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SUMMARY

INTRODUCTION

The purpose of this seminar was to share information and generate proposals with regard to a range of issues related to informed consent. Although the need to obtain consent before any medical treatment is now firmly established, there are still many unresolved issues. Some of these issues have arisen as a result of the introduction of new legislation. In particular, Spain's Law 1/1995 on the Legal Protection of Minors, which grants mature minors the capacity to exercise their basic rights on a gradual basis, and Law 41/2002 and Law 21/2000, of the Parliament of Catalonia, regarding the Rights of Patients which modernize and extend the General Health Act of 1985 with respect to informed consent.

In general, when the issue of medical consent is discussed, people tend to ignore an essential precondition for any consent: information. And although we talk of informed consent, the first half of this formula is granted only the most cursory recognition. This is because the informed consent process has generally become a routine in which the patient signs what is little more than a blank piece of paper. We are quite rightly quick to criticize insurance and bank agreements which hide their details in the 'small print'. In the case of informed consent agreements, the print is full size but what it says is so open that it means that the patient is accepting any risk whatsoever. In other words, this information is really 'non-information': anyone can operate on the patient, not just the health professional with whom the patient has spoken, all sorts of complications may arise, etc. I understand that medicine is not an exact science, that unpredictable situations may arise, and that individuals vary widely, but informed consent should not be used as tool for the practice of defensive medicine but should instead serve to explain to patients what is happening to them, what the possible solutions are, and what are the consequences of applying the treatment which, together with their doctor, they have chosen.

Taking this as our starting point, a number of questions arise with regard to the information process. Firstly, we need to be aware of the patient's condi-

tion, choosing our words and our timing carefully when providing information to make sure that we do not cause unnecessary distress. There are also a number of questions regarding the scope of this information. Should patients be informed about treatments which are not available in the centre but which could be provided elsewhere? Where there is a risk that the patient may lose the capacity to decide freely, we need to ask the patient to identify somebody who can be consulted and is able to grant consent.

This brings us on to the even more problematic issue of informing relatives. In the event that it is not possible to inform the patient, the law creates an obligation to inform the family. Inevitably, this raises a number of questions. Firstly, which family members should be informed? Anyone who is related by blood to the patient? And what about friends whose ties to the patient are closer than those of relatives? This is particularly relevant in the case of common law partnerships, especially where there is a legal relationship. Should the patient always be asked what his or her wishes are? The answer must be yes, whenever possible, given that the relative (or relatives) has the task of representing the patient's wishes and should therefore be someone who shares the patient's beliefs and philosophy most closely.

In those situations where the patient does not have the capacity to decide, we encounter questions regarding the efficacy of consent by representation and, in particular, whether this can have the same efficacy as direct consent. The question is a complex one, not least because Spain's Law 41/2002, on Patient's Rights, would appear to grant lesser weight to consent by representation. This approach strikes me as correct where the exercise of the fundamental rights of freedom, life and health is concerned and where the holder of these rights alone is entitled to exercise them. While it is possible to transfer the ability to exercise these rights, this should always be treated as a delegation of powers.

Spanish law provides a basis for this interpretation, but does not provide sufficient criteria with which to resolve the conflicts which may arise from such delegation. For example, what should happen when relatives fail to agree? Should the wishes of the family always be respected? What happens when the health professional believes that the family's decision is not in the patient's interest, in the sense established in art. 9.5. of Law 41/2002? In situations of conflict, addressed in sections 2 and 3, who should take the decision as to which procedure is best for the patient, in the sense established by the law? If there is a document containing advance directives, how should this be used? These are precisely the questions which these studies address in the search to identify ways of fleshing out the regulatory position.

The issue of consent by representation gives rise to even more complex problems when the consent of minors and, in particular, of mature minors is involved. For example, should health professionals always inform parents or guardians? In which cases and to what extent should the minor be informed? Recognizing the minor's wishes gives rise to both ethical and legal problems. The legislation supporting such an approach is contained in art. 9 3. b) of Law 41/2002 and in Organic Law 1/1996, on the Legal Protection of Minors. This law, in its introduction, sets out the desire of the legislator to recognize in full both the possession of rights by minors and a progressive capacity to exercise them, in line with the approach taken towards the construction of the human rights of minors in the majority of developed economies at the end of the 20th century. Specifically regarding the efficacy of the consent of minors in the context of healthcare, art. 9.3 b) of Law 41/2002 establishes, as a general rule, the age of majority for healthcare decisions as 16 years, with three exceptions (art. 9.4): abortion, clinical trials and assisted reproduction. These exceptions to an age of majority of 16 for health issues have been repeated in the proposed abortion law which would mean that, from 16 years of age, parental permission would not be required. What nobody appears to have noticed is that when the minor has already been granted her independence, she is considered to be an adult for all effects and her parents do not have any parental authority[1]. Because minors may be granted their independence at 14 years of age, this means that the age limit for parental consent for abortion for a young person in this position is not 16 years but 14. This is also the age at which the Catholic religion allows marriage.

1. Art. 9.3.c) Law 41/2002, regulating the autonomy and rights of the patient.

These are the issues addressed by the two speakers at this Seminar: Emilia Civeira, an intensive care doctor who provides a medical perspective, and Jacobo Dopico, lecturer in Criminal Law, who offers a legal perspective. The other contributions also reflect this interdisciplinary approach, including health professionals drawn from a range of disciplines and with different levels of responsibility, legal specialists, and specialists in ethics, all united by a shared interest in bioethics. This diversity is reflected in the structure of this publication. It begins with Emilia Civeira's paper, followed by the paper given by Jacobo Dopico, and then the contributions of the various professionals who took part in the discussion. The aim was to move from the specific to the general, giving as broad as possible a perspective on the issues raised by consent by representation. This is reflected in the excellent overview of the seminar provided by José Ignacio Gallego. Finally, I have offered some considerations and proposals in the hope that they may be of help in the search for solutions to the problems identified.

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Consent by representation: a challenge for critical care medicine

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1. Introduction

Modern medicine is characterized by the use of advanced technology. This is an ongoing process which cannot be reversed, and both diagnosis and treatment are increasingly aggressive and costly. Patients are diagnosed and treated earlier, and diseases which were once terminal have become chronic. As a result, we can now extend life, but sometimes the patient pays too high a price for this. The resulting quality of life is not always ethically defensible, while death itself becomes a drawn-out affair. Another interesting aspect of modern medicine is the way the doctor-patient relationship has changed. The recognition of patient rights in recent years has meant that patients now play a vital role in taking the medical decisions which affect them. Indeed, the right to make decisions about one's own health is one of the key ethical advances of the 20th century. Traditionally, the doctor (or shaman or witch-doctor) was seen as a possessor of knowledge; his opinion was not disputed, and the patient received whatever treatment was proposed almost as if it were a divine gift.

Today, doctors' decisions are based on scientific evidence. The doctor must be a scientist but must also be capable of transmitting his knowledge to the patient, enabling the patient to play an active role in managing his illness, choosing both diagnostic and therapeutic procedures. It is in this context in which informed consent arises, based on an active communication process in which the health professional provides information which is direct, complete, accurate and comprehensible, and the patient gives his consent. This relationship is expressed in the informed consent document, which brings together the doctor's proposed course of action and the patient's decision. This serves as evidence that the information process has occurred.

The concept of informed consent refers to a written document in which two parties, the doctor and the patient, agree on the application of specific therapeutic measures. It is a document, signed by the doctor and the patient or his or her representative, in which the doctor sets out the nature of the illness and the diagnostic and therapeutic procedures deemed necessary to address it, while the patient, exercising the full use of his faculties, states his free and voluntary agreement to this health intervention. The patient must both understand his pathology and the different options available, and decide between them. However, the informed consent document is not an end in itself; the purpose of this process is information. The document could be replaced in the medical notes with evidence that the information has been provided and the proposed treatment accepted.

Promoting patients' participation in managing their own lives is a long process, one which began several centuries ago and which has found expression in current legislation governing patient autonomy. In Spain, Law 41/2002, of 14 November[1], regulates patient autonomy and rights and obligations with relation to medical information and documentation. As a result, doctors are required both for legal and ethical reasons[2,3] to obtain the informed consent of all patients before commencing treatment. According to article 8 of Law 41/2002, the need to obtain consent is both a right (of the patient) and a duty (of the doctor).

My aim in this paper is not to provide the perspective of a specialist in bioethics, something which I do not claim to be, but rather to set out my viewpoint as an "intensive care doctor, convinced of the need for informed consent", with respect to some of the issues which have still to be resolved. My hope is that, after discussion with legal experts, we can arrive at a set of conclusions which will be helpful in our daily practice.

2. Informed consent: tricky questions

The informed consent document now forms an integral part of medical care, the correct completion and recording of which are used as criteria when evaluating service quality. But does this mean that everything is fine, or are there still problems with informed consent at the level of practice? Well, in my opinion there are relatively few medical professionals who question the necessity and importance of the informed consent process. As far as I can tell, the reason why some are not fully convinced of the need for it is not for the motives suggested by Pablo Simón, in his document on informed

consent "Abriendo nuevas brechas", where he argues that this is "*because they cling to outdated and self-pitying attitudes*". Rather, it is because serious and as yet unresolved issues still attach to the process of signing such documents.

The problem is not so much the question of information which has, I believe, been accepted. Instead, consent is seen as providing a form of protection rather than representing both a duty on the part of the doctor and an obligation for the patient. It is therefore essential that we resolve these problems in order to ensure that informed consent is not just *a piece of paper which is handed over* so that it can be signed by *somebody*.

In my opinion, informed consent is or should be something more than just a legal procedure but should be based on *shared decision-making*. It should not just be the signature off a piece of paper which provides legal cover, but should instead represent a shared commitment between doctor and patient. This commitment is easy enough to understand in the context of the daily practice of scheduled treatment, but it can be more difficult and challenging to apply to other areas of medicine, such as critical care.

Informed consent is very much a live issue in our discipline and as such it is the focus of a number of controversies, which here I will seek not so much to resolve as to identify.

3. Informed consent by representation: a new approach in critical care medicine

I shall discuss the problems which, in my opinion, are posed by the signing of informed consent documents in Intensive Care Units (ICUs), given the nature of such units and of the patients they treat. In ICUs, the aim of preserving life may come into conflict with another basic principle, that of respecting the patient's right to decide. In critical care medicine, we treat patients whose lives are in imminent danger, and we must take fast, accurate decisions which often entail the application of aggressive treatments. In addition, patients are not always in a position to decide for themselves. And here we come face to face with the problem of consent by representation which I will focus on today and which is the subject of this seminar. I shall consider this with respect both to the patient and his or her representative, and the information.

a) *The patient*: first of all, we need to consider whether there are some situations in which the patient is unable to decide. What are these situations, and who is responsible for identifying them? *The representative*: if a patient is unable to decide, who should do it for him or her?
b) The information process.

In other words, when and why does a critically ill patient need to be represented in taking decisions about his illness? And when, as a result, does informed consent need to be granted by representation?

3.1 When the patient does not decide: representation

Representation in decision-making is defined as substituting the decision of a critically ill patient, who is incapable of taking a decision, with that of another person who decides in his or her place. The question of representation is currently one of the key issues raised by the signing of informed consent agreements in Intensive Care Units (ICUs).

My aim here is, in the first instance, to identify what I believe to be the unresolved problems, and to contribute to the search for solutions which enable us to implement the regulations on consent in the ICU where this must be provided by representation.

3.1.1 Situations where the patient needs to be represented

Let us start with the main protagonist: *the patient*. "The person who possesses the right to information is *the patient*".[1] The first question we will consider is whether there is any situation in which the patient should be

represented. It is my belief that there is a wide range of situations in the ICU where patients are unable to decide, not all of which are covered by legislation. According to the law, the decision must be taken by *the patient or by the person who must legally substitute him.* But there are some clinical situations in which the patient is unable to give consent but where a legal surrogate does not exist. I shall illustrate with a few examples:

a) Patient is legally incapacitated

1. When a patient is legally incapacitated and is unable to give consent he always has a legal guardian who acts as his representative and legal surrogate. If this person is present then he or she grants consent and the situation does not pose any problems.

However, difficulties arise if the representative is not present or if the representative is not a single person but an organization where several people are involved in taking the decision. Such shared decision-making is not always possible in acute situations.

Case study 1:

Patient with severe progressive neurological deterioration, living in a home, presenting an acute, critical pathology. Such acute situations may pose problems which are genuinely difficult to settle. For example, if the patient needs to be admitted to the ICU, who makes this decision? In principle, the decision should be taken by a committee which meets regularly. However, it is often not possible to do this when the problem arises, with the result that the patient does not have a representative.

One option is to go to a judge. However, doing this in an emergency creates an additional problem, because the judge will be unfamiliar with the problem and unfamiliar with the patient's circumstances and the illness. Furthermore, it involves a level of bureaucracy which is incompatible with the intensive care doctor's need to take quick decisions. What is more, after all this the judge typically leaves the decision in the hands of the doctor anyway, regardless of how complex the situation may be.

We also need to bear in mind that the intensive care specialist often has to face such problems alone. We need to find a solution to what is becoming an increasingly common problem. One possibility would be to create a legal requirement to the effect that anyone who was legally incapacitated and represented by an institution would have to have an 'advanced directives' document signed by their representative. This could then be reviewed periodically if there was a change to the patient's condition, and would provide the basis for taking decisions about the patient's medical treatment. This solution, which perhaps sounds more complicated than it really is, would affect all care homes with elderly residents suffering from dementia or other conditions where the patient has permanently lost his or her decision-making capacity. (Decisions regarding the end of life should always be reached on the basis of careful consideration and agreement, and should not be left until a crisis has actually arisen.) This would protect institutions, who would not be placed in the position of taking their residents to hospital to die 'without dignity', and would also help avoid the problem of dying 'too quickly' as a result of ignorance of their circumstances and situation.

2. *Minors:* The situation of minors is very different, and requires a completely different type of document, one which is dynamic and continuously changing. This is an issue which I am not going to cover in this paper.

b) Patient is medically incapacitated

A patient who is *medically incapacitated* cannot give his or her informed consent. However, defining this incapacity for decision making is a very difficult task. Many of the studies and analyses of incapacity and representation with regard to consent relate to patients who are permanently incapacitated as a result of mental illness, schizophrenia, dementia, learning disabilities etc.

Little has been written about incapacity in the context of other pathologies, and acute ones in particular, yet this sort of psychological incapacity to decide is very frequently encountered in ICUs. Indeed, it is a daily issue for intensive care doctors, and not one which is easily resolved, both as a result

of the difficulty in defining it clearly and due to the wide range of situations in which it arises. A patient who was previously healthy and capable may suddenly and unexpectedly lose the capacity to grant consent. While the incapacity to take decisions is something which occurs very frequently in patients suffering from serious acute illness who are admitted to an ICU, it is very difficult to confirm this incapacity objectively.

We might frame the question as follows: Is a patient with a serious acute condition capable of deciding for him or herself? Do all ICU patients need a representative? An individual who previously retained his or her capacity to decide may rapidly lose it. This loss may be temporary or permanent, and the cause may be physical or functional. It is the doctor's job to detect and diagnose the problem, which may arise in any one of a number of situations:

1. *Temporarily incapacitated patient for physical reasons*

In these cases, the patient has an illness which temporarily causes him to lose consciousness and thus deprives him of the capacity to take decisions. The most common reason for such incapacity is coma, due to a wide range of causes. Such acute illness means that a patient temporarily requires a representative, for example in order to receive a blood transfusion, carry out an invasive diagnostic procedure, perform surgery, etc.

2. Temporarily incapacitated patient for functional reasons

On other occasions, this loss of capacity is not caused by a specific, physical condition. Instead, it is functional disturbance, as a result of the illness, which gives rise to the inability to take decisions. Situations such as fear of illness or of the unknown, anxiety or isolation from one's family can block an individual's capacity for rational decision-making at any given point in time, and specifically at the moment of taking a fundamental decision regarding one's own life.

This is usually a temporary situation, and one which is very difficult to diagnose and treat. Often, although the situation is only temporary, the patient needs a representative who by offering love and support helps the patient to take a decision. In such situations, the patient and his or her representative may also need the professional help of a psychiatrist or psychologist. In such complex situations, it is advisable that the decision-making process is a shared one which involves a number of professionals. In these situations, the psychiatrist can be extremely helpful for the intensive care specialist. We therefore need closer cooperation between the intensive care doctor and the psychiatrist, and there may even be a need for ICUs to include a psychiatrist or a psychologist on their staff to provide help and support in taking such decisions.

3. *Patient who is incapacitated due to metabolic disturbance*

On other occasions it is metabolic disturbance secondary to the serious illness itself which prevents the patient from taking a decision, and correcting this disturbance requires a course of treatment which the patient is not capable of deciding upon. This is another situation in which representation is essential.

4. *Patient who permanently loses the capacity to decide*

Finally, the patient may permanently lose his or her capacity to decide. The cause in this case is usually physical: an illness or injury as a result of which the patient becomes permanently incapable of taking decisions. In this situation, representation is also essential.

As we can see, these situations vary so widely and are so subjective in their nature that it is impossible to generalize about them or for them to be covered by a single piece of legislation. At the same time, it should be noted that in most of these cases a medical decision is required. The final word therefore lies with the doctor, who finds himself immersed in very difficult and challenging situations which complicate the process of taking purely medical decisions at critical moments. As a result, and not just because they are clinging to 'outdated' or 'paternalistic' beliefs, some health professionals argue it should not always be necessary to obtain informed consent in ICUs. There is no legislation which specifies, in these difficult cases, who the representative should be or what procedures require consent.

Case study 2:

Should the opinion of a medically incapacitated patient be taken into account?

This question has been addressed in the literature and, while there is no conclusive data as to how many intensive care patients lack the capacity to grant consent, the numbers are estimated to be large, a problem which is compounded by the difficulty of diagnosing such cases[4]. Diagnosis involves a large subjective element on the part of the doctor, and although some objective instruments have been created for this purpose, these are not always included or validated in the protocols of different health centres[5].

Proposal:

Because doctors are the only people who are able to diagnose the loss of decision-making capacity of a given patient in an acute, emergency situation, the scientific community and the law should provide instruments to help them take such decisions. We should try to avoid situations where a single professional has to take an emergency decision. Instead, decisions should be based on the broadest possible consensus. Such situations are a common and predictable feature of ICUs, and we need protocols governing informed consent in patients who have temporarily lost their decision-making capacity so as to reduce to a minimum the subjective role of the individual doctor. However, drawing up such protocols is far from easy, as this loss of decision-making capacity may be acute and unforeseen, and the patients affected may or may not have recorded prior decisions about their lives.

c) Other situations

1. What happens when an incapacitated patient has expressed prior wishes? In this case, we must seek to respect the patient's wishes, especially if these have been written down or are known to the patient's family. However, things are not always straightforward.

Difficult situations:

- The patient has taken a decision as a healthy individual, without suffering from any health condition or expecting to do so.

Case study 3:

A healthy, 42-year-old patient has signed a living will stating that he does not wish to be intubated. He is subsequently involved in a motorbike accident as a result of which he loses consciousness. It is difficult to know whether or not the patient's neurological condition will improve and it is possible that he will be left in a vegetative state, but initial medical treatment requires intubation for mechanical ventilation, induced coma and surgery.

Should we respect the patient's wishes? Or do we decide that this was not actually what he intended when stating that he did not wish to be intubated? How do we identify the intentions of a person who has signed a living will while in good health? Who would sign the consent for intubation? Can we act without a signature?

- The decision has been taken by an individual with a chronic, degenerative disease of which he or she is fully aware.

Case study 4:

Patient with chronic respiratory illness who has signed a statement saying that he or she does not wish to be intubated. Has pulmonary oedema (acute and reversible), hypoxia prevents the patient from taking a decision, and intubation is required. What should be done? Is a representative required or are the patient's wishes clear?

Case study 5:

The same patient presents with a deterioration of his condition. Would your decision be the same? (For example, deciding whether to admit to the ICU.)

Proposal:

These examples show just how difficult it is to interpret living wills in acute situations. While it may be easy enough to understand the wishes of chronically ill patients with a known pathology who do not wish to extend a difficult life, we still need to ask whether this applies to all situations.

Once again, we must stress the importance of the doctor in taking decisions, especially with regard to ICU patients. We may need to place greater emphasis on the relationships between doctor, legal advisor, ethics committee and nursing staff.

2. The acutely incapacitated patient *has not expressed prior wishes*. This is both the most common situation and the one which gives rise to most decision-making problems in critical medicine, and here a representative is clearly required.

Case study 6:

Young patient who has suffered a traffic accident, with unexpected deterioration of consciousness, prior to which the patient was competent and had not expressed any wishes.

There are, then, many different situations in which the patient does indeed require a representative.

The next difficult question concerns the representative.

3.1.2. The representative

a) Who should the representative be?

Spanish law states the following: "The people linked to the patient, *either by family ties* or *in practice*, should be informed in so far as the patient either expressly or tacitly permits." Even if the patient is incapacitated, he or she must be informed in accordance with *his or her comprehension capacity*, and the patient's legal representative must also be informed[1]. It is common practice to inform relatives without identifying whether the patient wishes to share information with them[6].

Problems:

Who are family? Who has a close relationship with the patient in practice?

Case study 7:

Male, 43 years of age, requires tracheotomy for long-term ventilation. He has a partner who was previously unknown to his siblings and whose role in the decision-making process is not accepted by them. They do not agree upon the decision. Who should decide? And what happens if the patient has offspring who have not lived with him since they were children?

At this point it is important to consider the legal concept of who is a family member. In fact, it is not clear legally who is entitled to take such decisions. There is no legislation stating how long a relationship needs to have lasted in order to be considered 'stable' or what conditions must be met. Where such conflicts arise, common sense must be applied to the decision-making process. And once again this puts the intensive care specialist in the difficult position of having to decide.

Proposal:

Advise or even compel patients to nominate a representative upon admission to hospital, to identify when the representative should be consulted, and who should be informed. Even better is to nominate a representative in advance, and it would therefore be desirable to publicize the need for everyone to put in writing who they want their legal representative to be, and what powers they should have.

b) How and when should representation be obtained?

It is often difficult to obtain representation upon admission to the ICU, and doctors therefore inevitably have a key role to play in reaching such decisions.

Conclusion: in intensive care medicine should the doctor take the final decision or do we always need there to be a representative? Should the representative be appointed in advance?

3.2 The patient decides: information from the doctor

The second significant aspect of the consent process concerns information, because in order to take a decision, the competent patient must be properly informed.

3.2.1 How to give information

For informed consent to be meaningful, it must genuinely involve a shared decision-making process, and not simply be a means of covering one's back for legal purposes. At any given point in time, the competent patient has the right to choose between the different therapeutic options which exist. In order to take such decisions, the patient must receive the best information available, but the reality is that this is not always possible in an intensive care setting. Are patients universally able to exercise this right? If not then why not, and how can this be rectified?

Spanish law states: "Any medical treatment requires the free, voluntary consent of the patient after he or she has received the information (described in article 4) and evaluated the available options.

Consent will normally be verbal. However, it should be given in writing in the following situations: surgical procedures, invasive diagnostic and therapeutic procedures and, in general, the application of procedures which pose known and predictable risks or discomfort to the patient's health."

