

- Transversal issues
- Relevant for all following modules



Transversality of the principle of informed consent: Example: transplantation of organs and tissues

- Consent of the donor
- Consent of the recipient



- ➡ General principle in module 2 and
- ➡ Additional requirements in module 8

Module 2: Free and Informed Consent Learning Objectives

- define free and informed consent and identify its components;
- internalise the legal and human rights principles applicable to it;
- discuss the application of the process of informed consent to persons not able to consent and in emergency situations;
- assess the responsibilities of health professionals in the process of informed consent.



Article 5 Convention on Human Rights and Biomedicine

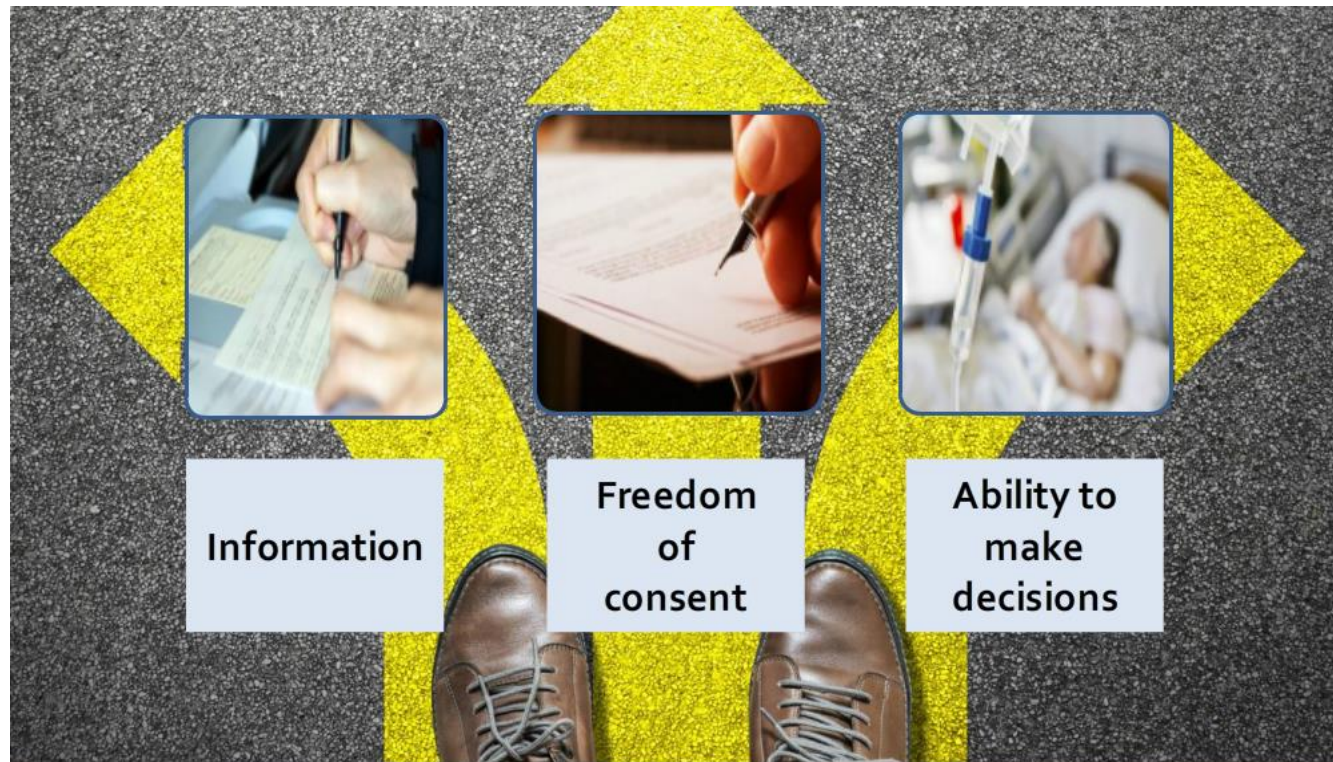
General Rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

