

## Guidelines for health professionals about informed consent procedures in Europe

### INFORMED CONSENT SUMMARY

- *The process by which an individual gives or refuses their permission for a medical procedure to be carried out.*
- *It is based on an understanding of all the relevant information, explained to them by a health professional.*
- *Some people may have difficulty giving consent. Factors such as age or mental impairment can affect an individual's competence to make or communicate choices.*
- *Informed Consent is a process, rather than an event. Sometimes people will be faced with difficult decisions, and may need time to make a choice that they are happy with.*
- *Making an informed decision is a function of being able to act freely and autonomously. Individual freedom and autonomy are rights enshrined in European law under the [European Convention of Human Rights](#)*

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## CONSENT IN MEDICAL PRACTICE

### *General aspects*

Consent is a process which is meant to ensure that a person understands the nature and purpose of giving a biological sample, or undergoing a medical intervention.

Generally, in medico-legal terms, 'valid consent' is ensured if anything that represents a significant risk that would affect the judgement of a reasonable person has been explained. However, it is necessary to specify that the consent process cannot always be totally comprehensive: all eventualities cannot be covered because of the possibility of unexpected clinical findings or test results.

Informed consent is based on the primacy of personal autonomy, and is a fundamental principle that has marked the emergence of modern medical ethics. Consent of a person constitutes one of the fundamental principles that clinicians must comply with in the application of the Universal Declaration on Bioethics and Human Rights. The principle of consent is closely related to the principle of autonomy (Article 5 of the Declaration) and the affirmation of human rights and respect for human dignity (Article 3 of the Declaration).

The concept of autonomy implies the responsibility of the individual to make decisions. The power to decide for oneself entails the fact that one accepts the consequences of one's actions, which, in health matters, can be highly significant. Therefore, it should be emphasized that the person needs to be informed of the precise consequences of his/her choice, and this in turn leads one to wonder about the conditions under which consent is "informed" and obtained.

In short, informed consent is a process whereby an individual decides whether or not to:

- Undergo a medical procedure or treatment
- Take part in an experiment or research programme

In each case the patient or research participant will want to understand the relevant medical facts and any risks involved.

Except in exceptional circumstances, consent should be obtained prior to a laboratory test, with the genetic implications having been explained. Consent should have been obtained before medical genetic information is disclosed.

## REQUIREMENTS FOR INFORMED CONSENT

### *What it means to be 'informed'*

A successful informed consent process is:

- A collaborative effort between the health professional or researcher, and patient or research participant
- One which will ensure that the donor or research participant is protected at all times and can make decisions that they are happy with, and enter into freely.

The process that leads the person in question to either accept or refuse a medical intervention is articulated by a health professional in three stages, occurring in a logical and chronological succession:

- The communication to the patient of information of diagnostic and therapeutic importance that justify the proposed action
- The assurance that the patient has understood the received information
- The ascertainment of the patient's choice

If the patient does not have the necessary information, then he or she will not be able to consent specifically: therefore any consent form signed by the individual would be neither legally valid, nor representative of an action of good clinical practice.

Therefore, consent must be:

- Informed
- Properly understood by the individual
- Confidential

- Clear, specific, and reversible

### ***Understanding what is being consented to***

In order to ensure that individuals know what it is they are being asked to give their consent for, they must be provided with information of the correct kind. The characteristics of such information are that it is:

- Personalized
- Comprehensible
- Truthful
- Objective
- Comprehensive
- Mindful of the mental capacity of the patient

### **Personalized**

This means tailored to the health, psychological, cultural and linguistic needs of the patient, and proportionate to the type of proposed medical action.

The information given to the patient must be appropriate for their age, in particular if the person is under the age of legal responsibility, or mentally incompetent to make autonomous decisions.

As much as possible, it must avoid the risk of an involuntary and not explicit conditioning, connected to the informative asymmetry between the figures of the doctor and the patient.

### **Comprehensible**

The information given must be expressed with clear and simple, but not simplistic, language. In the case of written text, make sure to use typographical characters and pagination style that is conducive to easy reading.

Moreover it is advisable to avoid grouping several decisions within a single consent form, because the accumulation of information of varied character can generate confusion in the reader.

In the case of foreign patients who don't understand the native language adequately, it is advisable to resort, where possible, to the support of a cultural mediator and to make use of translation services.