The patient may freely revoke his or her consent in writing at any time.

Problems:

1: It is not possible in daily practice to require consent for *all* interventions. The doctor is hired by the institution as a skilled and competent professional, and the doctor-patient relationship should in the first instant be based upon an assumption of honesty and trust.

Case study 8:

Patient aged 75, conscious and in cardiogenic shock. There is no possibility of reversing the condition. As a result, the intra-aortic balloon pump needs to be removed.

This is an instance of treatment limitation, but the question remains as to whether the decision should be put to the patient or whether somebody else should decide on his behalf. Who can decide to limit treatment of a competent patient?

The decision to limit treatment

It is not always possible for the patient to participate in this decision. Often, interests which are independent of the patient's wishes are involved, including resource considerations such as the demand for beds or the need to use the pump in treating another patient.

There is a conflict between therapeutic criteria, which would argue against the application of ineffective treatment, and the interests of the patient who does not want to die yet. As a result, there is a conflict between the patient's right to choose freely and the principle of justice. The decision is a difficult one. It is not always possible to reconcile individual and collective rights, and somebody therefore has to decide. In cases such as the one cited above, the solution is often to wait for the dilemma to resolve itself as the condition runs its course. In this case the medical decision should be shared, and not taken in an emergency by a single individual.

2: Receiving the information. How much information should be given, and how should it be given? How should we explain the different treatment options available in the public and private sectors?

Spanish law says that "Users of the National Health System will have the right to receive information about the services and care units available, their qual-

ity, and the requirements for accessing them." But can we guarantee the availability of all existing means to all the patients in the public health system? Do they have the right to decide where they will receive their chosen option?[7]

There is an interesting debate as to whether or not it is ethical to report comparisons between different centres and even between different doctors, given that the Spanish health system does not allow choice in these areas. We must involve patients in addressing our limitations, but at present we fail to do so.

Case study 9:

Woman, 52 years of age, diabetic, admitted with heart attack and rupture of the interventricular septum. Surgery is recommended, but we know that it has a very high mortality rate. How should we give her the information?

We know that our centre has less surgical experience than the hospital in the neighbouring region. Should the patient be told this? This is not simply a question of health resources; it also concerns the patient's right to receive accurate information. What provision does the law make for this situation? In fact, the law does not provide for situations such as this, which are the source of real problems when we seek to apply the principle of informed consent in practice.

Are we legally responsible if we fail to inform patients of the existence of other options elsewhere? And if we do so, will we be disciplined by our own institution?

Another major issue is the information provided to patients participating in clinical trials[8]. "All patients or service users have the right to be warned about the possibility of using prognosis, diagnosis and treatment procedures applied in the context of a teaching or research project, which may on no account pose an additional risk for the individual's health."

Informed consent provides the ethical basis for clinical research.

Case study 10:

Patient with breast cancer. We want her to participate in a research project[16]. How should we provide the information?

An important question here concerns how we explain the evaluation of risks. For a patient to reach a decision, he or she needs to know what risks our proposed action entails. Accepting risks when taking decisions is part of attempting to maximize benefit and minimize risk but we must be careful to explain that risk can never be completely eliminated.

3: Consent will normally be verbal.

"The patient's written consent is required for each of the actions specified in the preceding point of this article, which may be supplemented by appendices and other information of a general character, and the patient will have sufficient information regarding the procedure to be performed and the risks associated with it."

The Spanish Society for Intensive Care Medicine and Coronary Care Units (SEMICYUC) has drawn up a set of recommendations regarding which procedures require written consent in intensive care[9]. This rejects generic consent, due to the difficulty of documenting the full complexity of the procedure in ICUs, even if it offers advantages from a legal perspective. It recommends written consent for the following: tracheotomy, non-urgent blood transfusion, fibrobronchoscopy, urgent surgery, hemodialysis, non-urgent pacemaker, plasmapheresis, angioplasty, new technologies or technologies whose efficacy has not yet been demonstrated.

3.2.2 Can doctors assume powers of representation and decide without consent? If so, in what circumstances? There are various situations in which the doctor must decide[10]

Extreme emergency

This refers to the situation when arises when a doctor believes that the proposed treatment is absolutely necessary, even if the patient does not accept it. Who determines this?

Case study 11:

A 75-year-old woman with chronic ischemia of the lower limbs. Admitted with septic shock due to gangrene. Amputation is required, but the patient does not accept it. She has no family. Her own doctor knows her well[11].

This problem is very difficult to solve. While doctors are skilled professionals, they may also believe that what they propose is always right, as a result of which they will slip into paternalism or arrogance. The patient's inability to understand may be temporary and caused by fear, lack of education, organic disturbance, medication etc. The challenge is how to balance the patient's right to autonomy with her real medical needs.

Some authors[11,12] have proposed that decision-making is always preceded by psychiatric consultation. However, this is neither possible nor helpful in critical care medicine (Jeffrey P. Spike)[13].

"*Often in the ICU rapid treatment is more important than excellence*" The application of some treatments (such as fibrinolysis)[14] or of procedures to deal with situations such as sepsis, severe trauma and cardiopulmonary resuscitation do not give either the patient or his or her representatives the opportunity to choose.

Therapeutic privilege

A patient's right to health information may be limited where there are reasons for believing that knowledge of his or her condition would seriously threaten the patient's health. In this situation, the doctor must record the circumstances in the medical records and inform the patient's friends and/or family of the decision.

Case study 12:

A 45-year-old man is admitted to the emergency department with severe psychomotor agitation, and respiratory insufficiency due to pneumonia. He refuses to be admitted to the ICU and wants to be treated on the ward. The hospital is unable to guarantee care on the ward, but nor is it certain that the patient's condition will improve in the ICU. The family wants 'the best for the patient'. Does the patient need representation? If so, who will represent him?

Patient's refusal to receive information

When the patient expressly states his or her wish not to be informed, this wish must be respected and the patient's refusal recorded in writing, without prejudice to the need to obtain consent prior to treatment. However, this is limited by the health interests of the patient, those of third parties, of society as a whole and the therapeutic requirements of the case.

Where there is a threat to public health

For reasons of health established by the law. In accordance with the stipulations of Organic Law 3/1986, the legal authorities must be informed within no more than 24 hours of the relevant measures being taken where a compulsory detention order is issued.

Case study 13:

Patient aged 32, who has had difficulty finding work. Infected with TB with positive acid-fast bacillus smear. Doesn't want anyone to know, because he would be dismissed from his job. And what if it is swine flu?

Need for information

Can the need for information override a patient's wishes for confidentiality?

Case study 14:

A journalist calls to find out about the state of a politician, footballer or criminal. Should we provide information without the subject's consent?

4. Personal opinions and summary:

- In critical care medicine, the doctor-patient relationship is even more important than in less critical situations. The informed consent document, understood as the product of a decision-making process shared between doctor and patient, is an essential component of current medical practice.
- Informed consent plays an important role in the ICU, but implementing it is far from straightforward and requires further consideration. Patients need to be properly informed if they are to understand their illness and take decisions about treatment.
- There are a number of situations which render the patient unable to take decisions, and at this point the doctor has to decide. If possible, the doctor should not do this alone, and the existence of ethics committees at the hospital and even the ICU level can assist in taking such decisions. It can also be helpful to involve psychiatrists in the decision-making process in complex situations.
- Although surveys suggest that relatives are generally satisfied with the doctor-patient relationship in the ICU[15], I believe that there is room for improvement. One thing which could help to deliver such improvements and to facilitate the decision-making process would be if everyone identified a representative to take decisions on our behalf in the event that we were unable to decide for ourselves.
- Because it is difficult to legislate for every eventuality, there is a need for closer cooperation between doctors, legal advisers and ethics committees.
- The interests of the media should never take precedence over the rights of the patient.

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Problems of informed consent by representation[1]

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1. Introduction

When we talk about informed consent 'by representation', we automatically consider situations where decisions are taken about 'others': minors, the disabled, the terminally ill. We tend *not to identify* with the person whose rights are under consideration. But the first thing we need to accept when we consider this issue is that it involves *somebody else deciding on the most intimate aspects of another person's life*: their health and even whether they are to live or die.

Imagine for a moment that you find yourself on the emergency ward, with your health seriously at risk, but unable to communicate or express your wishes or opinions. Your situation is critical and medical decisions need to be taken urgently. You can hear the doctor explaining the situation to your cousins (who do not share your ideas about medical decisions at the end of life and are, moreover, your closest heirs) so that they can decide which option should be taken. You disagree, but nobody is going to pay any attention to your opinion[2].

This example illustrates just how important it is to appreciate that consent "by representation" means that *somebody else is deciding on the most intimate aspects of another person's life*.

Modern doctrine has seen in the requirement for informed consent prior to medical treatment a guarantee of the autonomy and dignity of the individual. Respect for the *autonomy* of the individual and for his or her rights requires that the individual is the person who defines his interests and decides who will treat him, and how.

2. The scenario is similar to the one in Alfred Hitchcock's short film, "*Breakdown*" (1955), in which a serious accident leaves businessman Joseph Cotten paralysed and unable to speak or to move anything more than a finger. When the police and the doctors negligently certify him as dead and order an autopsy, the terrified protagonist sheds a single tear: at this point, the medical staff realize what is happening and attempt to calm him down, reassuring the patient that they are aware of his situation and will take care of him, and that everything will be okay.

However, in cases of informed consent 'by representation'[3] we would appear in principle to be facing a very different situation. These are not situations in which the holder of the rights decides whether and how to be treated, but just the opposite: the patient undergoes treatment without having requested it, and without his or her consent being required, solely as a result of the decision of somebody else. Indeed, it is even possible that the patient will be subjected to *unwanted* treatment. This is *heteronomy* in its most radical form: an individual's body is subjected to external control.

This strikes us as perfectly natural when dealing with small children. The image of a child who, at his parents' bidding, is vaccinated against his will (expressed, what is more, *in the most vehement manner*) does not offend our notions of what is right: who, if not the parents, are to take decisions about the medical treatment of a child?

However, young children are not the only ones to undergo medical treatment or surgery without having granted their consent; such treatment also applies to adolescents and adults who are unable to express their wishes or who lack the intellectual or emotional competence to give their informed

3. Despite the fact that art. 9 of the LAP (Patient's Autonomy Act) uses the term *consent by representation*, legal rulings tend to consider that when parents or guardians grant consent for a minor or someone who is incapacitated, they do so not on the basis of representation (i.e., their consent does not indirectly express the wishes of the minor or incapacitated person), but rather by virtue of their duty of protection and guardianship (see López-Chapa, Sara. *Autonomía del paciente y libertad terapéutica*. Barcelona: Bosch, 2007, p. 120; Parra Lucán, Mª Ángeles,"La capacidad del paciente para prestar válido consentimiento informado. El confuso panorama legislativo español", in *Aranzadi Civil* 1-2003, p. 1901 and ss., 1908.; Santos Morón, Mª José, *Incapacitados y derechos de la personaldiad: tratamientos médicos, honor, intimidad e imagen*, Madrid: Escuela libre editorial, 2000, p. 34; Romeo Malanda, Sergio, "Un nuevo marco jurídico-sanitario: la Ley 41/2002, de 14 de noviembre, sobre derechos de los pacientes", in *La Ley* 2003-1, p. 1522 and ss., 1527. The last two references include extensive bibliographical references, including Díez Picazo/Gullón Ballesteros, Lacruz Berdejo, etc.; Berrocal Lanzarot, Ana I. "La autonomía del individuo en el ámbito sanitario. El deber de información y el consentimiento informado como derechos del paciente en la nueva Ley 41/2002, de 14 de noviembre", in *Revista Foro* nueva época, no. 0, 2004, p. 284; Gómez Rivero, Mª del Carmen, *La responsabilidad penal del médico*, 2nd ed., Valencia: Tirant lo Blanch, 2008, p. (63).

consent. In these cases, it is *somebody else* who decides what medical treatment will (or *will not*) be given to the patient. Doctors perform those actions which *another person* deems necessary.

We therefore face a group of situations in which informed consent is not (or not necessarily) an expression of our recognition of the *autonomy* of the individual, but rather of his or her *heteronomy*, that is of the individual's submission to another person's decisions.

This forces us to abandon certain firmly held beliefs to which as lawyers we have become accustomed, and to adapt them to a new situation. We are no longer talking of the decision of an autonomous subject, but rather of a *legal relationship* between two subjects, which may not be harmonious and which may give rise to problems.

In the event of conflict, does the autonomy of the patient or the decision of the surrogate take priority? How can we resolve conflicts between the decisions of the patient (real or assumed, current or past) and those of the other person? Or between the opinions of the other person and those of the doctor? Or between the opinions of the *different individuals* called upon to decide for the patient? Are they governed by an order of precedence? Can we reject 'paternalistic' decisions which protect the patient from his or her own decisions? Or is this precisely the environment in which such an approach is natural? These are some of the questions I will address in the following pages.

2. Competence to grant consent with regard to medical treatment. Basic concepts.

The granting of consent with regard to medical treatment is a complex process which involves a number of people. Although in principle the competent, free, responsible patient exercises *sovereignty* over his body, in general he would be acting in the dark[4]if the doctor did not provide, in understandable terms, the technical information needed in order to make a reasonable choice between one therapeutic option and another.

However, not everybody is *intellectually and emotionally* capable of adequately processing this information and taking reasonable decisions on that basis. How do we determine if somebody is legally competent to take decisions regarding medical treatment?

Broadly speaking, there are three ways of approaching this issue of competence[5]:

- The *consequential approach*: if the subject takes 'reasonable' decisions, this indicates his or her competence; if he or she takes 'unreasonable' decisions, this is indicative of incompetence.
- The *formal approach* (or status-based approach): the subject is competent if he or she enjoys full freedom; but if the subject's status is restricted in some way (minor, incapacitated, etc.) then he or she is not competent.
- The *functional approach*, which measures the subject's specific intellectual and emotional capacity to process the actual decision to be taken.

The *consequential approach* in reality equates to rejecting the patient's autonomy, because all it grants the patient is the freedom to adopt 'standard' decisions. This approach is not valid in a pluralistic society where different notions of life and health exist side by side, and there is not necessarily a

4. "The doctrine of informed consent is founded on the premise that self-determination ought not be blind" (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions. A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship. Volume One: Report.* Washington: U.S. Gov. Printing Office, 1983, p.56); Corcoy Bidasolo, Mirentxu, "Consentimiento y disponibilidad sobre bienes jurídicos personales. En particular: eficacia del consentimiento del paciente en el tratamiento médico-quirúrgico", in *El nuevo Código Penal: presupuestos y fundamentos. Libro homenaje al Profesor Doctor Don Ángel Torío López*, Granada: Comares, 1999, p. 275 ("No cabe consentir sobre algo que se desconoce").

5. Kennedy, Ian; Grubb, Andrew, *Medical Law,* 3rd ed., London: Butterworths, 2000, p. 597-599 (citing the Report of the President´s Commission on *Making Health Decissions*). This commission opts for a functional approach, similar to that of the Law Commission in the United Kingdom (p. 612)

single solution to any given problem. A consequential approach of the patient's decision-making capacity would prevent the 'groundless' or 'medically unjustifiable' rejection[6] of treatment (for example, the rejection of blood transfusion by Jehovah's Witnesses[7]) and the result would be that patients who rejected medically suitable treatments could be forced to accept these treatments[8]. This option is unsustainable in models which afford patients a sphere of real autonomy[9].

6. In "El consentimiento del paciente", Bueno Arús, Francisco, defines such decisions as "abnormal rejections" in Martínez-Calcerrada, L. (dir), *Derecho Médico, 1st vol., Derecho Médico General y Especial*, Madrid: Tecnos, 1986, p. 288.
   Despite frequent attempts to draw legal implications from Spain's Constitutional Court ruling 120/1990 (with regard to members of the far-left organization, the GRAPO), it is important to note that the ruling in favour of the forced feeding of prisoners was based on the specific relationship of subordination of the prisoners to the prison authorities, a situation which does not apply to the relationship between patients and medical staff (the literature on this case is extensive; see, most recently, Lamarca Pérez, Carmen, "Autonomía de la voluntad y protección coactiva de la vida", in *La Ley Penal* no. 60, 2009, p. 25).

7. The Jehovah's Witnesses base their rejection on passages from the Bible such as Genesis 9, 4 ("But flesh with the life thereof, which is the blood thereof, shall ye not eat") and Leviticus, 17, 11-14 ("[10]And whatsoever man there be of the house of Israel, or of the strangers that sojourn among you, that eateth any manner of blood; I will even set my face against that soul that eateth blood, and will cut him off from among his people.[11] For the life of the flesh is in the blood: and I have given it to you upon the altar to make an atonement for your souls: for it is the blood that maketh an atonement for the soul.[12] Therefore I said unto the children of Israel, No soul of you shall eat blood, neither shall any stranger that sojourneth among you eat blood ... [14] ... therefore I said unto the children of Israel, Ye shall eat the blood of no manner of flesh: for the life of all flesh is the blood thereof: whosoever eateth it shall be cut off.) Again, there is an extensive literature in this area; see, most recently, Sánchez Rodríguez, Francisco; Punzón Moraleda, Jesús "La responsabilidad médica y la problemática del consentimiento informado en la Jurisprudencia española –especial atención a su problemática en referencia a los Testigos de Jehová", in *Rev. Jca. Castilla La Mancha* 45, Dec. 2008, p. 89 and ss.

8. However, as Ronald Dworkin has argued, "We allow someone to choose death over radical amputation or a blood transfusion, if that is his informed wish, because we acknowledge his right to a life structured by his own values." (*Life's Dominion. An Argument About Abortion, Euthanasia, and Individual Freedom. New York:* Knopf, 1993, p. 243-244).

9. In particular, Santos Morón, Mª José, *Incapacitados y derechos de la personaldiad: tratamientos médicos, honor, intimidad e imagen*, Madrid: Escuela libre editorial, 2000, p. 74; De Lora, Pablo. "Autonomía personal, intervención médica y sujetos incapaces", in *Enrahonar. Quaderns de filosofía,* 40/41, 2008, p. 126, p. 134.

For its part, the formal approach, which considers whether or not the subject is an adult who has not been incapacitated – an approach which was once the dominant one – is no longer sustainable in the light of the advance of the rights of children and the incapacitated. In recent years, these individuals have come to be seen as possessing rights, and not just as the subjects of decisions made by their representatives.

Today, the unanimous position is based on the fact that competence to take medical decisions regarding oneself should not be confused either with a 'general' age of majority or with formal capacity under civil law[10]. The criteria established with regard to full political or economic capacity do not automatically define the capacity to take decisions in the medical context[11]. And nor is there an age prior to which an individual cannot take their own medical decisions and after which they can. On the contrary, the minor, who has full possession of his or her fundamental rights, progressively acquires the capacity to exercise these rights independently[12]. This gradual acquisition of competence means that minors are allowed to take some decisions, and then

10. Corcoy Bidasolo, Mirentxu, "Consentimiento y disponibilidad sobre bienes jurídicos personales...", p. 279. This perspective was expressly rejected by ruling 2.1 of *Beschlüsse des 63. deutschen Juristentages Leipzig 2000; Aláez Corral, Minoría de edad y Derechos fundamentales,* Madrid, Tecnos, 2003, Part II, 2.

11. López-Chapa, Sara. *Autonomía del paciente y libertad terapéutica*, p. 123.

12. According to the ruling of judge Blackmun in the famous case *Planned Parenthood of Central Missouri v. Danforth* [428 US 52, 75 (1976)], "**Constitutional rights do not mature and come into being magically only when one attains the state-defined age of majority. Minors,** as well as adults, are protected by the Constitution and **possess constitutional rights.**" This idea is clearly reflected in the Introduction to Organic Law 1/1996, on the Legal Protection of Minors. See also Maunz/Dürig, *Grundgesetz Kommentar,* volume II, 7th ed., 52 entr., Art. 19.3, n. m. 16-17; Romeo Casabona, "¿Límites de la posición de garante de los padres respecto al hijo menor? (La negativa de los padres, por motivos religiosos, a una transfusión de sangre vital para el hijo menor)", in *Rev. de Derecho Penal y Criminología,* n 2, p. 337; Domínguez Luelmo, Andrés, *Derecho sanitario y responsabilidad médica,* Valladolid: Lex Nova, 2003, p. 290.

others[13], with the most important reserved for that time when the individual acquires what in France has been termed the full 'age of medical majority'.

The functional approach (or, as it is usually described in Spanish law, natural capacity) is the one which currently dominates medical decision-making: with some exceptions, the individual is competent to decide upon the medical treatment proposed so long as he or she is capable of fully understanding the implications of the proposed treatment, its risks and possible disadvantages, and the alternatives available.

The criterion of functional competence, expressed in our legislation for several decades[14], really found expression a quarter of a century ago with the famous Gillick case[15], to the point where, when talking of 'natural capacity' in this context, we frequently refer to 'Gillick competence'.

The case was brought by Mrs Victoria Gillick, a mother of ten, against her local health authority because it had offered contraceptive advice and treatment to her daughter, who was not yet 16 years old. In Mrs Gillick's opinion, this not only constituted an encouragement to have sex but was also medical treatment without consent.

The House of Lords, in the judgements of Lord Fraser and Lord Scarman, concluded that an adolescent who is below 16 years of age is not thereby incapable of granting consent for contraceptive advice and treatment, so long as the individual fully understands the proposed treatment (something which must be decided on a *de facto* basis in each individual case)[16].

3. Who should be *substituted* in granting consent under Art. 9.3 LAP?

a) The legislation

Who satisfies the *standard* of natural competence or *Gillick competence*? How does Spanish law regulate this area? And, above all, who has the task of assessing whether the patient satisfies the intellectual and emotional requirements?

Article 8 of Spain's Law on Patient Autonomy starts by unequivocally stating the competence of the *capable, free, responsible* patient to decide upon which treatments to undergo.

> ***Article 8. Informed consent.***
>
> 1. *"Any medical treatment requires the free, voluntary consent of the patient after he or she has received the information described in article 4 and evaluated the available options.*
> 2. *Consent will normally be verbal. However, it should be given in writing in the following situations: surgical procedures, invasive diagnostic and*

13. "La madurez exigida no tiene por qué ser la misma en todo tipo de actos médicos" (Romeo Malanda, "Un nuevo marco jurídico sanitario...", p. 1529).
14. The wording of the President's Commission on Bioethics in the United States is unequivocal, rejecting both the *formal* approach and the *consequential* approach, and supporting the concept of natural or functional capacity: "***Decision-making capacity is specific to a particular decision and depends not on a person's status (such as age) or on the decision reached, but on the person's actual functioning in situations in which a decision about health care is to be made***" (President's Commission, *Making Health Care Decisions,* p. 55)
15. *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402 (House of Lords). Regarding the Gillick case, see Kennedy/Grubb, *Medical Law,* p. 607; De Lorenzo y Montero, Ricardo / Sánchez Caro, Javier, "El consentimiento informado", in De Lorenzo Montero (coord.), *Responsabilidad legal del profesional sanitario*, Madrid, 2000, p. 75-76; *Íbid.*, "El consentimiento informado y la información clínica en el Derecho español. Incidencia del Convenio Europeo de Bioética"; in AA.VV., *Derecho Médico. Tratado de Derecho Sanitario, Tomo I. Doctrina. Jurisprudencia del Tribunal Constitucional,* Madrid: Colex, 2001, p. 210; Rivero Hernández, Francisco, "Intervenciones corporales obligatorias y tratamientos sanitarios obligatorios"; in AA.VV., *Internamientos involuntarios, intervenciones corporalesy tratamientos sanitarios obligatorios,* Madrid: CGPJ, 2000, p. 214; Domínguez Luelmo, *Derecho sanitario y responsabilidad médica,* p. 291.
16. Of course, we must distinguish between the *criterion of competence* applied in the Gillick case and the specific treatment in question (the right to contraceptive advice and treatment) (Barnett, Hilaire, *Introduction to Feminist Jurisprudence,* London: Cavendish, 1998, p. 247-248; Wheeler, Robert, "Gillick or Fraser? A plea for consistency over competence in children", in *BJM* 2006, 332, p. 807).

therapeutic procedures and, in general, the application of procedures which pose known and predictable risks or discomfort to the patient's health.