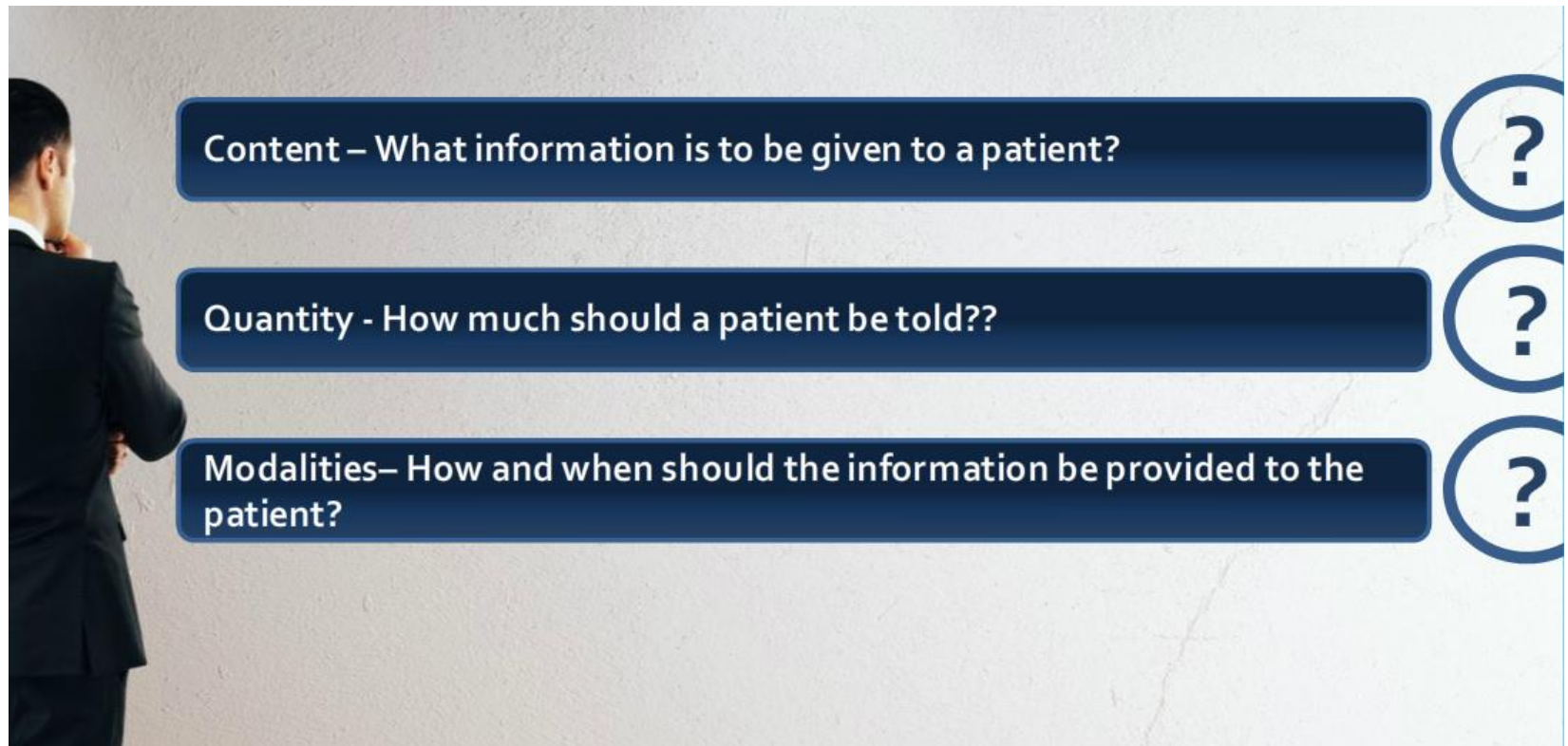
This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

Elements of Informed Consent



- Information



Case-law example: Freedom of consent:

Patient's consent is considered to be free if:

- there is a **lack of pressure or undue influence** (for instance scientifically unfounded warnings of an unwanted outcome in case of a refusal of the proposed medical intervention);

In [the case Konovalova v. Russia](#) the ECtHR found that the unauthorised presence of medical students during the birth of the applicant's child violated her right to respect for private and family life (Article 8 of the ECHR) on account of the lack of sufficient procedural safeguards against arbitrary interference with the applicant's rights in the domestic law at the time. The information provided on the involvement of medical students in the "study process" had been vague, without specifying the scope and degree of that involvement, and was presented in such a way as to suggest that participation was mandatory and that the applicant had no other choice.



Persons not able to consent

General Rule

Under [Article 6 paragraph 1 of the Oviedo Convention](#), an intervention may only be carried out on a person who does not have the capacity to consent for his or her **direct benefit**.

Exceptions

Article 17 - Protection of persons not able to consent to **research**

module 7

Article 20 - Protection of persons not able to consent to **organ removal**

module 8

Persons not able to consent

Specific rules - Minors

- authorisation
- opinion to be taken into consideration

Specific rules - Adults

Specific situations

Representatives/Support for persons not able to consent

Previously expressed wishes

Emergency situations

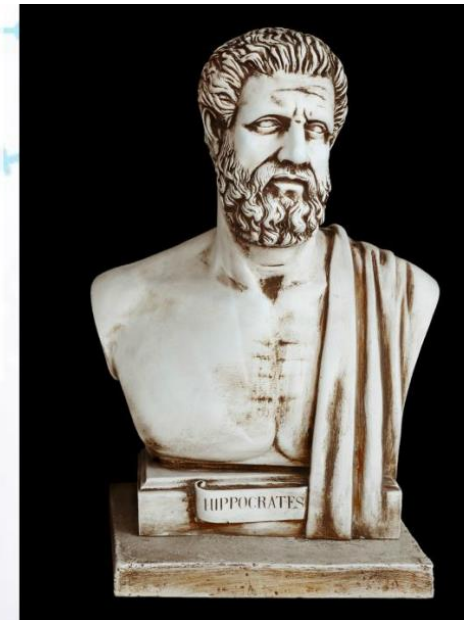
Module 3: Medical Confidentiality and Protection of Health related data Learning Objectives

- describe why medical confidentiality and protection of health related data are important;
- list key principles of data protection law applied to the biomedical field;
- differentiate situations where confidentiality is interfered with and assess the compliance of such situations with legal obligations;
- illustrate the boundaries within which processing of medical data is allowed.