### **Truthful**

The information must correspond to the effective clinical needs of the patient, and to the concrete implications of the proposed medical action.

### **Objective**

The information must be based on validated sources, or enjoy a meaningful degree of clinician-scientific legitimacy.

### **Comprehensive**

The information must provide the facts central to the proposed medical intervention, and must also satisfy every specific question that the patient has.

### **Mindful of the mental capacity of the patient**

Consent can only properly be given by somebody who is mentally competent to express it, and understand what it is that is being consented to. It is necessary therefore to estimate if the subject is in possession of the mental competence necessary to do so, as well as to appreciate the possible consequences of both consenting and refusing an intervention.

### **Confidentiality in consent**

The patient has the right to express consent to a clinician confidentially. Transmission of this information to third parties is only permitted with the explicit consent of the patient,

the parents of the patient in the event that the patient is underage, or from a legal representative of the patient

***Clear, specific, and reversible consent***

The will and desire of the patient must be manifested explicitly and unambiguously, ideally in written form.

Consent given must relate to the specific medical action proposed.

Consent must be given before the proposed medical action.

The patient must be able to revoke their consent anytime, including during the immediate time before the planned intervention.

## BEST PRACTICE IN PROVIDING INFORMATION

### *Consent as a collaborative process*

Often informed consent involves a number of health professionals who are dealing with a patient and share the responsibility for the final outcome of the medical intervention planned.

Professionals should agree a shared practice so that the subject does not have to repeat the consent procedure many times when dealing with these various clinicians independently, all of whom may have different ways of explaining the situation.

### *Who can acquire consent*

Consent must be acquired by the health professional that is able to supply the most comprehensive information on the planned medical intervention.

### *When consent should be acquired*

In order to express a truly valid consent, the patient must be provided with sufficient time to make their decision, and a calm environment in which to reflect on the information they receive.

The time required to make an informed decision varies in relation to the characteristics of the patient (clinical, psychological, cultural, functional, etc) and to the complexity of the proposed medical action.

### *The consent form: How consent is acquired*

The consent procedure must always contain a written report of the intervention in question and what will be involved in participating.

This written report is supplementary and never substitutive of the doctor-patient meeting.

The process must be adapted according to the needs of the patient, taking into account when any decision must be made, the appropriate linguistic register to be used, the speed at which the information can be communicated, and taking into consideration the people whom the patient wishes to inform of his or her situation.

The objective is to create with the patient the conditions necessary for being able to make a shared decision, and conscious participation in the clinical actions proposed.

It is always necessary to give documentary evidence that information has been communicated, independently from the acquisition of consent in written form. So it is recommended that records are made in the clinical folder the moment that the information is provided.

The consent which has been communicated, and undersigned by both the patient and the professional, must be attached and conserved inside the clinical documentation, of which it becomes an integral part, and a copy must be delivered to the same patient.

## RELATIONAL ASPECTS

### *The doctor-patient relationship in the consent process*

In the case of informed consent, the relationship between doctor and patient deserves attention. The success of a good informed consent procedure is conditional largely upon on the way in which the relationship between the doctor and the patient is managed.

For this reason, the traditional and paternalistic type of relationship, where the decisional prerogative lies in the hands of the doctor, is inadequate.

It is instead better to use a model which pays greater attention to the participation of the patient in the decision making process, with the dialogue and mutual exchange of information at the centre. This approach allows for the clearer emergence of the values of the patient.

The aspects of the procedure related to these values, combined with the technical-scientific considerations supplied by the doctor, are the basis of a shared decision making process in which also the patient is been involved in active way. Viewed in this way, informed consent is not limited simply to the acquisition of the patient's signature, but instead becomes a real process. Consequently the centre of the activity becomes the dialogue between doctor and patient.

In this way it is possible to reach a shared decision that is not limited to considering any risks in relation to the legal implications for the doctor of any undesired consequences, but that also considers the consequences of the proposed medical action on the quality of life of the patient.

Moreover, active involvement of this kind carries out the function of empowering the patient. Proper communication helps the patient to understand his or her own situation gradually, such that he or she is able to confront the choices available with his or her experiences and values. Where good practice such as this occurs, the doctor will receive more accurate and detailed information from the patient, and will therefore be able to develop a relationship with them of greater confidence and collaboration.