3. *The patient's written consent is required for each of the actions specified in the preceding point of this article, which may be supplemented by appendices and other information of a general character, and the patient will have sufficient information regarding the procedure to be performed and the risks associated with it.*
4. *All patients or service users have the right to be warned about the possibility of using prognosis, diagnosis and treatment procedures applied in the context of a teaching or research project, which may on no account pose an additional risk for the individual's health.*
5. *The patient may freely revoke his or her consent in writing at any time."*

Subsequently, art. 9.3 defines the level of *competence* which the patient must satisfy to have full capacity to choose; and it does this in *negative* terms, by defining who is *incompetent* to grant consent, and who should act as their surrogates for this purpose.

Art. 9. Limits of informed consent and consent by representation.

3. *Consent by representation is granted in the following situations:*

   a) *When the patient is not capable of taking decisions, at the judgement of the doctor responsible for care, or where the patient's physical or mental state does not allow him or her to take responsibility for the situation. If a patient has no legal representative, consent is granted by the people with family or de facto ties to the patient.*
   b) *When the patient is legally incapacitated.*
   c) *When a patient who is a minor is neither intellectually or emotionally capable of understanding the scope of the treatment. In this case, consent is granted by the legal representative of the minor after taking into account the minor's opinion if he or she is at least 12 years old. In the case of minors who are not incompetent or incapacitated and are emancipated or are at least 16 years old, consent by representation does not apply. However, in the case of very risky behaviour, in the doctor's judgement, the parents are informed and their opinion is taken into account when taking the relevant decision.*

4. *Voluntary termination of pregnancy, participation in clinical trials, and assisted human reproduction techniques are governed by the general provisions regarding the age of majority and by the relevant special provisions.*

5. *The granting of consent by representation will be appropriate to the circumstances and proportionate to the needs to be met, and will also favour the patient's interests and respect his or her personal dignity. The patient will participate, in so far as is possible, in decision-making throughout the health process.*

Art. 9.3 employs *functional concepts* of competence, although the definition is necessarily general because legislation cannot provide for all the factors, features and parameters to be evaluated in each individual case. For this reason, it is limited to setting out general assessment criteria. With regard to minors, it requires that they are *"intellectually and emotionally capable of understanding the scope of the treatment"*; and with respect to adults, defines them as incompetent if "they are unable to take decisions, in the opinion of the doctor responsible for their care" or when they cannot "take responsibility for the situation", due to their physical or mental state[17].

The somewhat elaborate structure of art. 9.3 LAP (which defines in principle who is *not* competent and therefore has to be substituted, and then goes on to define who *cannot be substituted*) requires some additional clarification.

a) Adults who have not been incapacitated are competent to grant consent unless the circumstances mentioned in the article obtain.
b) The briefness of the mention of the *incapacitated* is not particularly helpful. The extension of legal incapacitation depends on what the

17. Regarding the cognitive requirements for consent, see Gómez Pavón, Pilar, *Tratamientos médicos: su responsabilidad penal y civil*, Barcelona: Bosch, 1997, p. 92 and ss.

incapacitation ruling has specified, as not everyone is incapacitated for the same purposes. As a result, where art. 9.3.b states "when the patient has been legally incapacitated", this should be taken to mean "when the patient has been legally incapacitated *and his incapacitation specifically affects this class of decisions.*" Where there is a requirement to choose between legal incapacitation and natural competence, the latter should take preference[18].

c) The judgement of the *minor may only be replaced if the minor is not capable of understanding the scope of the treatment*. This legislation is in principle *heavily weighted in favour of the autonomy* of minors (perhaps *excessively so*), as it does not establish a minimum age threshold: in theory, a small child capable of understanding the treatment may validly oppose its parents wishes.

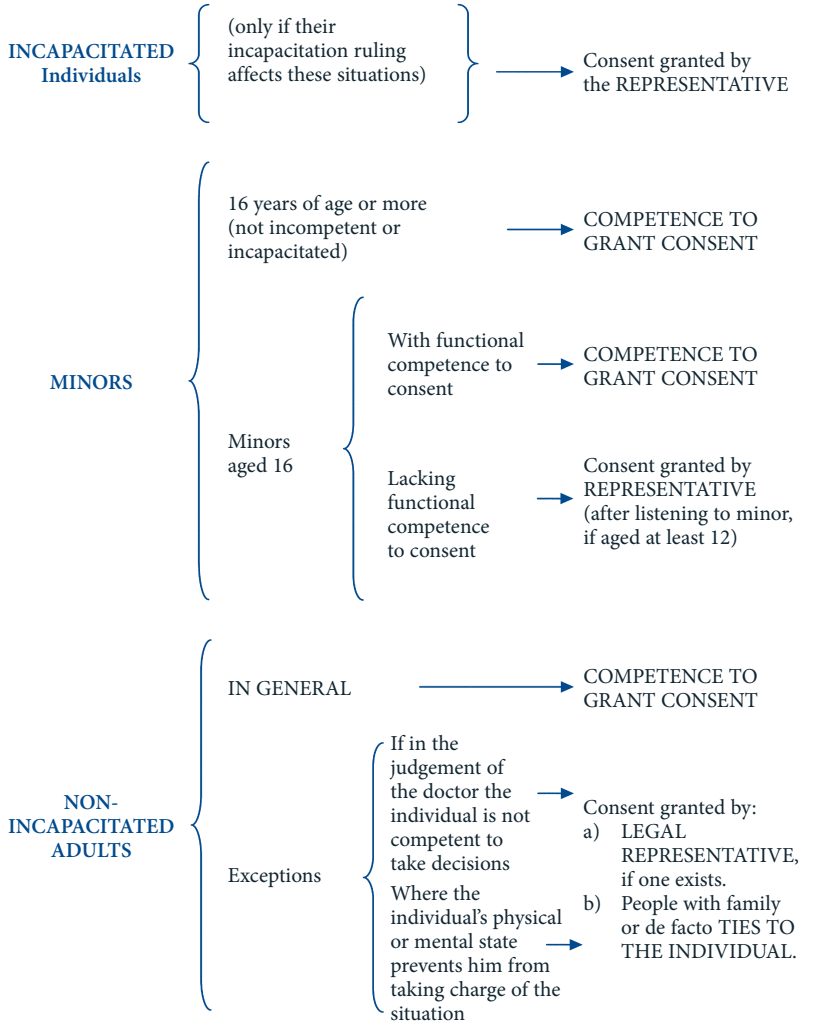
d) Article 9.3.c states that *in the case of "minors who are not incompetent or incapacitated and are emancipated or are at least 16 years old,* consent by representation *does not apply*." The legislation is confusing, because the same could be said *of any competent minor* (given that a few lines earlier it has established the substitution of the wishes of minors *only if they are not competent*). It therefore appears that art. 9.3.c establishes an *assumption of competence* in the emancipated minor or minor aged 16 years or over, with the result that only *incapacitation in the strict sense* or *legal incapacitation* may result in requiring the substitution of consent[19].

18. López-Chapa, Sara. *Autonomía del paciente y libertad terapéutica*, p. 92.

19. Gómez Rivero (*Responsabilidad penal...*, p. 62) explains this confusing legislation with reference to the wording of the original draft bill.

Table 1

Competence to grant consent according to art. 9.3 LAP



b) The assessment of the doctor responsible for providing treatment, as a non-specialist opinion.

The law states that it is the *doctor responsible for treatment* who in each case analyses whether or not the consenting individual is competent.

Specific mention of the *doctor responsible for treatment* only occurs in art. 9.3.a LAP (adults incapable of taking decisions), but should be understood implicitly to apply to art. 9.3.c LAP (immature minors), given that this paragraph does not mention *any party* as being responsible for assessing the patient's competence.

Medical practice would clearly become impossible if it were necessary to conduct a detailed psychological assessment of all patients before performing any medical treatment. The assessment of competence referred to in art. 9.3 LAP must be based on a *prima facie* evaluation made in the first instance by the doctor responsible for treatment. The very nature of the procedure makes it impossible to require an exhaustive evaluation (ongoing psychological or psychiatric assessment, etc.) apart from exceptional cases where circumstances demand a careful assessment of the patient's intellectual and emotional situation. If such evaluation were indeed required, the law would not make it an obligation of the *doctor responsible for care* (who will not necessarily be specialized in this area nor have a protocol for conducting a thorough assessment of the patient's competence), but would instead require *specialist* assessment.

In any event, the decision of the doctor can, of course, be *questioned*. If an adult believes that the assessment of *incompetence* made by the care doctor is incorrect and that he should not be subjected to the decisions of others, he can request an alternative assessment. If this is denied and he does not agree with the decision of the surrogate (or he simply wishes to assert his own competence), he may turn to the courts.

This does not mean that the doctor responsible for care has *no responsibility* in this regard and that he cannot be held to account if he accepts the consent of an individual who is clearly incompetent; but this will only be possible in cases where he has ignored evidence which would be clear to a non-specialist (that is, when he clearly fails to meet the standards applicable *in the first instance*). Minimum prudence would appear to call for more detailed analysis of patient competence where this is questionable and the treatment under consideration could be problematic.

As a general rule, and except where there is specific evidence to suggest that the patient is not able to understand, for adults this assessment should be made *as part of the patient information process*. in other words, it is by complying with the obligation to inform patients that doctors should detect whether the individual is capable of taking decisions with regard to his or her health. More detailed analysis is only necessary if this is indicated by the outcome of the information process.

Of course, the comprehension capacity required for each medical treatment varies, depending on what it entails and what the possible outcomes and risks are. The level of competence required to agree to open heart surgery is obviously not the same as that needed when deciding whether to be vaccinated or to take treatment for cold symptoms.

When the patient is a minor, then the younger the individual, the more detailed the analysis must be. For routine, non-surgical medical treatment of minors who are accompanied by their parents or legal representative, the procedure is of little importance unless the minor expresses a position which is *contrary* to that of his or her guardians.

c) What should the doctor responsible for treatment consider in this initial opinion?

The competence to take decisions in a medical context is defined by the LAP in extremely vague terms as being "*capable of taking decisions*" (art. 9.3.a; this, strictly speaking, is not a *definition* of competence but merely an *allusion* to it) or being "*intellectually [and] emotionally capable of understanding the scope of the treatment*" (art. 9.3.c).

It appears that competence in both cases must be understood in the same terms:

- an intellectual component (the basis of the *Gillick* ruling), which enables the subject to understand the implications of the treatment, the possible consequences both of treatment and of *non*-treatment, and the alternatives; and
- a *voluntary* element, relating to the *absence of extraordinary emotional pressure* which might prevent the individual from reaching a reasonable decision[20].

With respect to the intellectual component, the key is not whether an individual bases his or her understanding of the situation on a *rational and scientific* viewpoint. Our society accepts a range of accepted religious philosophies which take as their starting point ideas or beliefs which the majority might deem unreasonable or which openly contradict scientific knowledge. But citizens who adhere to these philosophies are not *incapacitated* for the purpose of taking medical decisions.

Instead, the key point is that, starting from this perspective (which we may find more or less convincing) individuals *"succeed in drawing logical conclusions (...) that is, that they possess instrumental rationality"*[21].

Along the same lines, the United Kingdom's *Mental Capacity Act* of 2005 establishes that a person is not *competent* if he is unable:

a) to understand the information relevant to the decision;
b) to retain that information;
c) to use or weigh that information as part of the process of making the decision; or
d) to communicate his decision (whether by talking, using sign language or any other means)[22].

20. Of course, when we are considering *extreme* medical situations, there is always an element of emotional disturbance inherent. We need to ensure that this pressure is not *incapacitating*, that is, that it does not block the individual's decision-making capacity.

21. De Lora, Pablo. "Autonomía personal, intervención médica y sujetos incapaces", in *Enrahonar. Quaderns de filosofía,* 40/41, 2008, p. 125.

22. Regarding recent British legislation, see Herring, Jonathan, *Medical Law and Ethics*, Oxford: Oxford University Press, 2006. 89 and ss.

This *minimum capacity*, however, poses problems in *extreme* cases, such as that of individuals who have faith in *pseudoscientific treatments* and reject the medical treatments advocated as current best practice. For example, a patient who rejects the indicated treatment for a malign tumour[23] in favour of homeopathic treatment or traditional tribal medicine from some remote corner of the world. The solution to these situations is simple when the decisions *concern a third party* (parents or guardians *cannot* reject medically recommended treatment on behalf of their child). However, the situation is far more complex where adults are concerned:

- Firstly, in these cases it is essential to provide *much more detailed and convincing* information than in normal situations, as the patient is clearly labouring under erroneous beliefs. As a result of this cognitive deficit, they need *much more information* than anyone else.
- Secondly, we should consider whether the patient's refusal is due to his or her having been fraudulently persuaded to consume 'magical' health products, in which case the law considers that the victim's consent has been obtained under false pretences[24].
- With these provisos, the law does not permit further action. *People who are stubborn and ignorant but do not suffer from cognitive disorder, have not been prevented from expressing their wishes, and have not been subject to extreme emotional pressure, are not incompetent in the medical sphere; and the legislation makes no provision for the substitution of their wishes in choosing medical treatment.*

23. I am referring here to rejection *by the patient himself*; for decisions made by a third party, see the next section.

24. See, in this regard, Spanish Supreme Court Rulings (2nd Chamber) 2464/2001 of 20 December and 778/2002 of 6 May.

4. What criteria should the surrogate or representative use when reaching their decision?

a) Introduction

The LAP tells us who has to provide consent in the event of a patient being incompetent, but does this mean that surrogates *are free to decide as they see fit* or do they have to meet certain standards? The response of the law in this regard is somewhat scant:

> *Art. 9.5 LAP. "The granting of consent by representation will be appropriate to the circumstances and proportionate to the needs to be met, and will also promote the patient's interests and respect his or her personal dignity"*[25].

The first two criteria (*appropriate to the circumstances* and *proportionate to the needs*) are extremely vague, and are really guidelines rather than criteria as such; the third criterion (acting *in the patient's interest*[26]) is a little more specific, but still requires further definition. A few examples serve to illustrate the range of responses which can result from applying the principle of *the patient's interests*:

25. The criterion of "the patient's interests" reflects the conclusions of the Oviedo Convention (Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine). Art. 6.1. establishes that "an intervention may only be carried out on a person who does not have the capacity to consent when it is to his or her direct benefit"; and art. 7, with respect to people suffering from mental illness, states that, "Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health."

26. Jorge Barreiro, Agustín, *La imprudencia punible en al actividad médico-quirúrgica,* Madrid: Tecnos, 1990, p. 85.

i. A 13-year-old boy insists on refusing a blood transfusion which is needed to keep him alive, in accordance with the traditions of the Jehovah's Witnesses[27].
ii. An incapacitated adolescent refuses a German measles vaccination because she has a phobia of needles. After several attempts to vaccinate her, the adolescent struggles and hurts herself, and eventually faints as a result of the tension.
iii. An elderly Alzheimer's patient, suffering from advanced cancer, could undergo treatment which if successful would prolong his life for up to a year; however, the operation is quite risky and his state of health so fragile that he is far from certain to survive. His granddaughter and only close relative (and also his sole heir) insists that her grandfather should not be disturbed during his final weeks of life.
iv. An adult patient who is unconscious urgently requires a blood transfusion. His wife and another companion insist that the doctor refrain from performing the procedure, as the patient is a Jehovah's Witness. The only proof of this is the statement of the wife and the other companion.
v. The parents of a 27-year-old man with a profound learning disability and a mental age of 6 want him to donate a kidney to his 28-year-old brother, who urgently needs one. Donating a kidney will reduce both his quality of life and his life expectancy; but the death of his brother would also have a very big impact on him[28].

What are the *patient's interests* in these scenarios? The treatment indicated by best practice or respect for the religious choice of the patient (and, from the patient's perspective, avoiding harm of a transcendental or spiritual nature)? The preventive benefit provided by vaccination, or avoiding the genuine suffering which the injection represents for the patient? The possibility of gaining a few extra months of life, or avoiding a risky operation which may ruin the last days of a fragile patient's life? Preserving quality of life or protecting a patient with a mental age of 6 from the trauma of losing

27. See Ruling 154/2002 of Spain's Constitutional Court.

28. Strunk v. Strunk (1969) 445 SW 2d 145 (Court of Appeals of Kentucky).

his brother? Assessing and deciding upon such issues is a very difficult problem, particularly when those called upon to decide for the incompetent or unconscious patient are often his or her *heirs*, that is, people whose decisions about the end of life of the patient could be distorted by financial incentives.

When analysing these issues, acting *in the patient's interests* may be understood by the surrogate in three different ways:

- In accordance with the *subjective assessment of the third party making the decision*;
- On the basis of an *objective consideration of the medically indicated options for the life and health of the patient* (in English law, the criterion of the patient's 'best interest'); or
- In accordance with *what the patient would have decided if he or she had been able to express a decision* (in English law, the criterion of *substituted judgement*).

In most 'normal' situations, these three criteria will lead to the same decision. However, because medical decisions in general and decisions at the end of life in particular are a delicate sphere in which the ethical, social and religious perspectives of individuals vary widely, it is important to note that these three criteria will not always lead to the same conclusions, while the criteria themselves are not equally legitimate.

b) Subjective assessment of the representative

Despite the fact that in some situations (such as, with restrictions, the *choice of religious education for their children*) the criterion of the *subjective assessment of the representative* is recognized as relevant, this does not apply in the context of informed consent granted by a surrogate. A father who is a Jehovah's Witness cannot force his son to reject a transplant; and a mother who is convinced that sex before marriage is wrong cannot reject contraception on behalf of her daughters if they have *'Gillick* competence'.

Moral and religious views will obviously play a key role in medical decisions; however, this does not mean that the parents or legal representatives of an incapacitated individual or the family of someone who has lost consciousness and needs treatment are authorized to *impose* their visions on a person who is incapable of granting consent. The surrogate *lacks the legitimacy* to apply their own beliefs to the patient when this involves choosing an option which diverges from the appropriate medical option or, where it is possible to demonstrate this, from what the patient would have wished for.

This strikes us as evident when we are referring to the substitution of an *adult*, and the situation is the same for *minors*. For these purposes, the parents do not in the strict sense have a *subjective right* with regard to decisions about the health of their child; their rights are *conditioned* by the requirement to act in the minor's interests. Their role with respect to the minor is that of *advocate*[29].

This having been said, it would be naive to ignore the fact that in the majority of cases the surrogate acts in accordance with his or her own criteria, regardless of whether these coincide with those of the patient[30]. It is precisely for this reason that it is so important to identify which decision-making criteria are actually applicable when assessing and analysing the surrogate's decision.

29. *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402 (HL). Clearly, parents do have certain *rights* with respect to their children with which the State may not interfere without justification (for example, the right to see them and to live with them); all that is being said here is that the legal position of the parent *with respect to care for the minor* is one of advocacy rather than the direct exercise of rights.

30. Indeed, in many cases the third party making the decision is a person who *may stand to benefit financially from the patient's death*. (This conflict of interests creates an incentive to take decisions which do *not* prolong the individual's life, and while in general this will not influence the relative's decision, nor does it help to *guarantee* the rights of the patient.)

c) The decision that the patient would have adopted ('substituted judgement'). Evidence of advance directive and hypothetical wishes of the patient

This is the criterion which most closely reflects the principle of *respecting patient autonomy*[31]: had the patient been able to express his wishes, which option would he have chosen?[32]

In attempting to identify the (real or hypothetical) decision of the patient, this criterion is only applicable in *situations involving the substitution of the wishes of a competent individual who has become incapable of expressing himself:* in other words, situations where an adult, or a minor of equivalent status, has become unconscious (by contrast, it is not applicable to individuals *who have never enjoyed competence*)[33]. In these cases, the surrogate's role is similar to that played by *prior verbal instructions*, transmitting to the doctor responsible for treatment the wishes of the subject before he or she became incapable of expressing them. When dealing with subjects who *did not possess the capacity to grant consent* prior to the medical situation arising (for example, small children), this criterion does not apply, and instead we must consider the patient's '*best interest*'[34].

31. Beauchamp, Tom L. / Childress. James F, *Principios de ética biomédica,* Barcelona: Masson, 1999, p. 161 and ss.; Romeo Casabona, Carlos Mª, "Los derechos de los pacientes: información clínica y autonomía del paciente", in *Las transformaciones del Derecho Penal en un mundo en cambio*, Arequipa (Peru): Adros, 2004, p. 32. More generally, see Rawls, John. *A Theory of Justice. Revised edition*, 6th. printing. Harvard Univ. Press, 2003, p. 183.

32. American Medical Association: Council On Ethical And Judicial Affairs. "Surrogate Decision Making" (2001), p. 3; *Beschlüsse des 63. deutschen Juristentages* Leipzig 2000, conclusion 4.1.

33. Santos Morón, Mª José, *Incapacitados y derechos de la personalidad...*, p. 83; De Lora, Pablo. "Autonomía personal, intervención médica y sujetos incapaces", in *Enrahonar. Quaderns de filosofía*, 40/41, 2008, p. 129.

34. Shepherd, Lois, "Dignity and Autonomy after Washington v. Glucksberg: An Essay About Abortion, Death, and Crime", in *Cornell Journal of Law and Public Policy* 7, (1998), p. 431 and ss., p. 443; Kennedy/Grubb, *Medical Law,* p. 831; Barrio Cantalejo / Simón Lorda, "Criterios éticos para las decisiones sanitarias al final de la vida del paciente", in *Revista Española de Salud Pública* no.4-2006, p. 306.

The concepts of *evidence of advance directive* and *hypothetical wishes of the patient* are not identical.

- We refer to *evidence of advanced directive* when an individual *has already expressed their wishes with regard to a specific class of treatment* and the surrogate provides *testimony* of the patient's *real* wishes. In the *Eluana Englaro* case, for example, Mr. Englaro testified that his daughter Eluana *had clearly and unambiguously expressed her wish* not to be artificially fed and hydrated in the event of her falling into a permanent vegetative state[35].
- However, the term *hypothetical wishes* refers to situations in which nobody has witnessed an advance declaration by the patient regarding the specific situation in which consent must be granted, but in which the surrogate decision-maker attempts to ***reconstruct*** what the patient's wishes would have been on the basis of other information (such as his religion, his philosophy, his values, his opinion regarding similar situations, etc.)[36].

