. Safety and efficacy

These therapies are perceived to be more natural and less risky compared to modern medicine, though the safety of all medicines needs to be examined scientifically. They also emphasize the preventive aspect of medicine, the personal responsibility in maintenance one’s health.

Indigenous and traditional medicines, based on the concepts of individualization and having often strong spiritual linkages, are more difficult to investigate from a laboratory point of view. For example, plants are usually administered in certain combinations, with specific rituals, which vary from person to person. Therefore, the classical instrument of drug validation, the randomized clinical studies, where all patients in a group suffering from similar symptoms are treated with the same drug, or a placebo, is not relevant.

Research by pharmaceutical companies and universities is being conducted to find out the active principles in medicinal plants, based on the traditional knowledge collected from indigenous peoples. There is hope that this information will lead to cures for wide-spread diseases like cancer, diabetes, etc.

Q6. How should traditional medicines and healing methods be tested for safety and efficacy, in order to secure the approval of the scientific community?

Q7. Are environmental aspects taken into consideration when using natural medicines?