## STYLES AND LANGUAGE

A good informed consent procedure demands some specific indications related to the language and style that a doctor should use to ensure that the patient is comfortable with the information that they receive. This can be crucial for ensuring that the patient can make a decision that is fully informed and free.

The discussion between doctor and patient is in reality the fundamental tool for constructing a relationship where informed consent can be ensured. Over the course of these discussions, the majority of the information is communicated and understood gradually.

### *Good practices*

- **Using clear but not simplistic language**

The primary need of the patient is to be able to understand clearly the information that they receive, without this information being trivialised. In this respect, the most important clinical aspects should not be omitted, but they must be explained in an accessible way. Thus, the scientific terms, acronyms and abbreviations should only be used after a full explanation of them in advance.

Generally speaking it is acceptable also to proceed directly to using them, but putting the scientific term in brackets after the first usage.

- **Offering an exhausting informative framework.**

It is not possible to predict exactly every aspect and implication of a medical intervention that someone is considering giving their consent to. What is more, an excessive amount of information may become an obstacle to understanding.

However, it is important to avoid significant gaps and omissions that are relevant to the overall clinical picture of the patient.

- **Sensitivity to the possible emotional impact of the information**

Sensitive information must be given gradually and expressed in a way that doesn't arouse excessive anxiety.

The aim is to make the patient aware. This means that it is important to ensure that the patient is given all the proposed contents. Presenting the most sensitive information from an emotional point of view, or explaining the situation in language that is very emotive may make a patient anxious and prevent them from assimilating further information, or from developing a complete picture of their situation.

- **Encouraging interaction with the patient**

The health professional plays a decisive role in communicating information on a proposed medical intervention. Equally, the contribution of the patient is of great importance either in order to build up a more complete picture of the situation with the doctor, or in order to enable the patient to ask questions, express doubts and fears, expressing views and preferences. In this way the patient can participate in the process of personalising the particular clinical path that will be taken.

Showing attention to the needs and fears of the patient, to reserve time specifically for conversation with them and to ask them explicitly to voice any doubts or questions that they might have are very useful professional attitudes in view of constructing an effective dialogue.

The consent form and printed information sheet are truly effective if they are placed side by side with and support the professional's conversations with the patient.

***Practices to avoid***

- **Do not use an intimidating language or register**

In describing the consequences of a refusal of consent to a proposed medical intervention, it is important that the eventual negative consequences to health of such refusal are made clear, but it is important to guarantee continuing assistance and care to the best of available medical ability in the event of refusal.

- **Do not use a defensive style**

The information given to the patient should not be understood as an instrument for protecting the doctor, but as the basis for building a well informed relationship between the doctor and the patient.

Language of an opaque and precautionary nature should therefore be avoided.

- **Graphics and / or numerical quantification for the illustration of probability of success, failure, risk or complication.**

The numerical indication of rates of success and risk is an important aid to securing accurate information from the patient. Percentages and an explanation of 'what chance' there is of a particular outcome can help to build trust between doctor and patient.

It is not always the case, however, that information is sufficient, especially when there is a wide variety of relevant data. For example, graphs which represent in a visual way the relevant variables can be used to achieve this.

The disclosure of this kind of data has a positive psychological impact if it is presented in a positive light. Therefore it is advisable to emphasise the chances of success, rather than the risks, especially when the risk is very low. This kind of communication directs the attention of the patient to the positive aspects of his clinical condition, rather than the negative, and therefore generates less anxiety.

## CONSENT IN THE PRACTICE OF MEDICAL GENETICS

### **Genetic testing**

Genetic testing is commonly defined as:

*"analysis of specific genes, their product or their function, and any other type of investigation of DNA or chromosomes, which aim to identify or exclude changes (DNA) probably associated with genetic diseases."*

Tests may also be used to define the degree of genetic difference between individuals, to resolve medical-legal issues and to assess genetic sensitivity, susceptibility and resistance of individuals to environmental factors.

Compared to other laboratory tests, genetic tests have some peculiarities, since the results relate to the biological identity not only of an individual, but also of his or her family.