The importance of this criterion is fundamental, as very few people at present sign Advanced Directive Documents as per art. 11 LAP (the most robust form of *living will*). As a result, if no such document is available but it is possible to identify the patient's wishes by some other means, then we will be able to go some way towards safeguarding the patient's autonomy. This is why most international documents take the view that the criterion of the patient's hypothetical wishes should take priority over the more objective concept of *best interest*[37].

35. Regarding this well-known case see, among others, Mestre Delgado, Esteban, "El caso 'Eluana Englaro' y el debate jurídico sobre el suicidio asistido", in *La Ley Penal* no. 60, 2009, p. 5 and ss.

36. Although, as we have noted, in the Englaro case Mr. Englaro testified as to his daughter's *advance directive*, the legal rulings are somewhat confusing regarding this point, and talk of *reconstructing* the decision of the patient Eluana Englaro as if there were no evidence of a *perfectly constructed* preference.

37. Some authors have argued that, in reality, a correct understanding of the criterion of *"substituted judgement"* incorporates the *"best interest"* of the patient: Dworkin, Gerald, "Law and

Although the LAP does not appear to make express, specific reference to this criterion, it is alluded to indirectly in the mention in art. 9.5 of the *dignity* of the patient (the decision of the representative must always be taken "in the patient's interests *and respecting his personal dignity*"): and imposing medical treatments or other options which went against the patient's wishes would constitute an affront to this dignity.

Notwithstanding this, we must also be aware that applying this criterion is far from easy:

- In the first place, the fact that a person has discussed a given position with friends or family (e.g., rejecting intensive treatment measures, the wish not to be artificially fed or hydrated, or expressing indignation in response to a controversial case of *'disconnection'* covered in the press) without having recorded such views in an Advance Directive may simply reflect carelessness[38] or may be because, whatever the individual said, *he or she did not really want to take this decision* (or was not so sure). It is one thing to take a binding decision in a document and quite another to make non-binding comments.
- Secondly, we should note the *precariousness* of this criterion, given that it may be sufficient simply for a family member or companion who is sufficiently close to the patient to *say* what the patient's wishes were for this decision to be taken. This significantly blurs the boundaries between this criterion and the subjective assessment of the representative[39].

Medical Experimentation" 1987, Monash University Law Rev. 1987, p. 189-200; along similar lines, Peñaranda Ramos (*Compendio I,* p. 360) stresses that people's health can be considered from a strictly objective perspective or by including the patient's subjective preferences. And the United Kingdom's *Mental Capacity* Act of 2005 (c.9, Part I., 4; see also Herring, *Medical Law and Ethics*, p. 114 and ss.) introduces the hypothetical preferences of the patient under the heading "best interest".

Despite such considerations, in this text we will use the term *best interest* to refer to the objective consideration of medical circumstances, and the term *substitutive judgement* to refer to the consideration of the individual's opinions and choices.

38. As we noted, very few people currently draw up Advance Directive Documents.

39. "The criterion of substitutive judgement requires great moral integrity. The surrogate must be able to set aside his own opinions to place himself in the position of the person he is substituting. There is a risk that what the surrogate expresses as 'substitutive judgement' is no more than his own opinion, wish or decision" (Barrio Cantalejo / Simón Lorda, "Criterios éticos para las decisiones sanitarias al final de la vida del paciente", in *Revista Española de Salud Pública* no.4-2006, p. 307).

- Finally, because what is at question here is a test of a factual issue on the basis of evidence, *there may be evidence to the contrary*. And this is precisely why there have been high-profile cases involving *family arguments* about what the real wishes of the patient were (for example, in the famous Schiavo case).

In response to problems such as this, authors such as Buchanan and Brock[40] have set out the key elements for the *moral credibility and authority of the witness* and have drawn up a test involving a series of *rules of thumb*. They argue that, other things being equal, a declaration has more weight:

- *The more specifically this is expressed* (e.g., if the patient has said that *in the event of permanently losing consciousness he does not wish to be maintained using assisted breathing* this has more weight than if he has said that he does not want 'to be kept alive with machines').
- *The more direct the patient's reference to himself* (e.g., if the patient had said that he did not want *himself* to be kept alive using certain methods, this would have more weight than if he had said that he thought it was wrong that *somebody else* was kept alive using these methods).
- *The bigger the number of sources* (e.g., if there is only *one witness* of a patient's statement, this will have less weight than if there are *several* unconnected witnesses).
- *The more reliable these sources are* (due to their emotional closeness[41] to the patient, the absence of conflicts of interest, etc.).

40. Buchanan, Allen E.; Brock, Dan W., *Deciding for Others: The Ethics Of Surrogate Decision Making,* Cambridge: Cambridge University Press, 1990 (reprinted. 1998), p. 120-121 (see also Barrio Cantalejo / Simón Lorda, "Criterios éticos para las decisiones sanitarias al final de la vida del paciente", in *Revista Española de Salud Pública* no.4-2006, p. 312 (Anexo 3).

41. López-Chapa, Sara. *Autonomía del paciente y libertad terapéutica,* p. 115.

- The *more frequently* the patient's statements have been repeated (the evidence of *a single statement* is obviously weaker than the evidence of a *consistent attitude expressed over a period of time*).

When applying the first two criteria, the evidence of a *real wish* ("the patient stated that he did not want to be artificially kept alive if he fell into a permanent vegetative state") has more weight than the *reconstruction* of a *hypothetical wish* on the basis of specific information about the patient's life ("because the patient regularly attended mass, we must follow Catholic doctrine, and this means he should be kept alive even if this means artificially prolonging the process of dying"); and all the more so, the *less direct* the evidence is (regular attendance at Sunday mass is not incontrovertible proof that an individual prefers artificial life support even if this means prolonging his suffering and the process of dying: Catholic doctrine encompasses a range of positions in this regard; and membership of a religion does not mean accepting each and every one of its precepts).

In section e) below we will consider this issue in more detail within the framework of analysing how to combine the criteria of substituted judgement with that of the patient's best interests.

d) Attending to the well-being, health and life of the patient in objective terms (patient's 'best interest')

In the absence of a specific expression of wishes by a competent patient (whether by means of an *Advanced Directive document* or through the testimony of a parent or companion)[42] or the possibility of reconstructing his *hypothetical wishes*, the criterion to apply is that of attending to the well-being, health and life of the patient, according to "medically and socially agreed objective criteria".

42. American Medical Association: Council On Ethical And Judicial Affairs. *Surrogate Decision Making* (2001), p. 4; Paeffgen, H..-U., in *Nomos Kommentar* I, 3rd ed., 2009, Commentary preceding §§ 32-35, n. m. 166.

This is the most objective and, therefore, the least controversial criterion. It entails seeking to take the decision which is *most beneficial in objective terms for the well-being, health and life of the individual*[43], on the basis of best medical practice. This interpretation is reflected in art. 9.5 of the LAP, which requires that consent *"by representation"* always be granted *"in the patient's interests"*.

The President's Commission for Bioethics, in the United States, defined the criterion as follows:

> *"Because many people have not given serious thought to how they would want to be treated under particular circumstances, or at least have failed to tell others their thoughts, surrogates often lack guidance for making a substituted judgment. Furthermore, some patients have never been competent; thus, their subjective wishes, real or hypothetical, are impossible to discern with any certainty. In these situations, surrogate decisionmakers will be unable to make a valid substituted judgment; instead, they must try to make a choice for the patient that seeks to implement what is in that person's best interests by reference to more objective, societally shared criteria. Thus the best interests standard does not rest on the value of self-determination but solely on protection of patients' welfare.*
>
> *In assessing whether a procedure or course of treatment would be in a patient's best interests, the surrogate must take into account such factors as the relief of suffering, the preservation or restoration of functioning, and the quality as well as the extent of life sustained. An accurate assessment will encompass consideration of the satisfaction of present desires, the opportu-*

43. *Beschlüsse des 63. deutschen Juristentages* Leipzig 2000, conclusion 4.3. Against this, authors such as Silva Sánchez argue that the guiding principle in cases concerning individuals who are not competent to decide should not be that of well-being but rather *in dubio pro vita*, "even where this will inevitably result in early death or in intense physical or mental suffering" [Silva Sánchez, Jesús-María: "Los 'documentos de instrucciones previas' de los pacientes (articulo 11.1 Ley 41/2002) en el contexto del debate sobre la (in)disponibilidad de la vida", in *La Ley* 2003-4, p. 1663-1671].

nities for future satisfactions, and the possibility of developing or regaining the capacity for self-determination."[44]

The basic criteria must start with the *relief of suffering*. In normal conditions, *the relief of serious, persistent suffering* must be the main criterion (unless there are specific circumstances which mean that it can be justified in order to deliver major therapeutic benefit); after this comes the criterion of therapeutic benefit, as expressed by the *maintenance or recovery of the patient's functions, quality and duration of life.* The simple duration of life in a vegetative state without any medical hope of recovery, apart from exceptional cases, is generally of significantly less importance than physical well-being, the absence of pain, and quality of life.

However, often there are *various solutions which are acceptable from the perspective of the interests of an incompetent patient*: to give two extreme examples, the decision as to whether to perform non-urgent minor operations (e.g., podiatric surgery), and the decision as to whether or not a terminally ill patient should undergo risky surgery which might extend the patient's life by up to a year. In these cases, we find that the criterion of 'best interest' establishes a *framework of acceptable decisions*, within which the surrogate decision-maker must operate, on the basis of the patient's specific circumstances.

In any event, the existence of an *objective* criterion assumes that it is possible *to objectively evaluate the representative's decision*. The representative *cannot validly choose an option which is not medically indicated*[45]: faced with a decision by the representative which is questionable from a medical point of view, both the doctor and other relatives or those with ties to the patient may ask a judge to rule that the representative's decision is contrary to the patient's interests and to take a different decision.

44. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *Deciding to Forego Life-Sustaining Treatment. Ethical, Medical, and Legal Issues in Treatment Decisions.* Washington DC: U.S. Gov. Printing Office, 1983, p. 134-135.

45. "Where, for example, there is more than one therapy available, a decision in favor of any one of those considered appropriate by health care professionals will be acceptable under the best interests standard. However, the *best interests* standard would preclude the surrogate from choosing a therapy that is totally unacceptable by professional standards" (President's Commission, *Making Health Care Decisions,* p. 179-180).

e) Specifying: 'best interest' vs. 'substituted judgement'. Can the representative take the same decisions which a competent, adult patient would be able to take?

The answer to this question depends on *which criterion the representative is able to apply: the 'objective' criterion of 'best interest' or the 'subjective' one of 'substituted judgement'*.

As we have noted, both the law and a range of international institutions have stressed the *primacy* of the criterion of the (*real* or *hypothetical*) *wishes* of the patient over the more objective concept of *attending to the well-being, health and life of the patient ('best interest')*. However, the question requires further consideration.

The representative con only act *in the patient's interests and respecting his human dignity*. As a result, as a matter of principle, *the fact that the representative is acting on the basis of the patient's best interest in objective terms means that the representative cannot take therapeutic decisions which are contrary to current medical practice.* A hypothetical decision to *reject treatment without medical justification*, for example, would lack validity because it would exceed the legal margins of the representative's mandate. *If the surrogate is deciding on the basis of the criterion of objective attention to the well-being, health and life of the patient, he can only operate within the boundaries of what is medically indicated, and any decision which oversteps these boundaries will be deemed invalid.*

Here we can clearly see the difference between the scope allowed to the representative deciding on the basis of the patient's *best interest* and that of a competent patient who is able to take decisions which are *contrary to what is medically indicated*, such as a 'groundless' or 'medically unjustified'

rejection of treatment (this is the position set out in art. 21 LAP regulating compulsory discharge due to the rejection of the indicated treatment, in which case the centre may even be obliged to offer non-therapeutic palliative solutions)[46].

Article 21 LAP. Discharging the patient.

1. *Where the recommended treatment is not accepted, the patient or user will be asked to sign a voluntary discharge agreement. If the patient refuses to sign, the management of the health centre, on the advice of the care doctor, may initiate compulsory discharge under the conditions established in the Act. Refusal to accept the prescribed treatment will not give rise to compulsory discharge where alternative treatments exist, even where these are of a palliative nature, so long as they are provided by the health centre concerned and the patient agrees to receive them. These circumstances must be properly documented.*
2. *In the event that the patient refuses to be discharged, the management of the health centre, after checking the relevant clinical report, will listen to the patient's views and, if he continues to refuse, will refer the matter to a judge who will confirm or reverse the decision.*

However, *if the representative can prove that he is acting in accordance with the criterion of the patient's real wishes, he would in reality be transmitting the patient's decision*. As we have noted, the representative's role here *would be equivalent to a "verbal advanced directive document", and could include authorising a medically unjustified rejection of treatment*. If the representative's testimony is reliable, his decision (or rather, his *declaration of knowledge of the patient's decision*!) *may have the same scope as that of the patient*.

46. The expression *"groundless or medically unjustifiable rejection" of treatment* refers to a rejection which is *not therapeutically indicated*. There are situations in which both continuing and rejecting treatment may be therapeutically indicated (for example, invasive treatments which offer little benefit, or in very fragile patients, etc.). However, in other cases it may be personal or religious motives, for example, which lead a person to reject treatment. The paradigm is the rejection by Jehovah's Witnesses of treatments which involve blood transfusions.

If a relative can provide valid proof that an unconscious, adult patient is an orthodox Jehovah's Witness, this may be considered to be sufficient proof that it is his wish *not to receive blood transfusions*; and therefore be binding upon the doctor.

Needless to say, great care needs to be taken with regard to the requirement for proof. Being a follower of a particular religion does not necessarily mean obeying all of its injunctions at all times, particularly when this may result in the follower's own death. This assumption is even weaker in the case of *mainstream religions*, where members often take part in religious practices for social reasons or due to inertia rather than as an expression of orthodox faith.

Despite this, the case of the Jehovah's Witness is a *clear* one. In the example proposed, the patient *ascribes to a set of beliefs recognizable by anyone* (the beliefs and rules of a particular religion), and this takes the form of his public identification as a Jehovah's Witness; and this set of beliefs *clearly, directly and unequivocally* involves the rejection of certain treatments, such as blood transfusions. However, most people do not publicly express their opinions or preferences regarding medical treatment. As a result, the testimony of relatives or those with ties to the patient often does not have the same force as the example discussed.

This is clear from famous examples such as the *Englaro* case. In this case, one of the central issues, according to the Ruling of the Court of Appeal of Milan, was *proof of the wishes of Eluana Englaro*. Given the enormous importance of this case (initially, because it concerned a decision which would result in ending a patient's life, and subsequently because it became a focus of media attention), the Court of Appeal of Milan, in its ruling of 9-7-2008, found that the accuracy of the reconstruction of the patient's wishes by her father had to be tested. For this purpose, the Court took into account the evidence of several friends of the patient, together with input not just from her parent and guardian, but also from a *special advocate* appointed to defend her interests. However, it should be noted that Mr Englaro testified that his daughter, while she was still able to express herself, *directly asked* that, in the event of her falling into a permanent vegetative state, she should not be submitted to

forced feeding and hydration, something which she considered to be a form of *therapeutic torture*[47].

In the famous *Schiavo case* (which also referred to the withdrawal of artificial nutrition and hydration of a person who had been in a permanent vegetative state for 15 years), one of the key points revolved around the question of what her wishes were with regard to such treatments. The patient's husband, Michael Schiavo, stated that his wife did not wish to receive this sort of extended intensive care, and adduced the testimony of several joint friends. For their part, the patient's parents claimed that she was a Catholic and did not want to go against the guidance of the Church with regard to euthanasia (*reconstruction of hypothetical wishes*). The courts supported the husband 's claim that his wife would not have wanted this situation (see *Schiavo I*, ruling. 24 January 2001 of the Florida 2nd District Court of Appeal (In re guardianship of Theresa Marie Schiavo, Incapacitated)[48].

If a *real* advance directive provides only partial evidence of the actual wishes of the patient, the reconstruction of what the patient's wishes would have been on the basis of his values, statements, etc. (*hypothetical wishes*) would scarcely be deemed admissible in other legal contexts. However, the dramatic nature of the interests at stake together with the absence of alternatives mean that it is frequently invoked. While it is true that this is an *informal* document, it is important to remember that in this regard the law deliberately opts for relatively informal approaches as a way of finding a flexible route to the most reasonable solution[49]. As a result, where the children of a dying parent disagree on what treatment should be applied and turn to the courts, the criterion of the *hypothetical wishes* provides a degree of guidance for the judge's decision.

As we have said, the legal uncertainty which exists in such cases would be unthinkable if we were dealing with *inheritance*, for example. Here, the law grants extensive powers to the donor, but also clearly establishes a set of rules which cover what happens when the donor *has not said anything* (the rules of *intestate* succession), with the result that the judge does not have to become involved in investigating what the deceased wanted (or would have wanted!) to happen to his estate. However, given the range of competing concepts in our societies regarding the end of life and its medical treatment, it is not possible for us to resolve this uncertainty by recourse to general rules or assumptions.

This does not mean, however, that faced with a lack of information regarding the wishes of the unconscious patient we can make no assumptions at all. *Of the different options available, priority should be given to those which contribute greater well-being when the patient can no longer be cured* (so, to give a clear example, the mere prolongation of life – or rather, the prolongation of the *process of dying* – is now almost unanimously considered to be an option which is only applicable when the patient specifically requests it). This is of great importance when we are considering decisions at the end of life of an unconscious patient[50]. In response to certain recent cases, Gimbernat Ordeig commented some years ago:

> "With regard to the *case of a terminal patient enduring severe physical suffering, and who is unable to grant consent to palliative care due to his low level of consciousness, because he is a minor or because he is not in full possession of his mental faculties*, the thesis which has recently been proposed from various sources that in this case it falls to the patient's relatives to decide whether or not he should be sedated is quite incorrect. There are two reasons for this:

47. Although the trial consistently refers to the "reconstruction of the assumed" or "hypothetical wishes", it would appear that rather than seeking a *reconstruction of her hypothetical wishes*, in this case the Court investigated the veracity of the evidence for an *informal statement of the patient's real advance directive.*

48. http://abstractappeal.com/schiavo/2dcaorder01-01.txt

49. The legal criteria for selecting who can provide consent by substitution in the case of unconscious adults are also very informal (people with family or *de facto* ties; vid. Romeo Casabona, "Los derechos de los pacientes: información clínica y autonomía del paciente", p. 31).

50. Gimbernat Ordeig, Enrique, "El problema jurídico de la muerte y el dolor", in *Diario El Mundo* 19 April 2005.

- The first reason is because, in the absence of any prior statement to this effect by the patient, whether explicit or tacit, the assumed wishes of the patient cannot be interpreted to mean that he belongs to that small group of people with masochistic tendencies or a vocation for martyrdom who ascribe greater value to - and prefer - a longer life which entails great suffering to a shorter one without such suffering, but rather we must assume exactly the opposite: that the patient's preference is for indirect euthanasia, something which when administered by a doctor is permitted by the law and the practice of which should be guaranteed by the health system, which has the obligation to provide terminally ill patients with "palliative care units" (arts. 12.2.8 and 132.E Ley 16/2003), and because both the European Parliament, in June 1999, and even the official teachings of the Catholic church have pronounced in favour of allowing the administration of opioids such as morphine and anxiolytics, even if this is likely to shorten a life for which the only prospect is that it will be lived out immersed in a hell of physical suffering.
- The second reason why the decision of relatives cannot be decisive in opposing palliative care for a patient who is unable to express his wishes, or who is only able to do so ineffectually from a legal point of view, lies in the fact that, in such cases of consent by representation, art. 9.5 of Law 41/2002 states that, "the granting of consent by representation will reflect the situation and be proportionate to the needs to be met, will always be in the patient's interest, and will respect his personal dignity,": in other words, the consent of relatives is only binding upon the doctor if it acts in the patient's interests and safeguards his dignity. And from this it naturally follows that the refusal of the surrogate to allow the patient to receive palliative care - that is, expressing the wish that the patient's agony be prolonged for days or weeks amid cries of pain - cannot be considered either to reflect the patient's interests or to respect his dignity, especially when we bear in mind that indirect euthanasia is both legally permitted and is accepted by institutions as diverse as the European Parliament and the Catholic church."

Gimbernat's position here is both brave and thoroughly reasonable, and I would like to make just one clarification:

a) In the case of *patients who are minors or incapacitated*, relatives are bound by the criterion of '*best interest'*, as a result of which any decision to prolong the painful process of dying and forbid sedation would be *legally invalid*. As explained above, prolonging the painful process of dying is against the objective best interests of the patient, and the representatives of minors or incapacitated patients are bound to defend these interests.
b) In the event of substitution of the wishes of *adult patients*, the relatives cannot adopt a decision which would prolong the patient's agony by rejecting sedation with *double effect ... unless they can reasonably demonstrate that this was the wish of the unconscious adult patient (substituted judgement)*, because the criterion of the patient's wishes takes precedence over his objective 'best interests'.

However, a decision of this nature needs to satisfy very high standards of evidence, entailing as it does one of the worst fates any human being may suffer: an agonizing death. As a result, only an *Advanced Directive* document or a *number of very reliable witnesses* (in the terms defined above, applying Buchanan and Brock's test) can reliably determine that this is the patient's wish.

And when it comes to testing whether the (undocumented) advance directive or 'hypothetical wishes' of an unconscious patient should be given this status, *the different potential outcomes do not stand on an equal footing, but rather those which depart furthest from the standard of the patient's 'best interest' require a higher level of proof*. When different medically indicated decisions exist (for example, in the Englaro case, both maintaining nutrition and hydration and withdrawing them were deemed medically correct), the decision to opt for one or the other can be based on evidence of an advance directive or on a reconstruction of the patient's hypothetical wishes. However, the further the patient's assumed decision deviates from the standard of protecting his health and life, the more difficult this becomes: in such cases, higher standards of evidence are required. In the extreme case (*medically unjustifi-*

able rejection of treatment), only if there is *absolute certainty* is it acceptable to follow the patient's assumed wishes.

> Example: an elderly hospitalized patient suffers from a urinary tract infection and requires treatment. As a result of her fragile state of health, she has fallen into a state of unconsciousness. Her closest relative (who is also her sole heir) is asked to grant consent to a simple treatment, but *rejects* it out of hand. When the medical staff insist, explaining that the rejection is not medically justifiable, he replaces that *this is what his mother had said*. In this case, the doctor should not accept the response, and should refer the issue to the courts. However, if this instruction was recorded explicitly in an *advance directive document*, it would be binding on the doctor.

This is even clearer when we consider the legal history of the criteria for surrogate decision-making. In general, when the courts have taken into account the reconstruction of the *hypothetical wishes* or other weaker evidence, it has been in order to decide which of two medically indicated decisions comes closest to the criterion of *best interest* (*Englaro case*[51]); and when they rejected them, it was because they indicated that the patient's wishes entailed *prolonging painful deaths or vegetative states without hope of recovery* (*Schiavo case*).