The foundations of medical confidentiality

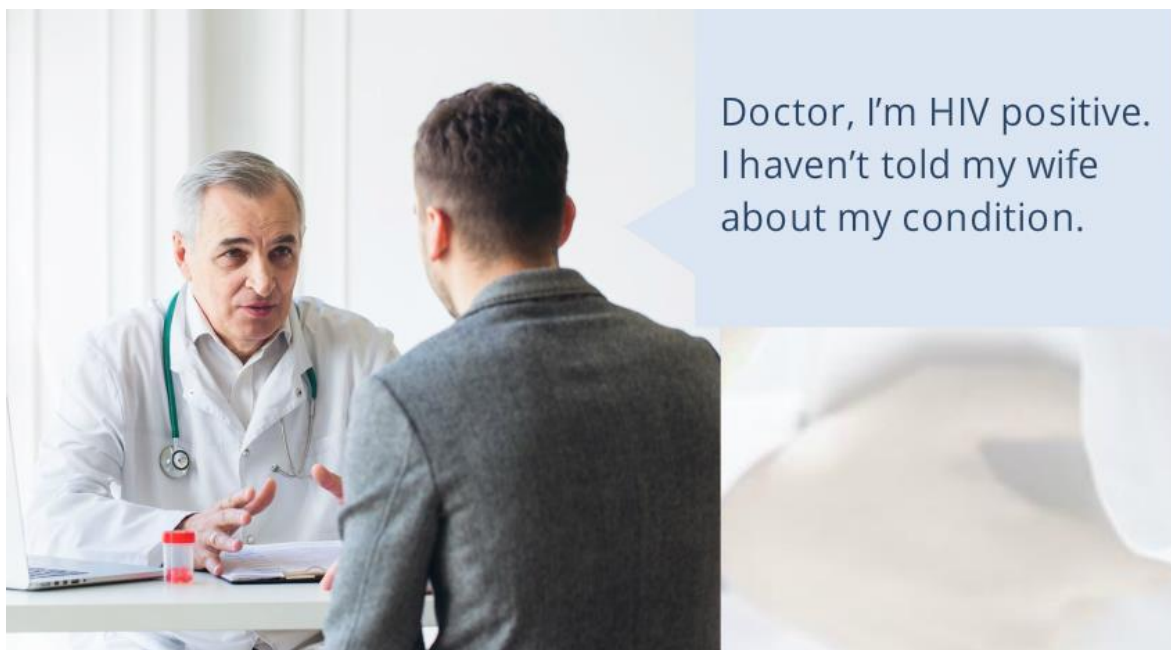
"whatsoever I shall see or hear in the course of my profession, as well as outside my profession in my intercourse with men, if it be what should not be published abroad, I will never divulge, holding such things to be holy secrets."



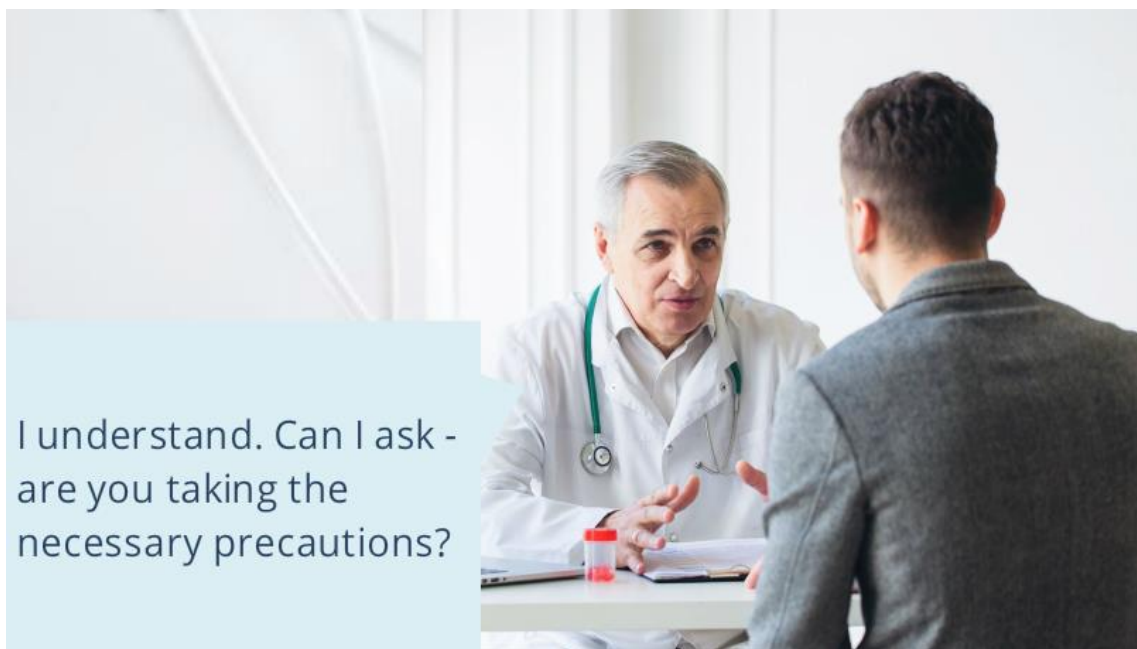
What is health-related data?