Unlike other laboratory tests, genetic tests have some traits that make them unique in the field of medical investigations:

- The results often present couples with difficult decisions involving reproduction, for example prenatal diagnosis, donor insemination, the interruption of pregnancy, adoption. These options may be contrary to the ethical principles or religious faith of the couple.
- The results of the test can provide genetic information about the possible future health of close relatives of those who agree to take the test, regardless of the current health status of these relatives.
- For many genetic diseases there are currently no effective treatments and therapies, but only palliative care or containment, which can only alleviate some complications and mitigate the effects rather than provide a cure.
- People who, without being affected, are identified as being at risk for certain diseases, may experience psychological stress, suffer discrimination, and face difficulties in insurance matters, in access to health care, and in work.
- In special circumstances, genetic tests can identify the risk of the occurrence of future diseases; but it is very unlikely that these risks can be established with a high degree of certainty.

- Confirmation of the result of a predictive genetic test can not always be validated by other clinical signs or symptoms. In these cases the prediction will be confirmed only by the appearance of the disease itself.

You can find more information and insights on genetic testing in Europe at the following websites:

<http://www.eurogenguide.eu>

<http://www.orpha.net>

### **Genetic screening**

Genetic screening is carried out either on an entire population or a section of one, all of whose individuals, considered individually, are at a low risk of being affected by diseases with a genetic base; however those identified as carriers of mutations which could cause diseases can benefit from further searches or preventive measures. Sometimes the target of the genetic screening is a part of the population that has an increased risk of a particular genetic disease.

Normally, initiatives in genetic screening are carried out by medical authorities, without the individuals to whom it is offered being subject to any medical interventions, on the basis of some specific symptom of a determined disease.

The effectiveness of screening is measured by the following conclusions drawn from the results:

- *sensitivity*: the ratio between the number of those who are affected based on a positive test result, and the total number of subjects
- *specificity*: the ratio between the number of those who have a negative test, and the total number of persons who are not suffering the disease
- *positive predictive value*: the ratio between the number of individuals affected, as indicated by a positive test result, and the total number of subjects with positive test results, both affected not affected.

### **Population and genetic discrimination**



The main ethical problem faced in surveys such as this is how to establish the correct criteria by which to select the population sample to be investigated.

The principle of equality requires that access to the screening, and distribution of any "benefits" arising from these studies, even in terms of simple knowledge, should be guaranteed at least to every group and every population selected. This entails the active and informed participation of the participants, besides of the need to safeguard the right to self-determination of every individual and of the community, through the giving of consent to conduct a test.

Cultural and social values differ from population to population, however. This can make it difficult to implement any strategy for the equitable allocation of any beneficial fallout from such research. In particular the developing countries will be involved increasingly in the coming years, in genetic investigations.

The execution of planned tests, however, must take place with the prior consent of the people concerned, and with supervision by the institutions and public authorities responsible. Many of these countries are still often devoid of any normative framework for consent, and decisions are often made on an individual's behalf and on the basis of assumptions regarding their wishes. This is contrary to the spirit of the consent process.

The discussion of these problems leads to some recommendations:

- From an ethical point of view is not correct to propose screening on which the international scientific community has not expressed opinions of reliability sufficiently broad and converging
- A model of communication must be prepared which ensures the communication of information that is correct, and can enable the expression of informed consent
- Genetic information about individuals must remain confidential
- All necessary measures should be taken to prevent the use of results as an instrument of discrimination
- Consent to conduct screening must be free and independent of the choices that individuals may want to make and will be able to make after finding out their test result
- The person who originally gave his consent is free to withdraw at any time he/she wishes with the highest degree of freedom

## ***Types of consent***

There are two levels of consent that can usually be offered to patients:

### ***STANDARD CONSENT***

This is consent for the use of samples in a certain specific test or research programme. This kind of consensus is the most commonly used until now and is required by most local ethics committees

### ***BLANKET CONSENT***

Permission to use the samples in future research projects. This kind of consensus is the most commonly used in research, and is becoming increasingly frequently used in institutions such as public hospitals. There is nowadays a stronger link between research and clinical practice, and blanket consent has developed in recognition of this.

## ETHICAL ASPECTS AND CONFIDENTIALITY

The practice of genetic testing raises complex legal problems regarding the collection and use of health data that it is used to obtain.

- **Principle of autonomy**

The freedom and autonomy of those involved in genetic research must be protected.

With the exception of some special cases, it is important to obtain the explicit expression of consent, freely and consciously given by the patient before any medical treatment or genetic testing commences. A part of this process must be to advise those participating in genetic research about factors such as the balance between the risks and expected benefits.