All of this points in one direction: *the concept of the 'assumed wishes' of the patient has provided a means of supporting this shift away from the absolutist principle of the preservation of life towards more humanistic approaches which place greater emphasis on the patient's well-being, and reject prolonging the process of dying*.

f) The representative in the context of advance directives

The powers of the representative appointed in advance directive documents are limited, by virtue of art. 11 CP, to *"ensuring the implementation of the advance directive instructions"*. The representative's capacity to act as a *surrogate* for the patient's wishes refers to instructions which are *vague or misleading* and to *situations which are not specifically anticipated but which are related to the provisions of the advance directive document*.

With respect to *issues which are neither directly nor indirectly anticipated* in the document, the representative should be treated as a person with "family or *de facto*" ties to the patient (art. 9.3.a LAP) and his role is essentially the same as that of any other "representative"; and the decision-making criteria should be the same as those used by surrogates as per art. 9.3: *1. advance directive or hypothetical wishes; and 2. objective consideration of the patient's interests*. However, in this case the application of the criterion of *advance directive or hypothetical wishes* is based on a higher standard of proof, because the representative has been *specifically appointed* by the patient, and this leads us to assume not just that he has a better knowledge of the patient's wishes, but also that he is more *reliable*, because the surrogate is trusted by the patient.

However, it is also possible that the document is not so much a list of instructions as a set of general guidelines or 'values' (what is referred to as a '*values history*', in which the individual establishes his principal ethical values with respect to decisions at the end of life)[52]. In these cases, the less specific the solution offered in the *'values history'*, the more important the interpretative role of the representative. In this case, the combination of *deliberate appointment* to interpret an *ambiguous instruction* means that the patient has expressly granted the widest scope to his surrogate's decision; at the same time, this scope is limited by the decisions which may reasonably be derived from the values history. In cases where this history does not provide guidance, the representative's role is exactly the same role as in other cases provided for by art. 9.3.a LAP.

51. Although, as we noted, rather than a *reconstruction of the hypothetical wishes*, the Englaro case involved *evidence of a real advance directive*.

52. Regarding "*values histories*", see Furrow, Barry *et al, Health Law,* 2nd ed., 2000, § 16-27 ("The Values History"); Doukas, David J., McCullough, Laurence B. "The values history: the evaluation of the patient's values and advance directives", in *Journal of Family Practice* 32(2), Feb, 1991, p. 145 and ss.

g) Patients who are minors and the representative's decision

g.1. Initial question. Restrictions on the representative which derive from restrictions on minors. Can a minor arbitrarily reject lifesaving treatment?

There are certain medical options which the minor's representative is not allowed to choose *for the simple reason that a competent minor would not be allowed to choose them either*.

Examples include taking part in medical trials or donating tissue which will not regenerate, both of which are expressly forbidden by the law. However, there is another restriction which the law does not specifically consider but which can be deduced from an analysis of the Act for the Legal Protection of Minors, and from the Patient's Autonomy Act: *the minor does not have full autonomy to reject a lifesaving treatment without medical justification* (that is, using the terminology employed above, a medically unjustifiable rejection: idiosyncratic, religious, etc.) *when this decision poses a significant threat to life*. This applies to minors aged less than 16 and for minors aged between 16 and 18 but who do not possess natural or *Gillick* competence.

In effect, the autonomy of minors is the object of gradual development until it is acquired in full. However, when we talk of minors, we are talking by definition of an individual who is subject to the *protection* of the state. It is the state's duty to protect the minor and this (at least until the minor has achieved full autonomy) extends to protecting the individual from his or her own decisions *where these are not medically indicated*. However much we may talk of *mature minors*, an individual's maturity is something which develops gradually and, with regard to such important issues as decisions at the end of life, continues to develop even after the individual is legally an adult[53] (irrespective of the fact that, under article 12 of the Spanish Constitution, the state removes all limitations on the individual's competence when he or she reaches the age of majority[54])[55]. As a result, according to De Lora,

> *"The best justification for disregarding the religious criterion* [e.g., in the case of a refusal to accept blood transfusions by a minor who is a Jehovah's Witness] *is, in my opinion, that by so doing we preserve the possibility that the minor will be able to exercise his or her autonomy in the future"* [56].

The Spanish Constitution (art. 12) grants full freedom at 18 years of age, although it seems clear that for these decisions the LAP treats as *fully* competent those individuals aged between 16 and 18 who are *competent* and have not been incapacitated, so this would not appear to be an area of legal gradations[57]: it would probably be advisable to develop the legislation further in this regard, delaying the possibility of taking a decision to reject lifesaving treatment *against medical advice* until reaching the full age of majority. Neither the social maturity nor the brain chemistry of a 16-year-old afford him

53. The objection that this is a *paternalistic* criterion is irrelevant: the authorities have an *obligation* to take on the role of parent or tutor with respect to minors, to a greater or lesser degree depending upon the age of the minor and the issue under consideration. A minor is someone who is *subject* in certain situations to the authority of a parent or tutor (see De Lora, Pablo. "Autonomía personal, intervención médica y sujetos incapaces", in *Enrahonar. Quaderns de filosofía,* 40/41, 2008, p. 127). As a result, *paternalism* may be appropriate for a *minor.*

54. There are some exceptional situations in which a *higher* age than that of 18 years established in article 12 of the Spanish Constitution is required, such as *adopting a child* (art. 175 CC).

55. Notwithstanding, Santos Morón ("Sobre la capacidad del menor para el ejercicio de sus derechos fundamentales. Commentary on Spanish Constitutional Court Ruling 154/2002, of 18 July, in *La Ley* 2002-7, p. 1634-1636) considers that mature minors (including those who are *less than 16 years of age*) should have the right to reject lifesaving treatment even if this were to result in their death.

56. De Lora, Pablo. "Autonomía personal, intervención médica y sujetos incapaces", in *Enrahonar. Quaderns de filosofía,* 40/41, 2008, p. 131. To use Caplan's paradoxical expression, we are "denying autonomy in order to create it" (Caplan, Arthur. "Denying autonomy in order to create it: the paradox of forcing treatment on addicts." In *Addiction,* no. 103 (12), 2008, p. 1919 and ss.). Also in this respect, see Romeo Casabona, "¿Límites de la posición de garante de los padres respecto al hijo menor? (La negativa de los padres, por motivos religiosos, a una transfusión de sangre vital para el hijo menor)", in *Rev. de Derecho Penal y Criminología,* no. 2, p. 327 and ss.; Romeo Malanda, "El valor jurídico del consentimiento...", p. 1457; *Íbid.,* "Un nuevo marco ...", p. 1531.

57. Guerrero Zaplana, José. *El consentimiento informado. Su valoración en la Jurisprudencia*. Madrid: Lex Nova, 2004., p. 82-83.

sufficient maturity to take decisions of this sort. Allowing an individual aged between 16 and 18 to reject treatment *without justification* when this will lead to death seems to be taking things too far[58], but the wording of art. 9.3.c) LAP is quite clear: "In the case of minors who are not incompetent or incapacitated and are emancipated or are at least 16 years old, consent by representation does not apply"[59]. Apparently, the only way round this is to show that an individual aged between 16 and 18 *is not competent* to fully understand or to decide with sufficient maturity (the *volitional* component of competence) upon a decision of such importance[60]. (Although we should stress the word *apparently*.)[61].

58. Along the same lines, see *Documento sobre la disposición de la propia vida en determinados supuestos: declaración sobre la eutanasia*. Barcelona: Observatori de Bioètica i Dret, 2003 (*"Sería razonable aceptar la pauta –ya reconocida en diversas ocasiones y lugares– de que los mayores de 16 años puedan decidir por sí mismos, con el requisito de que los padres sean oídos y se involucren en la decisión*").

59. This approach is also supported by Díez Ripollés, José Luis. "Deberes y responsabilidad de la Administración Sanitaria ante rechazos de tratamiento vital por pacientes. A propósito del caso de Inmaculada Echevarría", in *Revista Electrónica de Ciencia Penal y Criminología* no. 11 (11-r1) (May 2009), p. 8.

60. Domínguez Luelmo, *Derecho sanitario y responsabilidad médica,* p. 294. By contrast, Santos Morón, ("Sobre la capacidad del menor...", p. 1636) criticizes the use of this argument by the English courts to restrict the decision-making capacity of mature minors.

61. The legislation contained in Act 41/2002 is *so incomplete* that not even this situation is clear. Art. 9.3.c) states at the end:
"In the case of minors who are not incompetent or incapacitated and are emancipated or are at least 16 years old, consent by representation does not apply. However, in the case of very risky behaviour, in the doctor's judgement, the parents are informed and ***their opinion is taken into account when taking the relevant decision****."*
The phrase "*their opinion is taken into account ...*" immediately begs the question, "by whom?" The text appears to assume that ***someone other than the minor and his parents*** *will decide*, and must do so taking into account the parents' wishes. Certainly, it would be absurd if this section were to be understood to mean "will be taken into account *by the minor himself*". (One need only imagine a minor saying "*I reach a decision which is in contradiction with the law,* ***without taking into account*** *what my parents think*": in this case, his decision would be contrary to the law, and he would have to be represented *by somebody*!) In other words, this section is incomprehensible when interpreted in light of the logic of the rest of the law.

For this reason, with respect to decisions at the end of life, a person aged less than 16 but who has natural competence is not authorized to *reject a lifesaving treatment without any medical motive*. As we have seen, the rejection of lifesaving treatments may be *medically indicated* (when, for example, the treatment only provides a limited extension of life expectancy and causes significant pain and discomfort to the patient); apart from such cases, a minor cannot validly reject treatment which will save his life.

By the same token, the minor's representative would be similarly prevented from taking such a decision, because the criterion of *surrogate decision-making* does not allow a decision to be taken *which the minor is not authorized to adopt*, while the criterion of *best interest* does not permit a decision which is *not medically indicated* to be taken.

It is for this reason that, in the event of *patients who are minors and Jehovah's Witnesses*, neither the parents nor the minor may reject certain treatments which are essential for the maintenance of the young person's life (such as blood transfusions where no alternative treatment exists).

g.2. Decision-making criteria for the representative of an incompetent minor.

When does the representative have to decide in the case of patients who are minors? Clearly, in the case of *unconsciousness*; but also in situations where minors do not have the *functional competence* (or *natural competence*) to understand what treatment (or non-treatment) entails, what alternatives exist, and what the likely effects of treatment are.

When we talk about *minors who have not yet reached natural competence* (whether conscious or unconscious at the time of treatment), as we have already noted the criterion of *substitute judgement* cannot come into play, for the following reasons:

a) *unconscious minors:* if the minor's decision is not binding when he or she is *conscious*, then it obviously cannot be binding when he or she is *unconscious*;

b) *conscious minors:* it is meaningless to ask what the incompetent minor would decide *if he or she was not an incompetent minor*"[62].

For this reason, in cases where the intervention of a representative is necessary, the decision-making criterion to be adopted is that of the *best interest* of the minor in objective terms[63]. *A decision by the representative which goes against what it is medically indicated is invalid*, regardless of any references to parental authority, the wishes of the minor or any other motives.

62. De Lora, Pablo. "Autonomía personal, intervención médica y sujetos incapaces", in *Enrahonar. Quaderns de filosofía,* 40/41, 2008, p. 128-129: "The notion of the best interests of the incompetent minor or adult commits the person advocating it to an *objective* vision of the factors which contribute to, or undermine, the well-being of the individual. To start with, this means that the wishes of the individual are postponed. This should apply to all cases involving individuals who will never become competent or who have not yet achieved competence, the obvious instance of the latter being provided by minors. In other words, just as it is possible to seek to identify what a formerly competent individual would have wanted, to then sacrifice his best interests in favour of his assumed wishes, the decision reached by those acting as surrogates due to the lack of autonomy of a minor or of someone who has been incompetent since birth is necessarily paternalistic; that is, it must be guided by a desire to meet the needs of the incompetent individual, identified on objective grounds. The reason is very simple: when we consider the treatment of minors or adults who have been incompetent since birth, there is no trace of that past life which could help us to adopt their perspective. Because there is no such trace - that is, because they have never had a perspective of their own (a perspective which expresses their character, personal history, the ideological, philosophical and religious beliefs which have formed the framework for their lives and which may, often, lead adults to choose courses of action which strike us as absurd), it is misleading and indeed childish - there is no better word - to speculate as to their assumed wishes." Against this, however, see Campoy Cervera, Ignacio, *La fundamentación de los derechos de los niños. Modelos de reconocimiento y protección*. Madrid: Dykinson, 2006, p. 984-986.

63. Cañizo Fernández-Roldán, Agustín; Cañizo López, Agustín, "El consentimiento informado en asistencia pediátrica", in AA.VV.,. *Bioética. Perspectivas emergentes y nuevos problemas.* Madrid: Tecnos, 2005, p. 278; De Lora, Pablo. "Autonomía personal, intervención médica y sujetos incapaces", in *Enrahonar. Quaderns de filosofía,* 40/41, 2008, p. 127-128.

g.3. Decision-making criteria for the representative of an unconscious minor aged between 16 and 18

In the case of individuals who are *over 16 years of age and in an unconscious state*, the LAP does not allow us to deduce with any clarity which criterion we should apply.

- In principle, given that the patient's wishes, where expressed, are decisive, one might think that this would mean that even if informed consent had not been granted while the patient was conscious, a representative could testify as to what the decision would have been, informing the doctor of *the patient's advance directive, whether real or hypothetical.*
- However, and paradoxically, the LAP *does not permit those aged less than 18 to sign Advance Directive documents*[64], and it would therefore appear that if the patient's advance directive *in writing* is not binding, then nor would it be so if transmitted *orally* (and even less so when reconstructed by means of hypothetical reasoning)[65].

This second argument would appear to be decisive, because the rule which prevents minors from signing Advance Directive Documents is *unequivocal*. The progressive acquisition of competence by minors means that the

64. The law in Andalucia is more flexible in this regard, and accepts that emancipated minors may sign such documents (see Díez Ripollés, "Deberes y responsabilidad de la Administración Sanitaria ...", p. 13).

65. This paradox is criticized by, among others, Rodríguez González, José Ignacio, "La autonomía del menor: su capacidad para otorgar el documento de instrucciones previas", in *La Ley* 2005-2, p. 1419-1424; Beltrán Aguirre, Juan Luis, "La capacidad del menor de edad en el ámbito de la salud: dimensión jurídica", in *DS: Derecho y salud*, vol. 15, no. extr. 1, 2007, p. 9 and ss., p. 16. Berrocal Lanzarot, Ana Isabel; in Berrocal Lanzarot , Ana Isabel/ Abellán Salort, José Carlos, *Autonomía, libertad y testamentos vitales* (Régimen jurídico y publicidad), Madrid: Dykinson, 2009, p. 179-180. Parra Lucán ("La capacidad del paciente para prestar consentimiento informado...", p. 19), however, argues that it is not inconsistent, given that "living wills" directly involve *instructions about the individual's life*, and that an extra level of competence is therefore required. However, this conclusion would require us to conclude that *a competent 16-year-old patient cannot reject lifesaving treatment,* something which, as we have noted above, is not clear.

informed consent of an individual who is 16 years old and conscious is binding upon the doctor, while the same individual may not yet issue *binding advance directives* (either written or oral).

5. A particularly controversial example: granting consent for abortion in minors.

a) Introduction. Regulation in the Spanish General Health Act (LGS) and the Patient Autonomy Act (LAP)

In many cases, the Patient Autonomy Act (LAP) provided significant *clarification* of situations which had only been indirectly regulated by Spain's General Health Act. For example, establishing the *age of majority for health decisions* at 16 makes the legal position more secure, regardless of whether or not one agrees with the actual age selected.

However, in other areas it has been criticized for precisely the opposite reason: for introducing *unclear* or openly contradictory concepts where the previous legislation was reasonably clear. This is the case with regard to the substitution of consent for *incapacitated individuals*[66] and also with regard to the issue discussed below, consent for abortion in patients who are minors.

Article 10.6 of the General Health Act, now repealed, regulated consent by substitution by means of an open formula which, like the current legislation, referred to natural competence, and stipulated that the patient cannot grant consent "when he or she does not have the competence to take decisions, in which case, this right will be exercised by the patient's relatives or those who are close to the patient"[67]. This rule also applied in cases of abortion[68].

However, in 2002 the LAP introduced a very different rule. Together with the three general rules governing consent in the case of minors which, except for the age of medical majority, were already contained in the previous legislation (criterion of natural or *Gillick* competence; taking the individual's opinions into account when substituting the incompetent minor aged 12 years or older; "medical age of majority" of 16 for competent individuals), art. 9.4 introduces a set of *exceptions* to these rules:

Art. 9.4 LAP	
Voluntary termination of pregnancy,	governed by — **the general provisions on the age of majority** and — by the **relevant special provisions**.
participation in clinical trials and	
the performance of human assisted reproduction techniques	

66. Santos Morón, "La situación de los discapacitados psíquicos desde el Derecho Civil", in Campoy Cervera, I. (ed.) *Los derechos de las personas con discapacidad: Perspectivas sociales, políticas, jurídicas y filosóficas.* Madrid: Dykinson / Univ. Carlos III, 2004, p. 175.

67. Jorge Barreiro, Agustín,"La relevancia jurídico-penal del consentimiento del paciente en el tratamiento médico-quirúrgico", in *CPC* 1982, no. 16.

68. This was the position held by the overwhelming majority of authorities. See, for example, Romeo Casabona, *El médico y el Derecho Penal. I,* Barcelona: Bosch, 1981, p. 317-318; *Íbid.*, "El diagnóstico antenatal y sus implicaciones jurídico-penales", in *La Ley* 1987-3, p. 813; Arroyo Zapatero, "Los menores de edad y los incapaces ante el aborto y la esterilización", in *EPCr* no. 11, 1986-87, p. 14; Dolz Lago, Manuel Jesús, "Menores embarazadas y aborto: ¿quién decide?", in AP no. 29, 1996, p. 548; Molina Blázquez, C; Sieira Mucientes, S. *El delito de aborto Dimensión constitucional y penal.* Barcelona: Bosch, 2000; Laurenzo Copello, comentario a los arts. 144 and ss., in Díez Ripollés (dir.), *Comentarios al Código Penal,* Valencia, Tirant lo Blanch, 1997; Lema Añón, Carlos. "Sobre el consentimiento de las menores para la interrupción voluntaria del embarazo", in *Jueces para la Democracia* no. 43, 2002, p. 34-35; González Rus, J. J., *Compendio de Derecho Penal Español. Parte Especial,* Madrid: Marcial Pons, 2000, p. 81; Galán Cortés, Julio César, *Responsabilidad médica y consentimiento informado,* Madrid: Civitas, 2001, p. 89; Romeo Malanda, Sergio "El valor jurídico del consentimiento prestado por los menores de edad en el ámbito sanitario", in La Ley 2000-7, p. 1460.; *Íbid.*, "Minoría de edad y aborto: algunas cuestiones sobre consentimiento y confidencialidad", in *Humanitas* no. 28, June 2008, p. 4. The opposing position, that a minor could never grant consent, was a minority one (e.g., Martínez-Pereda Rodríguez, J. M., "La minoría madura", in *IV Congreso Nacional de Derecho Sanitario,* Madrid: AEDS, 1998, p.89). 89).

Because in *elective abortion* (which is only legal if pregnancy poses a serious risk to the mother's health, is the result of rape, or if the embryo suffers from a serious pathology, art. 417 bis CP TR 1973) there are no "relevant special provisions", the granting of informed consent is considered to be "governed by the general provisions regarding the age of majority".

What does this mean? Many authors suspect that *what the legislator intended*[69] was to prevent minors from consenting to abortion for themselves, and being required instead to do so in collaboration with their parents or guardians. However, more and more authors now argue that this is not what the current legislation says.

b) The impossible art. 9.4 LAP

Art. 9.4 LAP is doubly problematic[70]: firstly, because it seems clear that the legislator sought to use it to introduce a politically *unacceptable* law; and secondly, because he did it in such a technically flawed manner that *he did not achieve his aim.*

69. See, for example, García Arán, in Córdoba Roda; Juan; García Arán, Mercedes, *Comentarios al Código Penal. Parte Especial I,* Madrid: Marcial Pons, 2004, p. 73.

70. Parra Lucán, Mª de los Ángeles. "Dos apuntes en materia de responsabilidad médica", in *DS: Derecho y salud,* Vol. 11, No. Extra 1, 2003, p. 1-14, p. 3 and 4: "It is quite clear that the process of drafting the law was not accompanied by a consideration of the problems which it raises in practice, nor of the significant consequences of this issue (...) The authors responsible for drawing up art. 9 of the Act demonstrate a worrying ignorance of the subject. The law did not need to state the validity of consent granted by women who are adults. The problem arises with regard to minors and those who do not have sufficient competence to grant consent. Article 9.4's failure to offer a solution in these cases means that it is flawed, and it would have been better if the legislator, instead of introducing further confusion, had said nothing." Its origin probably lies in the statement by the Constitutional Court in FJ 14 of Constitutional Court Ruling 53/1985 ("Regarding the means by which a minor or an incapacitated individual grants consent, the legislation established in private law may be applied"; see, Parra Lucán, "Dos apuntes en materia de responsabilidad médica", p. 3). See also Romeo Malanda, "Un nuevo marco jurídico...", p. 1533.

b.1. Formally impossible

Because, in reality, art. 9.4 refers to "the general provisions on the age of majority". But what are these provisions regarding the age of majority? The general provisions applicable in such cases (and already in force when the LAP was being drawn up and passed) are:

> **Article 162.1 Civil Code**
>
> Parents with responsibility for their children are their legal representatives so long as they are unemancipated minors. The exceptions to this rule are:
>
> 1. Acts relating to rights to of the individual or other rights which the child, in accordance with the law and depending upon the child's level of maturity, is able to perform for him or herself. (...)
>
> **Art. 2 L.O. 1/1996, on the Legal Protection of Minors (General Principles)**
>
> In the application of this Act, the best interest of the minors will have precedence over any other legitimate interest which may apply. Likewise, any measures which are adopted under the auspices of this Act must include an educational element.
>
> Limitations on the capacity of minors to act will be interpreted in a restrictive manner.

Without a shadow of a doubt, both the decision to *terminate a pregnancy* and the decision to *continue gestation until its end* are acts which relate to the right to of the individual[71] that the daughter may exercise for herself; and if an alternative interpretation is possible which would impose greater restric-

71. According to the reasoning of Justice Blackmun in the Ruling of the United States *Supreme Court Webster v. Reproductive Health Services* 492 U.S. 490 (1989), (given in Shepherd "Dignity and Autonomy after Washington v. Glucksberg...", p. 440), the decision to have an abortion is "uniquely personal, intimate, and self-defining", "quintessentially intimate" and "belongs to that 'certain private sphere of individual liberty' that the Constitution reserves from the intrusive reach of government", an expression of the moral principle reflected in the Constitution that "a person belongs to himself and not others nor to society as a whole." See also Parra Lucán, "La capacidad del menor..."; p. 17-18.

tion upon the minor's consent, this should be overruled by the interpretation set out here by virtue of art. 2 of the Act for the Legal Protection of Minors[72]. The same conclusion was reached in the Ruling of the Provincial Court of Malaga of 20 April 2002:

> *"Long before reaching 18 years of age, women can conceive and, as a result, find themselves in a situation where they need to terminate the pregnancy; and this must be reflected in the exceptions to the representation of children by their parents established in article 162.1*[73] *of the aforementioned Code"*[74].