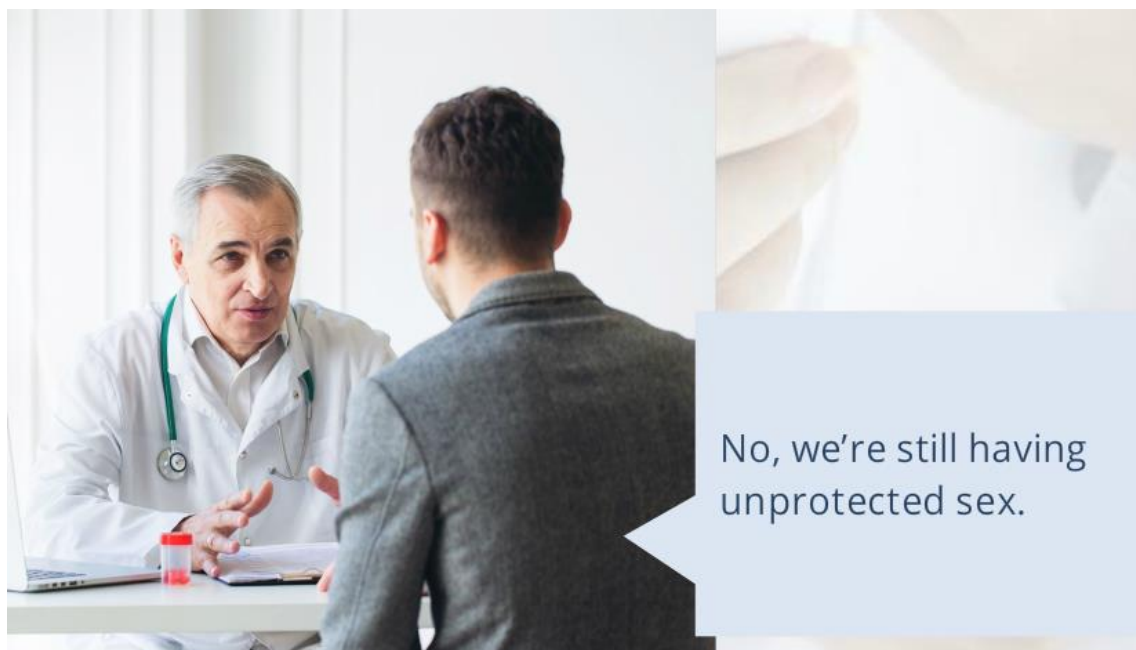
Medical Confidentiality Case example



Medical Confidentiality Case example



Medical Confidentiality Case example



Medical Confidentiality Case example

**Do I have to let his
wife know or do I have
to keep this a secret?**



Legitimate aims: Prevention of serious crime (protection of others)

The prevention of crime is an obvious example of a public interest justifying breach of confidentiality. But does this mean that a doctor is forced to report any suspicion of a criminal offence and any non-violent misconduct that he may encounter in the course of caring for his patient?

Look at the two conditions below to explore more then click 'Next' to continue.



Only where there is **a clear and significant risk of the patient causing harm towards an individual** or society as a whole, **which cannot be reduced or excluded by any other means, can confidentiality be breached**. For example, if a depressed mother confesses her violent intentions towards her new-born baby and the doctor cannot persuade her to seek help, he acts lawfully in contacting social services, police or other competent institution and/or her family to protect the child.

Review the ECtHR case [Colak and Tsakiridis v. Germany](#) for more information. When you have finished reviewing the facts, click the button at the bottom of the page to read the judgment.

Click 'Next' to continue.

The domestic court in its judgment on the applicant's compensation claim, expressly acknowledged that the doctor had violated his professional duties towards the applicant by failing to inform her about her companion's infection. The Court, however, found no violation of Article 8, as there was not sufficient evidence to prove that this behaviour caused the damage.

- Data protection by health professionals
- Patients' access to health data/limitations
- Specific situations: confidentiality of data concerning deceased persons
- Data security and storage

www.coe.int/bioethics

Thank you!