- **Confidentiality**

There is a dual need for protection. Firstly, those involved in genetic research have a right to privacy, and secondly third parties related to those participating have their own rights and interests. Relatives may not be involved but it may be possible to assume from research results that they have a predisposition to a disease that may run in the family.

A particularly delicate area is that of predictive tests, due to the uniqueness of their aims, since they widen the boundaries of the traditional doctor / patient relationship, and necessitate the discussion of issues of increasing complexity. Nonetheless, in these cases, the principle of patient autonomy should take precedence over the principle of confidentiality.

## NORMATIVE SITUATION

### ***Informed consent as a legal-normative issue***

The relationship between health professional and patient is also a legal relationship which assumes rights and duties the same as any other.

The patient has a right to be provided with any clarifications requested about information provided to them during the consent process in relation to any proposed medical intervention. There is a corresponding professional duty to provide this clarification in an appropriate manner, and then put the patient in a position to provide free and informed consent.

The individual can then exercise his or her right in relation to clinical options, making choices that affect him or her significantly in relation to his or her life and health.

### ***European regulatory framework: general principles***

At a European level, the primary legal standard which must be upheld, whether in relation to the authorisation, refusal, or interruption of a medical intervention, is the expression of the will of the individual. This is considered to be a basic and fundamental right.

Regarding any proposed treatments or medical procedures, the normative documents that are binding from a legal point of view, today correspond with those that are recommended from an ethical perspective.

- The "Convention for the protection of human rights and dignity of human beings regard to the application of biology and medicine", also known as the 'Oviedo Convention', is today the central reference point for the European legislation on informed consent. The Oviedo Convention expressly demands that information, on the basis of which consent is granted must be "appropriate" in relation to the "purpose, nature of the action, its consequences and its risks"
- With specific regard to the issue of consent, the Convention explicitly brings information and individual self-determination in relation to medical interventions to the sphere of "*fundamental rights and freedoms in relation to the application of biology and medicine*" (Article 1 - referring to the right of the human being to the respect of his dignity, identity and integrity, in relation to medical acts which will have an effect on his or her body and health).

- Equally, the paper of the Fundamental Rights of the European, also known as the 'Paper of Nice' and the 'Declaration on the Promotion of Patients Rights in Europe', define informed consent as:

*'the right to physical and mental integrity of a person and as a right to his/her self-determination'.*

- The Declaration on the Promotion of Patients' Rights in Europe expresses the patient's right to:

*"to be fully informed about their state of health, proposed medical procedures, together with the potential risks and benefits of each procedure; about alternatives to the proposed procedures, including the consequences of refusal to submit to any treatment" (paragraph 2.2.).*

- Moreover, the information must be communicated to the patient in an appropriate manner:

*"taking into account the capacity for understanding, minimizing the use of unfamiliar technical terminology" (paragraph 2.4.).*

All the documents referred to agree in defining the consent informed as an ineluctable condition of the legitimacy of any medical action, in lieu of it being provided otherwise by the domestic law of each country member of the European Union.

## COMPETENCE TO GIVE CONSENT

The issue of individual capacity to give valid consent in the health field is very complex.

- Legally speaking, it is assumed that a person of legal age is capable of giving valid consent, and that on the contrary a child under eighteen years is not. This capacity to act is defined as *"the ability to make expressions of will that are fit to change their legal situation."*
- In accordance with the law, consent may therefore be expressed by a person of legal age and must be the manifestation of an explicit and freely decided act of will (*i.e.* which is free from constraints and suggestions), and of a decision making process not affected by disturbances in perception and thought.
- This implies that subjects who are underage or who otherwise do not satisfy these criteria of ability, cannot be said to give valid consent to any treatment. The implication of this for clinicians is that, in professional practice, he or she must assess the suitability of the patient to give valid consent. He or she must draw, at the same time, on the concepts of competence and natural ability. In doing so, the specific parameters of consent in each different case can be established.

Even though every adult patient whose consent is sought is deemed capable until proven otherwise to grant it, it is good to keep in mind that the subject is competent to consent only if he or she is:

- Able to receive information
- Able to understand and remember the relevant information upon which a decision will have to be made
- Able to comprehend the clinical information in relation to him or herself, think about the implications of any decision and assess any possible alternatives
- Able to agree consistently and repeatedly to his or her choice