72. This is the conclusion reached, by one route or another, by the great majority of commentators. See, for example, Casado, M. (ed.), *Documento sobre salud sexual y reproductiva en la adolescencia,* Barcelona: Observatori de Bioètica i Dret, 2002, 5th conclusion; Parra Lucán, "Dos apuntes en materia de responsabilidad médica", p. 3; *Íbid.*, "La capacidad del paciente..."; p. 40; Feijóo Sánchez, in Bajo Fernández (dir.), *Compendio de Derecho Penal. Parte Especial I,* Madrid: CEURA, 2003, p. 322 and ss. (although he considers that the legislator should clarify the "multiplicity of positions"); García Arán, in Córdoba-García Arán, *Comentarios* t. I, 2004, p. 73; Domínguez Luelmo, *Derecho sanitario y responsabilidad médica,* p. 302-303; Muñoz Conde, Francisco, *Derecho Penal. Parte Especial,* 17th ed., Valencia: Tirant lo Blanch, 2007, p. 84 (in what he considers to be one of two possible criteria); Beltrán Aguirre, Juan Luis, "La capacidad del menor de edad en el ámbito de la salud: dimensión jurídica", in *DS: Derecho y salud,* vol. 15, no. extr. 1, 2007, p. 21; Gómez Rivero, Mª del Carmen, *La responsabilidad penal del médico,* 2nd ed., p. 63; Alonso de Escamilla, Avelina, in Lamarca Pérez (dir.), *Derecho Penal. Parte especial,* 4th ed., Madrid: Colex, 2008. The opposing position is currently a minority one (see recently Jericó Ojer, Leticia, *El conflicto de conciencia ante el Derecho Penal,* Madrid: La Ley, 2007, p. 500.

73. Legal doctrine recognizes that art.162 may also apply to *incapacitated* individuals (see, for example, Santos Morón, Mª José, *Incapacitados y derechos de la personalidad,* p. 33 and ss.; Méjica, Juan; Díez, José Ramón. *El estatuto del paciente. A través de la nueva legislación sanitaria estatal.* Madrid: Thompson-Civitas, 2006, p. 82).

74. In the United Kingdom, the only requirement for a minor seeking an abortion is the test of natural competence (that is, she must be *Gillick-competent;* in May 2004 there was a controversy because a 14-year-old girl had an abortion without her mother's knowledge; the mother lodged a complaint based on the fact that her daughter stated that she would not have decided to have an abortion if she had spoken to her mother first. Since then, the Department of Health has recommended that minors discuss the issue with their parents, but this is not compulsory: Herring, Jonathan, *Medical Law and Ethics,* p. 239-240). In Germany, women aged 16 years or over are considered competent to consent to abortion, while in general they are not deemed competent before this age (Laufs, Uhlenbruck et al., *Handbuch des Artzrechts* 3rd ed., Munich: C.H. Beck, 2002, § 143, n. m. 29, § 159, n. m. 9, § 161, n. m. 2; *Schönke-Schröder*-Eser, § 218ª, n. m. 61).

We can therefore deduce that *under current legislation, abortion in minors is governed by the general provisions of consent to medical treatment or surgery on minors, without any additional special provisions.*

It is true that this sits uneasily with the notion of *exception* expressed in art. 9.4 LAP; but this merely means that we are faced with a confused piece of wording which does not make it clear which rule should be applied:

- The wording reveals that the legislator sought to establish, in art. 9.4 LAP, an *exception* to the provisions of art. 9.3.c) LAP.
- But to this effect it refers to a piece of legislation ("the general provisions on the age of majority") the contents of which *are in fundamental agreement with the general rule of art. 9.3.c)* LAP and which prevents representation where the minor has (natural) competence to grant consent.
- On the basis of this rule, we can resolve the (apparent) contradiction of art. 2 LPJM, which obliges us to adopt that rule which *recognizes the greatest decision-making competence of the minor*.

This interpretation does not simply have the effect of repealing the legislation to which it refers[75]. It simply interprets the reference, *at present*, as agreeing in essence with the regulations contained in art. 9.3.c) LAP. It would, however, be perfectly possible for "the general provisions on the age of majority" to change in the future, in which case the solutions offered by arts. 9.3.c) and 9.4 LAP would be different. Interpreted in this way, the only thing which art. 9.4. ensures is that, regardless of possible changes to the general legislation on surrogate decision-making in art. 9.3 LAP, the solution applicable to minors who wish to grant consent to abortion should be in accordance with *"the general provisions on the age of majority"*.

75. As is argued by Romeo Malanda, "Minoría de edad y aborto: algunas cuestiones sobre consentimiento y confidencialidad", in *Humanitas* no. 28, June 2008, p. 8-10. Regarding the position of this author, see below.

However, for some authors who have considered the issue in depth[76], the conclusion set out here is not possible, because art. 9.4 refers to the regulations on the age of *majority*, and not to those on the age of *minority* or on competence in general.

In principle, the objection does not appear to be a significant one. Indeed, the author himself points out that interpreting the reference as one to the rules of *the age of majority* leads to absurd results[77], as a result of which he argues that we should seek to identify *what the legislator sought to achieve*, which in his opinion was *to prevent minors from granting consent for themselves*, excluding them from the provisions of art. 9.3.c and subjecting them to the wishes of their parents, whether this entailed a decision *to have an abortion* or a decision *to continue the pregnancy*[78].

The first thing to notice about this line of reasoning is that, having recognized that art. 9.4 consists not of a rule but rather a *reference*, because we are unable to identify *which rule is being referred to, instead of adopting the rule which is most similar to it* (the regulation on *competence* instead of the one on the age of majority), *it opts for the creation of a new rule* which is not recorded anywhere, which allows the author to conclude that *abortion in a minor must be authorized by her parents*.

In my opinion, the solution proposed here is not acceptable: in the sphere of the rights of minors, we cannot apply a hypothetical rule of *ex contradictione, quod (legislator) libet* (in the case of contradiction, that which the legislator intended) or rather *libere videtur* (would appear to wish) as the legislator's wishes cannot be anything more than an assumption. And this is not possible because *there is another rule specifically designed for resolving problems of interpretation in this area*: art. 2 of the Legal Protection of Minors Act, (Ley de Protección Jurídica del Menor) by virtue of which where there are several possible solutions, art. 2 LPJM obliges us to apply the option which grants the greatest decision-making capacity to the minor.

76. Romeo Malanda, Sergio, "Minoría de edad y aborto: algunas cuestiones sobre consentimiento y confidencialidad", in *Humanitas* no. 28, June 2008, p. 8-10.

77. *Ibíd.*, p. 9.

78. *Ibíd.*, p. 11; clarifies some of the consequences of his conclusion on p. 13; and provides a brief summary in "Un nuevo marco jurídico-sanitario...", p. 1533.

b.2. Impossible at a practical level

Furthermore, *any other interpretation leads to perverse outcomes, which are incompatible with the fundamental rights of the minor*[79].

The decision to terminate or continue a pregnancy is one of the clearest examples of *"an act relating to the rights of privacy" of art. 162.1*, perhaps even the clearest example of all; and apart from very rare exceptions, it almost always involves a minor who is more or less *mature*, given that there are very few pregnancies before the age of 13. The highly personal nature of the decision becomes clear if we imagine a situation where the decision to terminate or continue with the pregnancy is taken with the representative's consent and *against* the will of the pregnant minor:

a) The option of *forcing a mature minor to have an abortion against her will* represents *an act of unimaginable violence in* a state based on the rule of law[80].
b) The option of *forcing a minor to continue with a pregnancy against her will is not necessarily less traumatic*[81]. It involves forcing a minor to

79. In this regard, one begins to suspect why the contents of art. 9.4 are so confusing: because *if it had stated clearly that a minor's consent to abortion had the same status as that of an adult, it would have been too blunt.*

80. In reality, those who seek to ensure that consent remains the preserve of parents are usually anti-abortionists, and what they really seek is to exercise a *right of veto*, which appears to be far less cruel than *forcing* a minor to undergo an abortion. This right of veto (which, for 'pro-life' campaigners, would be one more obstacle to be overcome before a pregnancy could be terminated) would *apparently* be less traumatic for the minor: it only requires that no hospital could legally provide treatment without the consent of the parents. However, as is indicated in the text, the option of forcing a minor to continue with a pregnancy against her will is not necessarily less traumatic than that of forcing her to continue with a pregnancy.

81. "[E]l Estado no debe obligar a las mujeres a tener hijos no deseados y menos recurriendo al Derecho penal" (Casado, M.; Corcoy, M.; Ros, R.; Royes, A. (eds.) *Documento sobre la Interrupción Voluntaria del Embarazo,* Barcelona: Observatori de Bioètica i Dret, 2008, p.

> undergo a brutal series of physical and chemical transformations which are extremely uncomfortable and painful, and a series of restrictions on her freedom which would be scarcely imaginable for another person; and finally forcing her to complete her pregnancy by going through childbirth or surgery[82].

In reality, the general understanding is that the role of parents or tutors in this regard is purely that of a *tutor*, and consists of advising, accompanying and protecting the minor during the difficult process of making and implementing a decision. Nobody would assume that parents should be able to take decisions either for or against the wishes of the pregnant person when she is a mature minor.

In this regard, the famous ruling of the United States Supreme Court in *Planned Parenthood of Central Missouri v. Danforth* [428 US 52, 75 (1976)] established a benchmark which many legislators would follow. This ruling considered that *"the State may not impose a blanket provision (...) requiring the consent of a parent (...) as a condition for abortion of an unmarried minor during the first 12 weeks of her pregnancy.. Just as with the requirement of consent from the spouse, so here, the State does not have the constitutional authority to give a third party an absolute, and possibly arbitrary, veto over the decision of the physician and his patient to terminate the patient's pregnancy."*[83]

Finally, we should not ignore the fact that, under the current Spanish legislation, when we talk about terminating a pregnancy we are talking about a *particularly dramatic* pregnancy.

27).

82. "Only on the basis of anti-abortionist prejudice can one arrive at such surprising conclusions as that of imposing maternity on a woman regardless of her competency or her stated, informed, mature wishes to the contrary. But likewise, only a perfectionist mania could lead one to advocate imposing abortion on a mature minor" (De Lora, Pablo. "Autonomía personal, intervención médica y sujetos incapaces", in *Enrahonar* 40/41, 2008, p. 140).

83. On the same lines, see the ruling of United States Supreme Court *Bellotti vs. Baird* [443 U.S. 622 (1979)].

Article 417 bis. CP TR 1973 1. Abortion when performed by a doctor, or under his direction, in a registered health centre, whether public or private, and with the express consent of the pregnant woman, will not be an offence under any of the following circumstances:

1. When it is necessary to avoid grave danger to the life or physical or mental health of the pregnant woman, and an opinion to this effect has been issued prior to the operation being performed, by a doctor in the relevant specialty, other than the doctor under whose direction the abortion is to be performed.
   In the event of an emergency which poses a threat to the pregnant woman's life, express consent and medical opinion are not required.
2. Where the pregnancy is the result of an act which constitutes rape under article 429, so long as abortion is performed during the first twelve weeks of pregnancy and the act as been reported to the police.
3. Where it is believed that the foetus would be born with serious physical or mental defects, so long as the abortion is performed within the first twenty-two weeks of pregnancy and an opinion has been issued, prior to abortion being performed, by two specialists at the public or private health centre registered for this purpose, other than the doctor who is to perform the abortion or under whose direction the abortion is to be performed.

Therapeutic requirements, victim protection and *embryo pathology* all constitute a *serious conflict* between the interests of the mother and the interests of the State in protecting the legal entity of *prenatal life*. In these situations, if I may be allowed to say so, the choice is not between the protection of pre-natal life and an unwanted pregnancy in a minor (something which in itself is a very serious conflict), but rather between the interests of pre-natal life and an unwanted pregnancy *which poses a threat to the life or health of the mother* or *which is the result of rape, or which entails the gestation of a foetus which is either non-viable or very seriously ill*. It involves, for the minor, an *even greater* imposition than a normal pregnancy; and it makes no sense that *another person* should be the one to decide whether the minor should bear this imposition, irrespective of her wishes.

c) Consent for abortion on a minor whose life is at risk

In this case, the solution reflects the fact that this is a decision not just *about abortion*, but also that it may be a decision *about the minor's very life*.

In such cases, clearly, it would not be possible to impose upon the minor, and against her will, a decision to continue with the pregnancy and forbid abortion: not just for the general reasons already set out, but also because this would entail exposing her to mortal danger. This would not be *in the interest of the health, well-being or life of the patient* ('best interest'), and the representative would therefore not be allowed to take such a decision.

However, *if the decision of the minor aged less than 16 years was to continue with the pregnancy and face a significant risk of death, this decision should be deemed invalid; and the parents or guardians should grant consent to abortion*[84]. And this, for the reasons set out above, which entail denying mature minors the right to reject treatment *when this is not to the benefit of their own health or well-being*. The state, through the parents, must protect the minor, *including from her own decisions,* until she reaches full autonomy[85]. As we can see, this is exactly the same system which applies to other instances involving the rejection of life-saving treatment by minors.

d) The confusion between consent and information in the public debate of the white paper on sexual and reproductive health and voluntary termination of pregnancy legislation

The government has recently presented a *White Paper on sexual and reproductive health and voluntary termination of pregnancy legislation* in which, among other significant changes, it proposes to *remove from art. 9.4 reference to voluntary termination of pregnancy*, as a result of which there would be no legal mention whatsoever which could serve as the basis for an interpretation seeking to exclude abortion from the general system.

This has led to a political outcry. Of course, any modification to the abortion legislation is always the focus of great political concern, but in this case the focus has been on whether it the minor or her parents should give consent for this purpose.

However, as we have seen, only a minority would support parents having the right either *to force a minor to have an abortion*, or *to force her to continue with a pregnancy after rape, in the event of a serious risk to her life or health or in the case of serious malformation of the embryo*.

The debate has been somewhat confused, because although it referred formally to *consent* by the minor or her parents, in reality it concerned whether the minor could undergo these operations *without the knowledge* of her parents.

This question is quite different. Parents and guardians, in so far as they are responsible for the protection and education of a minor, may of course seek *not to have concealed from them major developments regarding the minor's health* such as the need to have an abortion (and all the more so when this may be the result of *rape* or poses a *threat to the life or health of the mother*).

However, the issue is an extremely tricky one:

- On the one hand, proponents of this viewpoint argue that a minor could be forced to abort (or *not* to abort) by her partner, her peers, etc., and that when taking a decision of this scope she requires the protection granted by the state through her parents or other institutions such as guardians, foster parents, etc.
- On the other hand, it is argued that if legal abortion where to be subject to the condition of *informing the parents*, many minors, eager to hide the pregnancy from their parents, could turn to backstreet abortionists, offering no guarantees of any sort whatsoever. And this, not just in *dramatic cases* in which a family member has sexually assaulted

84. Domínguez Luelmo, *Derecho sanitario*, p. 304; for the previous regulations, see Arroyo Zapatero, "Los menores...", p. 16.

85. In the event that the decision taken by both the parents and the minor is to accept a significant risk of death, this decision will be invalid and the doctor must put the matter in the hands of the law.

the minor, but also out of mere fear of parental reaction to the pregnancy[86]. Indeed, from the outset the United States Supreme Court took the position that the requirement of parental consent for abortion was unacceptable, because it restricted the constitutional rights of minors by imposing an illegitimate restriction on their right to request an abortion[87].

This conflict has already been addressed in a number of other European countries, which have opted either for *absolute* solutions (at one extreme, the explicit absence of any duty on the part of doctors to inform the parents, as in the Swedish and British Abortion Acts, Finnish Act no. 239 of 24 March 1970 or the Swiss Penal Code; at the other extreme, an obligation to inform the parents, as in the Penal Codes of Portugal and Luxembourg), or for *intermediate* solutions. These intermediate solutions establish a medical duty to inform the parents, which can be circumvented if the minor turns to *some other institution which protects her and acts as her legal guardian during this process*[88].

The French Public Health Legislation allows the minor to inform the advisor of her intention not to inform her parents, but stipulates that in this event she should be accompanied by an adult to defend her interests. The ruling of United States Supreme Court in the case *Hodgson v. Minnesota* (497 U.S. 417, 1990) established that the Law of the State of Minnesota making the right of the minor to have an abortion subject to both parents being informed, was only constitutional in so far as it permitted a *judicial bypass*, in which as an alternative to involving the parents, *a court* could take their place[89].

Probably, the best model is one which guarantees sufficient protection of the minor where necessary (in general, that provided by parents or guardians) with the possibility of avoiding informing the parents – at least, *in advance* – in cases where such an obligation could result in the coercion of the minor. In general, this sort of substitution can only occur within the framework of the health system or the social services (both of which, in Spain, fall within the competencies of regional government), or within the judicial system, where the public legal officer would act to protect the interests of the minor.

The more advanced the pregnancy and the more difficult the decision as to whether to abort and its consequences, the more necessary such guardianship becomes: it would not appear to be necessary at all when the question at issue is not the termination of a pregnancy but rather preventing the fertilized egg cell from becoming embedded in the uterus (*"the morning after pill"*[90]), and in general it will not appear to be particularly necessary in the

86. This argument is even more relevant in the context of the proposed legislation allowing abortion on demand within a limited time period, because in this event the minor would not be restricted to deciding whether or not she wishes to have an abortion in a specific medical and legal context (therapeutic, victim protection, embryo malformation), but would have a much wider decision-making margin: she could decide with absolute freedom whether or not to have an abortion.

87. Galán Cortés, Julio César, *Responsabilidad médica y consentimiento informado*, Madrid: Civitas, 2001, p. 88, citing the cases *Planned Parenthood of Central Missouri vs. Danforth* [428 US 52, 75 (1976)] y *Bellotti vs. Baird* [443 U.S. 622 (1979)].

88. Legislation such as that in Denmark (Act no. 350, of 13 June 1973, ref. 14 June 1995) or Italy (Act no. 194 of 22 May 1978) establish that, while consent is the prerogative of the parents, the minor may ask the Regulatory Committee (Denmark) or the Judge with Responsibilty for the Protection of Minors (Italy) to dispense with this parental consent.

89. See Williams, Susan Hoffman. "Comment: Autonomy and the Public-Private. Distinction in Bioethics and Law. Susan H. Williams", in *Indiana Journal of Global Legal Studies,* Volume 12, Issue 2, Summer 2005, p. 487-488

90. Casado, M. (ed.), *Documento sobre salud sexual y reproductiva en la adolescencia,* Barcelona: Observatori de Bioètica i Dret, 2002, 1st and 3rd conclusions (also, more generally, Casado, M.; Corcoy, M.; Ros, R.; Royes, A. eds., *Documento sobre la Interrupción Voluntaria del Embarazo,* Barcelona: Observatori de Bioètica i Dret, 2008, p. 30); De Lorenzo y Montero, Ricardo. *Derechos y obligaciones de los pacientes. Análisis de la Ley 41/2002, de 14 de noviembre, básica reguladora de autonomía de los pacientes y de los derechos de información y documentación clínica,* Madrid: Colex, 2003, p. 69. However, the Chief Justice of Aragón in his *Informe y sugerencia sobre el consentimiento informado y la prescripción a menores de la llamada píldora del día después* (2006) [Report and suggestions regarding informed consent and the prescription to minors of the so-called morning after pill] has suggested that parents should be informed to prevent abusive or dangerous consumption of such medication. It is worth noting that such abuse is only feared with regard to these medications (and not *any others,* with regard to which there is no duty to inform). In any case, control and support for such purposes should be provided, as with any other medication, at the moment of prescription within the context of the medical consultation.

case of very early termination of pregnancy performed using pharmacological methods (within seven weeks of menstruation having ceased).

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Contributions from medical professionals

THE HEALTH PERSPECTIVE

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I would like to explore further the issue of *"The intellectual and emotional competence of the minor to understand the scope of health interventions,"* from a health and legal perspective.

The health dimension

Competence – a concept which is used more frequently in clinical practice – refers to those psychological qualities which enable patients to decide whether to consent to or reject the diagnostic or therapeutic interventions proposed to them by their doctor. What is usually evaluated in the clinical relationship is what we term natural or *de facto* competence.

Competence refers to a patient's capacity to receive, understand and retain information regarding his or her medical situation and, as a consequence, to choose between the different options available, in accordance with the patient's value system[1].

In the natural (or functional) competence approach which currently dominates medical decision-making, the patient is competent to decide upon the medical treatment proposed so long as he or she is capable of fully understanding the implications of the proposed treatment, its risks and possible disadvantages, and the alternatives available[2].

By competence, we understand the patient's ability to understand the situation and reach a decision. This varies, and depends on a number of factors: psychological, level of pain, state of inebriation, anguish or disorientation. The more far-reaching the decision, and the more risk and the less benefit it entails, the higher the level of competence required[3].

Natural competence is a concept which refers to whether the individual, in a specific context, has sufficient judgement to understand the scope and consequences of the decision to be taken. An individual's natural competence to perform certain acts and not others can therefore only be evaluated on a case-by-case basis and not in the abstract, because the level of judgement required to consciously and freely arrive at a decision will depend upon the nature of the choice to be made, and the consequences which flow from it[4].

There are no instruments for measuring competence in tricky, one-off situations. In clinical practice, we should start from the assumption that the mature minor is competent, and any lack of competence must therefore be convincingly demonstrated.

There are four aspects to consider when determining whether a mature minor is competent to take a decision independently:

1: Capacity to express a choice.
2: Capacity to understand the information relating to his or her situation before taking any decision.
3: Capacity to assess the meaning of the information with respect to his or her situation, and in particular the illness and the consequences which each option may have for his or her health and quality of life.
4: Capacity to reason logically, on the basis of the information received, taking account of the individual's situation, to reach a coherent decision which weighs up both risks and benefits[5].

1. Padrós, Joan y Fernández, Joaquim. *Annals de la Medicina*: volume 87, no. 3. August-September 2004.
2. Dopico Gómez-Aller, Jacobo. Problems of informed consent by representation. Víctor Grífols i Lucas Foundation. Barcelona 16.10.2009.
3. Comitè de Bioètica de Catalunya. *Guia de recomanacions sobre el consentiment informat*. Edició actualitzada 2003.
4. Santos Morón, Maria José. *Incapacitados y Derechos de la personalidad*. Madrid 2000.
5. Comitè de Bioètica de Catalunya. Informe sobre la persona menor en l'àmbit de la salut. July 2009.

In Spanish, as in English, there is some confusion between use of the terms '*competence/competencia*' and '*capacity/capacidad*'. In English, individual abilities such as those listed above are '*capacities*', while the more general ability which derives from them is '*competence*'. By contrast, while Spain's Act 21/2000 regarding the rights to information with respect to the health and autonomy of the patient and health records uses the term '*competente*', Act 41/2002 regulating the autonomy of the patient and rights and obligations with regard to health information and records, prefers the term '*capacidad*'. Indeed, this sense of '*competencia*' is actually a neologism introduced as a result of literal translation from British and North American literature, and there is no previous history of its use in Spanish. The term actually used in Spanish legal tradition is '*capacidad*', while the Spanish term '*competencia*', in the individual context, is a measure of an individual's powers on the basis not just of this '*capacity*' but also of their suitability or training[6].

The legal dimension

The Civil Code does not contain any specific legislation offering a general definition of when a minor should be considered to be mature. However, both the Civil Code and individual pieces of legislation contain rules relating to specific issues in which the minor is either granted autonomy for legal purposes or where the minor's opinion must be taken into account. For example, the Criminal Code does not consider sexual relations with a minor who is aged 13 or over to be an offence; in Civil Law, a minor aged 14 can testify to agreements; and a minor aged 16 or over can achieve emancipation, which brings with it full legal competence. As a result, the competence of minors expands gradually as a result of different pieces of legislation[7].

Act 21/2000, of 29 December, regarding the rights to health information, the autonomy of the patient and clinical records and Act 41/2002, of 14 November, regulating the autonomy of the patient and rights and obligations with regard to clinical information and records, only provide that, when the minor is not intellectually or emotionally capable of understanding the scope of the intervention, consent must be granted by the minor's legal representative after listening to the opinion of the minor if he or she is at least 12 years old.

Otherwise, it must be concluded that the minor of between 12 and 16 years of age is intellectually and emotionally capable of understanding the scope of the medical intervention; that is, that he or she has sufficient maturity and competence to understand the consequences of the intervention and the personal consent of the minor must therefore be obtained.

As a result, consent by representation only applies to minors aged between 12 and 16 years when they are not intellectually and emotionally capable of understanding the scope of the intervention.

It must therefore be accepted without reservation that a minor may have the maturity to grant informed consent before the age of 16.

The aforementioned legislation omits all reference to a potential conflict of interests between the wishes of a minor who possesses natural competence, and his or her parents or legal representatives. In this case, the wishes of the minor must prevail, because we are dealing with something which affects the freedom, health and life of the patient; in other words, fundamental individual rights[8].

Protecting the minor entails finding a balance between recognition of his or her progressive capacity for individual decision-making, on the one hand, and his or her legal condition as someone who is dependent upon legal representatives until reaching the age of majority, on the other. In this regard, the legislation gives prevalence to the autonomy of the minor if he or she is sufficiently mature[9].

6. See, for example, Boletín Congreso de los Diputados. 24.09.2001. Amendment no. 70 Grupo Parlamentario Popular.
7. Instrucción 2/2006, 15 March 2006, regarding the protection of the rights of minors to respect, privacy and to control over their own image.
8. Beltrán Aguirre, José Luis. La capacidad del menor de edad en el ámbito de la salud: Dimensión jurídica. "Derecho y Salud". Extraordinario XV Congreso.
9. Dolz Lago, Manuel-Jesús. *Diario Médico.* 02.11.05

When the minor has sufficient natural competence, the parents or guardians have no power to intervene in the sphere of his or her personal rights. This means that parents cannot act as surrogate decision-makers on behalf of the minor and nor, in the event of disagreement, can they impose a decision against the minor's will. If the minor has sufficient capacity to understand or decide, he or she should not be subjected to medical treatment against his or her will on the basis of a parental decision[10].

To complete this analysis, we should discuss Spanish Constitutional Court Ruling 154/2002 of 18 July, regarding the case of a 13-year-old minor, a Jehovah's Witness, who absolutely refused to receive a blood transfusion and ultimately died.

The Constitutional Court analyses three specific questions: firstly, whether a minor possesses the right to religious freedom; secondly, the constitutional significance of the minor's opposition to the prescribed medical treatment; and thirdly, the significance, where applicable, of the minor's opposition.

a) Minors have the right to religious freedom.

   From the perspective of art. 16 of the Spanish Constitution, minors have full possession of their fundamental rights, in this case, of their rights to freedom of belief, and their moral integrity, but at the same time this does not take absolute priority over the decisions of their parents or guardians or, as in this case, of the state, whose degree of influence over the minor's enjoyment of his or her fundamental rights will be in accordance with the maturity of the minor and the different levels of capacity to act set out in the legislation (arts. 162.1, 322 and 323 of the Civil Code or art. 30 LRJPAC).

b) Constitutional significance of the minor's opposition to the prescribed medical treatment.

   Refusal of the prescribed medical treatment by the minor, where no alternative treatments exist, is of particular importance because, in opposing external interference with his or her own body, the minor is exercising a right to self-determination which relates to his or her own body — as distinct from the right to health or life — and which, within the constitutional framework, corresponds to a fundamental right to physical integrity (art. 15 of the Spanish Constitution).

c) Significance of the minor's opposition to the prescribed medical treatment.

   The law accords minors significance with regard to certain acts or legal situations. These include acts relating to the rights of privacy (including, precisely, the right to physical integrity) which are excluded from the power of legal representation held by parents as holders of parental powers, as is explicitly stated in art. 162.1 of the Civil Code.; but this exclusion does not affect the duty to defend and supervise the minor and his or her interests.
   There is insufficient data to allow us to conclude with certainty that the dead minor, who was 13 years old, had the maturity of judgement necessary to take such a vital decision as the one before us. As a result, the decision of the minor was not binding upon the parents with respect to the decision which they had to take.
   Despite this, it should be noted that the reaction of the minor to attempts to take medical action made it clear that he had strongly held convictions and was fully aware of his decision and that this, clearly, must have been known to his parents, when responding to the requests subsequently made to them, and to the legal authorities, when evaluating whether they could demand the cooperation of the parents.

Conclusions

Health issues which affect the life, the health, the physical and mental integrity, and the medical and sexual care of the minor belong to his or her private and personal sphere, and the minor's capacity for self-governance should therefore be exercised on the basis of criteria of maturity.

10 Beltrán Aguirre, Juan Luis. La capacidad del menor de edad en el ámbito de la salud: Dimensión jurídica. Extraordinario XV Congreso "Derecho y Salud".

A minor's capacity to understand the situation and reach a decision will vary depending on a range of factors. The more far-reaching the decision, and the more risk and the less benefit it entails, the higher the level of competence required.

Consent by representation only applies in the case of non-emancipated minors or minors aged below 16 years, when they do not have a sufficient level of maturity, although the opinion of minors aged over 12 years must always be taken into account.

The minor is sufficiently mature when two conditions are met: the capacity to understand what he or she is being told, and the ability to choose freely[11].

11. Dolz Lago, Manuel-Jesús. *Diario Médico.* 02.11.05

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Consent by representation: some considerations regarding possible improvements

In practice, the actual situations in which consent by representation is required are often complicated, particularly when these involve decisions at the end of life.

In these cases, emotions are usually running high and the decisions involved may be controversial. At times, relatives simply deny the reality of their situation; what the doctor proposes and what the patient's family want may be incompatible; family conflicts may come to the surface; and relatives may even act irrationally and demand action which is simply not appropriate. All of these issues are difficult to handle.

In addition, consent by representation must usually be granted by individuals who are not medical experts and who must, therefore, be 'informed'. The doctor has to provide the information necessary for a correct decision, but there is plenty of evidence that the way in which this information is presented can have a decisive influence on the final choice.

Totally neutral information which presents a choice between two alternative courses of action and leaves the decision completely in the hands of the family, taking the principle of autonomy to the extreme, may actually constitute poor professional practice and could well lead to extreme solutions being adopted which are often not in the patient's interests.

Instead, a good medical professional must be able to 'share' decisions with the family, starting by finding out as much as possible about the patient and his values or preferences, so that the professional is then in a position to advise or even persuade without ever exerting pressure.

However, to perform this task, doctors are assumed to have a set of *skills* which are not addressed in medical training, as a result of which, the 'information' interview is left to the discretion of the individual doctor, if not simply to improvisation. More serious still, interest in this area is viewed as an expression of the friendliness or approachability of the doctor, and not what it really is: an essential professional skill.

So we need to improve *education* in this area, given that *communication* between doctor and patient (or the patient's relatives) constitutes the foundations upon which vital clinical decisions are based; only in this way can we close the gap which currently exists between theory and practice.

Communication skills can be taught and learned, and these skills should be seen not as a series of superficial strategies, but rather as a *change in the attitude* which informs the clinical interview. We need to move from 'handing over information' as if it were a parcel, to 'listening and understanding' in order to help.

Medicine students should be provided with the knowledge and tools to deal with the difficult situations they will encounter, and to make them more sensitive to other people's misfortunes (a sensitivity which they often have at the start of their studies and gradually lose as they seek to emulate their seniors, supposedly 'hardened' by time and experience).

This means learning to listen, not to judge, to understand wishes which have not been expressed verbally but which may explain certain attitudes, to persuade and be assertive without being overbearing, to know how to get involved and to involve others in decisions, to keep one's counsel when necessary, and to accompany throughout the process.

Although shortage of time is often given as a reason for the poor quality of medical consultations, it is clear that better training and skills and better time management will help to deliver greater satisfaction for both parties and help to resolve situations which might otherwise lead to conflicts and disputes.

Another perhaps somewhat utopian approach is to seek to *value* those qualities which make doctors into good professionals, and not just to reward the skills of 'diagnosing and treating' illnesses.

The doctor receives more training in 'technical-scientific' skills than in those concerned with relationships and communication; and this disassociation is even clearer in hospital medicine. Technology and humanity are almost always in opposition to each other. It would be good if we could change that part of hospital culture which establishes a dichotomy between efficacy and human contact, because they are not in conflict. And we need to strengthen (perhaps through professional recognition) such vital attributes as respect, tolerance and compassion, understood not as 'charitable pity' but as the urge to take effective action to help another as a result of being personally moved by that person's plight.

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The speakers have explained the distance between the legislation and clinical practice, and the challenge of bringing the two together. This distance reflects the difficulty of applying informed consent in the context of intensive care, a challenge which is further complicated when the patient is incapacitated and consent by representation is required, something which occurs frequently as I will discuss below.

I will start by considering the person *who should decide about the natural competence of individuals in the health context*: the care doctor. This is a responsibility which has not yet been fully recognized legally; although it is recognized and regulated in Act 41/2002 on Patient's Autonomy, the authority of medical professionals to decide in this area has been questioned by legal rulings. This law does no more than make explicit and regulate a basic competence which is a necessary part of the consent procedure. One can only grant consent if one has the capacity to do so, and nobody is better placed to verify the comprehension and acceptance of the consequences of intervention by the patient than the doctor who is to perform the intervention and has to provide the appropriate information.

The doctor-patient relationship, if it is to be productive and to contribute towards achieving the aims of medical care, must be based on mutual trust: the trust which must inspire the medical professional and which is created in the consultation as a result of the doctor's ability to display empathy and to inform in an appropriate manner. But this trust is also based on the degree to which the doctor judges the patient to have the capacity to take responsibility for treatment decisions. Because respect for people in a healthcare context, the ethical basis of consent, requires respect for the decisions of autonomous individuals, but also involves protecting those whose autonomy is reduced or limited.

This assessment of natural competence is particularly important when caring for the elderly and for minors, for patients with dementia and individuals with mental health problems. In these spheres, it is advisable to start from the assumption that people are competent unless they give indications to the contrary, and assessment of competence should therefore be circumstantial. As a result, we must be careful not to be guided by prejudices and 'labels', such as those generated by a diagnosis of mental illness, and we therefore need to check, on each occasion, the degree to which the patient is capable of expressing his consent.

The competence required to grant consent varies and depends, among other factors, on the complexity of the proposed treatment and the balance between expected benefit and potential risk. Simple treatments, with a high likelihood of delivering real benefits and minimal risk, require a lower level of competence than more complex procedures, for which outcomes are uncertain and the risks are high.

Competence is usually assessed as part of the consultation, checking how the patient expresses his understanding of the situation and of the consequences of the treatment, together with whether the decision is reasonable in light of the patient's beliefs and values. However, where there are doubts, the doctor can ask for the support of expert professionals such as psychiatrists, even though the final decision regarding natural competence lies with the doctor responsible for treatment.

We hope soon to have access to a tool for assessing competence, in the form of a structured interview with weighted responses, which has been translated from English and is being validated by a team of health professionals at Parc Taulí, led by Pablo Hernando.

Recently, the Sitges Document (2009) was developed for use when assessing the decision-making competence of patients suffering from dementia. This document correlates different mental functions with the decision-making sphere, and proposes a unified scale to classify the level of the interviewee's mental functions.

There are those who argue that it is difficult to identify who the doctor responsible for care actually is, but in the primary care sector we all have a family doctor, while in a hospital setting there is a single health professional

who must be identified to the patient as being responsible for authorizing his or her discharge. A separate issue concerns the responsibilities which are shared with other professionals involved in patient care, for example, during shifts, in the absence of the doctor in charge or when a professional has to perform an invasive procedure on a colleague's patient. Team work and cooperation between different professionals should not dilute the responsibility of the doctor in charge.

A second issue concerns *the person responsible for granting consent by representation*. I believe that, from a legal perspective, there are only three situations in which it is correct to talk about the patient's representative: a) the person designated by the patient in his or her advanced directives document (ADD); b) the person designated as guardian by the judge in a process of incapacitation; c) the parents or legal guardians of minors.

As a result, the patient's family, partner or friends do not automatically have the status of legal representatives. This means that, in reality, there is unlikely to be a legal representative, because relatively few people have an advanced directives document and even fewer are legally incapacitated. Nor, in my opinion, is admission to hospital the best moment at which to draw up an ADD. To do this, one should be emotionally prepared and in full command of one's autonomy, and the moment of hospital admission is therefore unlikely to be ideal, not least for reasons of health.

One way of getting round this problem is to identify, at admission, the main person to speak to, and to record this in the patient's medical records. If the patient is competent, then he should be the one to nominate somebody whom he trusts and who can substitute his wishes in the event that the patient's illness renders him unable to do so. If the patient's state of health prevents him from doing this at the time of admission, the care team should seek to reach agreement with close friends and relatives as to who they should be speaking to.

This is a practical measure which can assist decision-making if the patient's health deteriorates and health professionals need somebody to share difficult decisions with. It can also help prevent the conflicts and disagreements between relatives which always interfere with and hinder the task of health professionals. Care institutions should seek to include this procedure into their care protocols, something which would go some way towards lessening the current situation of legal uncertainty.

Thirdly, I would like to consider *surrogate representation in intensive care units*. We must start by recognizing that this is one of the areas where we face most difficulty in obtaining consent, due both to the frequency of aggressive interventions, and to patients' state of health.

While there is no question that consent for the insertion of a dialysis catheter must be recorded in the relevant document, it is not clear whether the same applies to the catheters which are routinely applied to patients in intensive care units. The procedures are similarly invasive, but in the first case the treatment is exceptional and is a necessary requirement before dialysis can be performed, while in the second case it is part of the daily routine for the monitoring of the patient's vital signs, one of the reasons for admission. Furthermore, they are one of the minor but necessary aggressions undergone by an ICU patient. This normal, daily procedure may be included in a general document setting out the routine interventions undergone by patients in such units. The exceptional interventions which require specific documentation are another issue. Hopefully, clinical ethics committees (CEC) can help to identify how to find an equilibrium between normal procedures in ICUs, which can be included in a consent document to be signed upon admission, and those procedures which require a specific document.

Another added difficulty in these units is that patients are rarely in a position to consent, either because of the seriousness of their condition, because they are sedated, or because they are in a coma, all frequent reasons for admission. Our comments regarding the identification of a principal contact person for granting consent by representation may be particularly pertinent in the case of intensive care patients, when complex decisions must be taken in the middle of the night, and when it is not always possible to identify all the interested parties, or when the dramatic nature of the decision may lead to conflict within the family.

In the cases discussed by the speaker, one would need to differentiate between those where the objective difficulty concerns the problem of communicating with the patient, due to the state of his health, and where, as a result, consent by representation is applicable, and those where the difficulty is the result of a moral concern or dilemma. In the latter event, it is worth consulting the clinical ethics committee. While its recommendations are not binding, they can be useful in helping to identify reasonable arguments and preventing arbitrary conduct and the abuses of medical paternalism. However, in order to be of use, CECs must have emergency procedures enabling them to be accessible 24 hours a day.

Finally, I cannot finish without referring to a question which probably falls outside the scope of today's meeting or which only tangentially affects it, and this is the issue of *care for immigrants*, with other beliefs and customs which, from our own perspective, might be deemed 'irrational'. Beliefs and convictions which are the product of another world view should always be respected, so long as they do not compromise the individual's life. As health professionals, we sometimes find ourselves trapped in a conflict between the duty to attend to patients in accordance with their personal values, and the obligation not to be maleficent when it is possible to prevent harm. This is particularly important in the case of minors, when their parents request or advocate interventions for religious or cultural reasons, such as the practice of circumcision in boys or genital cutting in girls. The fact that such damage is objectively measurable and irreversible may justify preventive action to protect the minor.

THE LEGAL PERSPECTIVE

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The right not to consent to prescribed medical treatment

The patient's right to autonomy can be analysed from a number of angles, but one which is particularly problematic is how to determine which should prevail when there is a conflict between best practice and respect for the patient's freedom and wishes. On the legal-constitutional level, Spain's Constitutional Court has issued rulings in which it has favoured the ideological (religious) freedom of a minor and the parents over prescribed medical treatment. In the case resolved in Constitutional Court Ruling 154/2002, granting protection to parents who had been prosecuted for the crime of neglect and for failing to provide the health care needed by their son who was a minor – a Jehovah's Witness like his parents – and who died after refusing to receive a blood transfusion which the medical services deemed vital. The legal basis cited for the ruling allows us to identify at least two basic criteria or premises: firstly, the right of the patient to exclude the prescribed medical treatment [this power has now been given explicit legal recognition in Act 41/2002, on Patient's Autonomy in art. 2. 4 ("*All patients or service users have the right to refuse treatment, except in the situations determined by the law*")]; secondly, a broad definition of the right to reject prescribed treatment, due to the fact that the priority accorded to the patient's wishes in preference to medical advice is based not on the patient's religious or ideological freedom (art. 16 of the Spanish Constitution), but rather on the right to self-determination as a basic right to physical integrity (art. 15. of the Spanish Constitution). In other words, the wishes of the patient take priority, irrespective of the grounds on which his or her decision may be based. This approach attributes to the patient an almost absolute right to decide with regard to any clinical or

medical treatment. However, this right, which is attributed to almost any patient, raises a very thorny issue because it is not yet clear just what scope it has; that is, to what degree the patient's autonomy and its consequences should be respected, and specifically whether the authorities must accept the consequences of this recognition for their care provision. The issue has already been raised to a degree before the Constitutional Court with respect to a claim against the Social Security system for the financial costs incurred by a Jehovah's Witness for a surgical intervention in the private sector which did not require a blood transfusion. And Constitutional Court Ruling of 28 October 2008 (CCR 166/96) refused to recognize the right to reimbursement of these costs. As a result, at least in terms of Spanish constitutional law, all that results from a patient's refusal to accept treatment is that he or she renounces any action within the health sector and accepts any potential negative consequences for his or her health, without this right to refusal giving rise to any further right to health provision.

The right to control personal information

Together with the right to consent to a health intervention, another sphere of power which is of particular relevance to the patient's autonomy is the capacity to control information relating to one's health and, as a result, the capacity to reject the interference of third parties and in particular of one's family.

Act 41/2002 contains an important provision in this regard. Art. 5.1 states that, "*The person who possesses the right to information is the patient. The people linked to the patient, either by family ties or in practice, should be informed in so far as the patient either expressly or tacitly permits.*"

The first thing which is clear from this rule is that it is the patient, alone, who holds the right to the information. The law balances this provision by also setting out the right of relatives to have access to information regarding the patient's health; however, this is established as a relative right which is conditional upon the prior authorization or consent of the patient.

We should also note here that we are talking about information regarding the patient's health which constitutes the core of the individual's privacy and is subject to additional protection. As a result, when we provide information about the patient to third parties (relatives or common law partners), this affects the fundamental rights of the patient: both the right to privacy (art. 18.1 Spanish Constitution) which protects the individual against any unauthorized interference in his personal or family life, and the right to data protection (art. 18.4 Spanish Constitution) which "*consists of the right to have access to and control one's personal data and to decide which of this data to make available to a third party*" (Constitutional Court Ruling 254/1993).

It seems clear that, under these two basic rights, the patient is entitled to prevent or limit access to information about his state of health by his relatives or others to whom he has close ties. As a result, it is not possible for somebody simply to demand that the doctor provide information about a patient's health on the basis of being related to him; any such right to information is subject to the consent of the patient.

At the same time, we must recognize "the right not to be informed". Art. 4.1 of Act 41/2002 establishes that "*everyone has the right to have their wish not to be informed respected*" and adds in art. 9 that, "*when the patient expressly states his or her wish not to be informed, this wish must be respected and the patient's refusal recorded in writing, without prejudice to the need to obtain consent prior to treatment.*" This right is one which the patient can exercise with regard both to himself and to his family and friends. And the doctor must respect this right by ensuring that this information is not provided either to the patient himself, or to his family and friends.

Furthermore, this right is absolute and cannot be overridden. Not even the generic invocation of the greater good and the protection of the patient would serve as justification if the patient had clearly stated that certain relatives should not be informed.

As a result, medical staff should not provide information when the patient himself opposes this, nor supply this information to anyone other than those expressly authorized to receive it; informing the patient or those whom he has chosen to exclude, would, in this event, constitute a violation of the patient's basic rights.

In the light of the above, before informing the family, health staff must always seek to identify the patient's wishes. Where the patient is able to understand the information, health staff should ask him if he is willing to give his family or those close to him access to information about his state of health. The patient may be reluctant to give information to certain relatives or may even be made uncomfortable by their presence in the health centre, in which case the doctor and health staff in general must respect his wishes.

Perhaps the most practical solution is for the doctor to create a separate document to be appended to the medical records, containing the relevant observations about the patient's right to be informed or not and the identification of recipients of this information (relatives and those close to the patient to whom information should be supplied or from whom it should be withheld).

This problem arises in the case of incompetence due to the patient's physical or psychological state, but in such cases the doctor responsible for care must take the decision, because section 3 of art. 5 of Act 41/2002 leaves it to the judgement of the doctor in charge to decide upon the necessity of informing those linked to the patient by family or *de facto* ties.

The access of parents and guardians to the medical records of mature minors

In the case of a mature minor (emancipated or aged 16 or older), the legislation only creates an obligation to inform the parents in the event of behaviour judged by the doctor to be very risky, and specifying that their opinion will be taken into account when taking the relevant decision (art. 9.3,c). From this we can deduce that, in the event of a non-serious risk to the health of the mature minor, health professionals are not obliged to provide this information. The logic of this restriction lies in the fact that, "*In the case of minors who are not incompetent or incapacitated and are emancipated or are at least 16 years old, consent by representation does not apply.*" (art. 9.3, c), as a result of which the minor has a full right to autonomy.

Notwithstanding, art. 18.2 of Act 41/2002 recognizes that "*the patient's right to access his medical records may also be exercised by a duly accredited representative.*" And this raises the question as to whether the parents or the holder of parental authority, as provided by article 154.2 of the Civil Code, must be considered in all cases to constitute a "duly accredited representative" and, as a result, whether this representative has the right to have access to all the available information regarding the health of the mature minor.

This issue has been considered by the Spanish Data Protection Agency (AEPD), on the basis that access to data relating to the minor's health could compromise the right to privacy of personal data.

In its Report 409/2004, the AEPD does not hesitate to conclude that, "*access to medical records constitutes an instance of exercising the right of access, regulated by article 15 of Basic Law 15/1999, of 13 December, on the Protection of personal data (…) and is part of the essential content of the basic right to the protection of data and, as a consequence, an essential part of the individual rights of the person whose data it concerns, in this case, in the medical records.*"

In light of this and the fact that art. 162.1 of the Civil Code excludes from legal representation by the parental authority, "*those acts referring to the individual or other rights which the child, in accordance with the law and his or her maturity, may exercise for him or herself,*" the AEPD concludes that "*minors aged 14 years or over satisfy the conditions of maturity to exercise for themselves the right to access their personal data, without there being any possibility of accepting legal representation (and, as a consequence, unaccredited) of the person holding parental authority, given that it is precisely these acts which are excluded from the aforementioned representation by article 162.1 of the Civil Code.*

In this way, it reaches the conclusion that, *"if the father or mother of an individual aged 14 years or over attends a health centre and requests a test report or any other information included in the medical records of his or her child, without any authorization from the child, the provisions of article 18.2 of Act*

41/2002 will not apply, and the information should therefore be withheld in so far as the official authorization of the child has not been provided. With the exception, of course, of those cases where the child has previously been incapacitated."

However, in a later consideration of whether the express consent of minors aged 14 years or over should be obtained before performing a medical examination and if the results of the examination should be communicated to the minor or to his or her parents, the AEPD modified its stance.

In its response, issued in Legal Report 0114/2008, while it repeated its opinion that those aged 14 years or over have sufficient maturity to grant consent to the processing of their personal data, and that mature minors may therefore request an examination themselves without requiring their parents' consent, at the same time the Agency recognized the competence of parents to access these reports. Despite recognizing that this is an instance of transferring data of a personal nature defined in article 3i of Basic Law 15/1999, as "[a]*ny disclosure of data to an individual other than the person to whom it pertains",* the Agency considers that, *"having access to the health information of one's children is fundamental to [a parent's] ability to adequately look after their health,"* and, as a result, its understanding is that, *"the Civil Code permits the disclosure of health information to those who exercise parental authority."*

It is clear that the Agency's second report corrects a key aspect of the position originally taken by the Agency. This correction more closely reflects the logic of the situation, where it does not seem reasonable to adopt an approach which clearly discriminates against allowing the parents access to the minor's information, given its importance in enabling parents to comply with their duties.

However, this right of access is restricted exclusively to those exercising parental authority or guardianship:

> *"… this right pertains to the holders of parental authority and not to any family members, who may only obtain the data in the event of their exercising guardianship, given that article 269 of the Civil Code establishes a similar legal provision when it states that, "The guardian must look after the charge and, in particular (…) educate the minor and ensure that he or she receives a well-rounded upbringing."*

In summary, although parents do not have the competence to represent a mature minor who has not been incapacitated to act in the health sphere, or to persuade or influence their child of the need for treatment, as can be inferred from Spanish Constitutional Court Ruling 154/2002, they do have the right to be informed about and have access to the health information of their children who are mature minors.

Blanca Mendoza

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I will consider some of the issues which have been raised recently regarding the efficacy of the *wishes of minors* with respect to certain medical treatments, together with the *limits* on the representation by parents or legal representatives in this area.

In the first place, there are issues which from a legal perspective one might classify as prior matters, concerning how to *determine* or *assess* the *competence* of minors to take decisions about their health, especially minors who are not yet 16 years old. Given that Act 31/2002 on Patient's Autonomy (LAP) assigns to the doctor responsible for care the task of assessing the minor's competence to take decisions, in reality this is in the first instance fundamentally a medical problem, and I will not therefore consider it in detail except to note, firstly, that the law does not (and clearly should not) establish a *minimum age limit* in order for a minor to be recognized as possessing sufficient maturity to decide or, at least, to make a significant contribution towards the decision. And secondly, one of the criteria which should be taken into account when determining somebody's competence to take a decision is the issue of the degree to which this decision entails major and irreversible *consequences for the individual concerned*. As a result, if the consequences are particularly far-reaching, the minor should be granted more autonomy in order to avoid the contradictory situation where the minor is deemed incompetent to take a decision for himself and is, instead, subjected to the criteria of his parents, only to subsequently be forced to live with the very consequences of that decision when these affect the minor's present and future autonomy, and accepting them requires great maturity.

The competence of mature minors to grant consent: the case of abortion in adolescents

I would like now to consider the highly topical debate around the proposed reform of the abortion laws, with regard to the proposal that women between 16 and 18 years of age should be allowed to decide whether to have an abortion without requiring parental consent or intervention.

Those who argue for the necessity or desirability of imposing restrictions which require the involvement of a minor's parents or legal representatives to grant their authorization when the minor has requested an abortion put forward two basic arguments. The first of these is that minors (at least before the age of 18) are not sufficiently mature to take certain key decisions and instead require adult supervision, or even for a decision to be taken on their behalf. These arguments regarding the immaturity of adolescents and the wisdom of their parents are the ones must frequently deployed, but allusion is frequently also made to the "guiding role of parents in the education and upbringing of their children, which would justify restricting the freedom of minors," and even to the notion that parents are responsible for their children's destiny and have the right to instil in them their own moral standards and religious beliefs.

The question which arises in this regard is whether this provides sufficient grounds for the State to subject a minor's decision to terminate an unwanted pregnancy to the absolute veto of her parents or a third party, on the basis that the adult's superior wisdom entitles him or her to impose an unwanted pregnancy on the minor or to force her to undergo abortion.

Against this notion that parental consent or notification should be a requirement before allowing a mature minor to undergo abortion, there are a range of arguments which go beyond the unquestionable duty of parents to act to educate, guide and support their children. From recognizing that the fact that somebody is a minor does not mean that he or she ceases to possess constitutional rights such as personal autonomy, dignity and privacy, to the idea that what is at issue here is not whether, in the final analysis, parents or another adult are more mature or more astute at taking decisions, but rather that it is the minor who is best placed to take the decision, precisely because it affects her so directly and so personally, and as a result it is not acceptable to substitute her wishes or to impose another's wishes on her. Preventing a mature minor from terminating an unwanted pregnancy and forcing her to continue with it and become a mother against her will, on the one hand, or

forcing her to have an abortion against her firm and reasonable decision, on the other, constitute not just unacceptable interference with her autonomy, privacy and the right to lead her own life, but are also an affront to her very dignity. This is a very personal issue, perhaps the most personal which can affect any woman regardless of whether she is a minor or not, and for this reason the imposition of another person's decisions strikes me as morally unacceptable, as providing a potentially dangerous pretext for abuse, and as legally inconsistent and unsustainable.

Several international agreements have identified the fact that the reproductive health needs of adolescents as a group have been ignored in most countries. The basic approach of societies with regard to the reproductive health of adolescents should be based on providing information which helps them to reach the level of maturity necessary to take responsible decisions and, in particular, on ensuring that they have access to information and services which help them to avoid unwanted pregnancies and sexually transmitted diseases, and abortions performed under unsafe conditions; this should be accompanied by education designed to ensure that young people respect the principle of women's self-determination and share responsibility for issues relating to sexuality and reproduction[12].

I believe we must stress the need to promote the *status, autonomy and reproductive rights* of women in general, and of young women and minors in particular, whose autonomy is not sufficiently recognized and protected, with the result that their decisions often have to be supervised by others.

Both legal and pragmatic arguments clearly lean towards recognizing the competence of a mature minor, including minors aged below 16, *to decide whether or not to continue with a pregnancy*. The main argument, in my opinion, is that reproductive rights should be considered as a fundamental aspect of the right to privacy, the right to freely develop one's personality, the

12. United Nations. 1995. *Population and Development,* vol. 1: *Programme of Action adopted at the International Conference on Population and Development: Cairo: 5-13 September 1994,* paragraph 7.41, 7.44. New York: Department of Economic and Social Information and Policy Analysis, United Nations.

right to a private sphere, in which interference by others is not acceptable. Maternity can never be imposed because of the individual's age or even her lack of maturity or incompetence, just as it is never legitimate to perform an operation such as surgical abortion against the will of a mature minor.

At the strictly legal level, in my opinion, the confusion generated by the defective wording of art. 9.3 and 4 of the Patient's Autonomy Act (LAP) and its interpretation by some in a sense which is in direct contradiction to what it actually says, has led to proposals for the (unnecessary) reform of paragraph 4 of art. 9, as part of the recent Draft Legislation 121/000041 on sexual and reproductive health. Although this proposal has been brought forward with the aim of clarifying the issue of the age of majority at which one can automatically grant consent to abortion, in fact all it has done is focused attention on an issue which is already regulated in the LAP, giving rise to an overblown controversy about an issue which, until now, had been resolved without significant problems by reference to the criterion of natural competence to take medical decisions which are of a particularly personal nature.

Art. 9 of the LAP is headed "*Limits* on informed consent and consent by representation" and paragraph 3 establishes that "consent by representation may be granted in the following situations": a) when the minor "*is not capable of taking decisions,* at the judgement of the doctor responsible for care, or where the patient's physical or mental state *does not allow him or her to take responsibility for the situation*", b) when "he or she has been *legally incapacitated*", and c) when "he or she is not intellectually or emotionally capable of *understanding* the *scope* of the intervention." The same section expressly states the *general rule* that in the case of *minors who are neither incompetent nor incapacitated and aged 16 or over* "consent by representation does not apply," although in cases of *very risky* behaviour - understood from a *medical* perspective - the parents will be *informed* and their *opinion* taken into account when reaching decisions. At the same time, section 4, establishing a clear *exception* to the possibility of accepting consent by representation specifically in such cases, states that, together with other situations, the voluntary termination of pregnancy, "is governed by the general provisions regarding the age of majority and by the relevant special provisions."

If we are to be consistent, this can only be interpreted as a return to the *general provisions* regarding *decisions on medical treatment:* that is, to the provisions on *the age of majority in the health sphere*, given that the decision to terminate a pregnancy is also a medical decision[13]. And in this regard, the preceding paragraph of art. 9 lays down the general criterion of *natural competence to take decisions*, in the opinion of the doctor responsible for care: *that is, the physical, intellectual and emotional capacity to take responsibility for one's situation and to understand the scope of the treatment*, a state which *is reached by 16 years at the latest*, unless the minor is incompetent or has been incapacitated. Therefore, and despite the fact that the defective drafting of the legislation has led a minority strand to argue the opposite, the issue had already been resolved by the legislators some time ago, and without controversy, using the criterion of natural competence.

What is more, if one wishes to argue that this was not the intention of the legislator in drafting article 9 of the LAP, then one must conclude that the legislation which forms the basis of a solution to this question supports the notion that there is no point in seeking to establish a restrictive exception[14] to the general rule of consent in health issues, and precisely in a matter as intimate and personal as the decision to terminate an unwanted pregnancy. The Spanish Civil Code, in art. 162, rules out the legal representation of children by their parents with regard to acts relating to rights of the individual or other rights which the child, in accordance with the law and depending upon the child's level of maturity, is able to perform for him or herself. And it would appear obvious that medical decisions in general, and in particular those relating to whether or not to continue with a pregnancy, directly concern the rights of the individual and, to this extent, that the potential imposition by force, and against the woman's wishes, of 'obligations' which affect her body, her privacy and her personal development constitute a direct attack on her personal dignity.

On a practical level, space restrictions mean that I can only refer to the danger that the requirement to notify the parents could cause minors to delay their decision or end up having abortions later, at greater risk, and possibly at the hands of illegal practitioners, and could conceal situations of abuse.

13. As Professor Tomás-Valiente Lanuza explains, consent to abortion is simply a specific instance of the more general issue regarding the competence to consent to or refuse health treatment (Comentario editorial, *Humanitas* no. 28, June 2008, consulted *online* http://www.fundacionmhn.org/revista.html).

14. In addition to art. 2 of the Legal Protection of Minors Act, which states that any limitations on minors´ competence to act should be interpreted conservatively, one could refer to the legislation which establishes the minimum age for criminal responsibility or for sexual consent.

Núria Terribas

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The concept of consent by representation, as contained in the current legislation on patients' rights (Basic National Legislation Act 41/2002 and Act 21/2000 in Catalonia), gives rise to a variety of problems. While I have no intention of embarking upon a detailed analysis of the different perspectives presented by the speakers, I would like to comment on some of the more controversial points raised during the debate.

To start with, I would argue that it is not possible to analyse these issues solely from a theoretical, legal perspective. Instead, we must draw on bioethics to develop criteria for use when interpreting and resolving such problems in practice, and these criteria should be designed to be of real help to professionals faced with these situations in their daily work, where the issues at stake in each case may vary widely and a single solution is therefore not possible. Despite the theoretical distinction in the legislation between hypothetical scenarios of full, partial or non-existent competence, where surrogate decision-making would be required, the range of intermediate situations occurring in widely varying contexts, is extremely wide.

The role of the family as 'surrogate decision-maker'

Both Catalan and Spanish national law on patients' rights clearly establish that, in the event of the incapacity or incompetence of the patient, his family or "those close to him" will be responsible for taking decisions, as representatives. Here we encounter a first difficulty, which the law does not resolve and which in practice becomes a real problem: what is the order of priority between the decision criteria? Often, there is a long list of people who are related to the incompetent patient, and these relatives disagree when it comes to taking decisions. More problematic still is the situation in which the family is in conflict with a third party, such as the patient's partner or main carer, who is not recognized as having any right to participate in the decision-making process. How can we settle this issue when the law refers only to "the [patient's] family or those close to him" without establishing any order of priority? Does the opinion of the patient's eldest son carry the same weight as that of his wife, or his daughter-in-law? What should we do when some say 'black' and others say 'white'? And in the case of small children, whose parents have separated and who appear to be more concerned with getting one over on their ex than on looking out for the welfare of their offspring, what should we do if father and mother disagree?

These conflict situations, in which a choice must often be made quickly, put health professionals in a very difficult position.

I believe that the only way of solving this problem is by changing our social and professional culture so that, while they are still fully competent (minors represent a separate issue), patients appoint or are asked to identify the person who they judge suitable to act as sole representative during the care process in case it becomes necessary for decisions to be taken by a surrogate. This approach, which would offer security to health professionals and would educate patients to share responsibility for their health, comes up against the still widespread assumption that patients and their friends and family constitute a single, undifferentiated block. As a result, in our daily practice we relay information first to one relative and then the next, and we describe the whole process to anyone and everyone, without first checking whether we have the patient's approval or whether we are violating his confidentiality by providing this information to third parties without his authorization. And the matter is more serious still if this approach is extended to the taking of decisions affecting the patient, where everyone has their own opinion and medical advice may be contested.

The importance of advance directives in the decision-making process

The speakers offered a somewhat pessimistic view of this issue as a result of the practical problems in applying them. It is true that the decision-making context of the Intensive Care Unit differs from that of other hospital depart-

ments or in primary care (e.g., palliative care at home) or in social care settings. The elements of urgency, the need for rapid decision-making and the challenge of interpreting advance directives correctly when the context may differ from the one envisaged by the patient, further complicate the task of applying such documents in practice. However, we should also remember that when dealing with patients who may end up being admitted to a hospital ICU, we need to seek to find out about their background and their preferences in order to try to avoid taking measures which the patient would not have wanted. Of course, it is true that finding out about a patient's past requires additional effort, something which may not always be possible or which the health professional may simply not be keen to do. And if the patient is 'unknown', health professionals take the attitude that any measure which is clinically justified in the ICU falls outside of the scope of application of advance directives.

However, going beyond the specific sphere of intensive care, I believe that we should promote both the use of advance directives in society as a whole and their respect by health professionals as a way of avoiding the need for consent by representation, something which can only be achieved through education. Basic education of society as a whole, which can be delivered in part by the health system itself (with a key role to be played by the family doctor and health centres), and in part through the authorities by raising awareness of this instrument, what it is for and why it is helpful, the need to be properly informed before drawing one up, the responsibility for reviewing it if circumstances change over time, etc. And training for health professionals and particularly the doctors who will be responsible for assessing and applying the advance directives in each specific situation. Even today, years after we first began discussing this issue, many health professionals do not know what these documents are.

As part of the appropriate use of advance directives, I would like to make special reference to the figure of the representative designated there. Often, when applying directives, doubts arise as to how to interpret the patient's situation. And this is why it is essential for there to be a surrogate decision-maker who has been expressly appointed by the patient in the knowledge that he or she will apply the same criteria and principles as the patient. The figure of the representative who has been appointed in an advance directives document is the most clear-cut example of consent by representation, far more so than decisions deriving from relatives or others identified as representatives by the law, but not confirmed by the patient.

Decision-making by 'mature minors'

Current regulation of the 'mature minor', which endorses the taking of health decisions without the need for representation by the parents in specific contexts and situations, gives concrete expression in health legislation to the rights of minors already regulated in a general sense in Act 1/1996 on the Legal Protection of Minors. However, the manner in which the regulations set out this provision is not without difficulties and there are many grey areas regarding how it should be applied.

To begin with, it leaves full responsibility for assessing the maturity of the minor (thereby excluding representation by the parents) to the judgement of the health professional, who usually lacks the time, experience and resources necessary for this task. If we are lucky and the health professional involved is the family doctor, then he or she will know the minor, be familiar with their social and family setting, and may be better placed to reach a decision. However, this will only happen in a small percentage of cases, and it is far more likely that the minor will be unknown to the health professional, who will therefore have to make a decision without being certain as to whether or not he is acting correctly.

When taking decisions, we also need to distinguish between the different kinds of decision to be taken: attending a hospital emergency service for post-coital contraception is not the same as rejecting potentially lifesaving treatment, such as chemotherapy or a transplant when suffering from cancer. For this reason, any assessment of the maturity of the minor must take into account the seriousness of the decision to be reached, and must identify the balance between risk and benefit. However, we cannot simply exclude minors from taking particularly serious decisions, because the maturity of

individuals varies greatly, depending on factors such as personal experience, education, cultural values, etc. As is always the case in ethical conflicts, we must deal with the specific case rather than seeking universal solutions.

In addition to the issue of the decision to be taken, another problem arises, which is the question of whether or not to inform the minor's parents, regardless of whether she is considered mature enough to decide for herself. Here, the professional has to reconcile respect for the confidentiality of the minor, with whom there is both a therapeutic relationship and a bond of trust (or at least there should be), with the parents' obligation to exercise their parental duties, in the light of which they may demand access to the information. This issue has not been resolved by the legislation, and is potentially a source of serious conflict.

Thirdly, national legislation in Spain (Act 41/2002), including the case of minors who are at least 16 years of age and are considered to have reached the age of majority for all practical purposes (unless they are clearly incompetent), provides for the possible exception of evaluating the situation as one of 'considerable risk', thereby legitimating consulting the parents when taking decisions. This exception, which would be positive if applied with caution in genuinely serious cases, can become a means simply of excluding the minor on the basis of the health professional's assessment of the risk. The law does not define what it means by 'serious risk', and this therefore creates considerable room for discretion.

Special consideration of termination of pregnancy in minors

Finally, I would like to discuss the decision to terminate a pregnancy, when it concerns a minor. One of the speakers discussed this issue in some detail, starting from the current exclusion of mature minors from taking this decision under the current patient's autonomy legislation and in the light of the regulation contained in the draft legislation, currently before the Spanish Parliament, which would accept the right of a 16-year-old minor to decide for herself.

As I see it, there are two aspects to this issue: on the one hand, the decision in itself, which I believe cannot be separated from legislation regarding the 'mature minor', with the result that if the pregnant woman is 16 years or older she should be considered to have reached the age of majority for this decision which has such far-reaching implications for her life, as she is for other health decisions. However, if the minor is below 16 years of age, in my opinion we should apply the criterion of maturity, not just of chronological age, assessing on a case by case basis the degree to which the girl understands the scope and scale of the decision. It does not strike me as acceptable that a question of this nature, with major physical and psychological implications for a woman's life, should be resolved on the basis of parental authority just because the individual concerned is a minor. Whether this imposition involves continuing the pregnancy to term or forced termination, either option strikes me as constituting an extreme attack on the dignity of the woman concerned, which is not acceptable either ethically or legally.

A separate issue concerns not the decision itself but rather the information provided to parents and their role in the decision-making process. This is where one of the main controversies of the draft legislation lies, because the current version of the act does not impose an obligation to inform the parents of minors who are 16 or older, and if the minor asks for her confidentiality to be respected then the parents cannot be informed. In this conflict we need to balance the minor's right to confidentiality in this delicate matter with the parents' duty to exercise their parental authority in a responsible manner, something which they will find difficult to do if they are unaware of a problem of this magnitude.

However, in resolving this conflict, we must assess the balance between risk and benefit very carefully. If we inform the parents, this may make it impossible for the minor to exercise her autonomy. If we accept that she is the one who should decide, then we must ensure that this decision really will be autonomous, and free from pressure or coercion. Making it mandatory to inform the parents could so condition the minor's freedom to decide as to render it meaningless.

At the same time, we should also consider the risk of encouraging the rise of backstreet or clandestine abortions if this offers the only way for an adolescent to terminate her pregnancy without her parents finding out. This would be very harmful because it would effectively recreate a 'two-tier system' with the additional problem that clandestine abortions do not ensure the safety and health of the person who is pregnant.

It would seem reasonable, therefore, to avoid making it obligatory to inform the parents, something which would not prevent potential legislation from containing solid guarantees to ensure that adolescents receive appropriate support when taking decisions. This support should ideally be provided within the minor's family, building the relationships of trust necessary to overcome the initial fear of the parents' reaction, and ensuring that communication with them is healthy and based on respect for the minor's decision.

Unfortunately, it is not always possible to achieve this ideal, because each situation is unique. And for this reason it is advisable to provide for other mechanisms to facilitate this support within the system (social services, team of adolescent psychologists, etc.) even if is not possible to involve the family.

ETHICAL PERSPECTIVE

Marc Antoni Broggi

Vice-president of the Víctor Grífols i Lucas Foundation

A representative offers the best way of identifying and respecting the wishes of the individual when that person is incompetent; it is the best form of surrogate decision-making, and normally involves obtaining consent from a close relative or partner. The same should be true in the case of a representative appointed by the patient, for example in an advance directives document; but it is advisable to make this explicit in order to resolve the ambiguous wording of Basic Law 41/2002, in which the representative's role appears to be limited to defending the instructions contained in the document; as a result, if the representative is to act as surrogate in unforeseen situation, then he or she should be explicitly appointed as such.

If we are to respect the incompetent patient as a person and not simply treat his or her illness, we must be sure to understand that, although the individual may be unable to exercise his or her rights directly, this does not mean that the individual has no rights. We therefore need to ensure that the exercise of the patient's autonomy is not restricted by the patient's inability to express it, and to ensure that the patient's wishes, if known, are respected. This is why it is important to hold a dialogue while the patient is competent, so that the patient's stated wishes can be taken into account and are still deemed relevant if the patient ceases to be competent. Invoking 'therapeutic privilege' to justify an alleged higher professional duty to impose treatment against the patient's wishes is an abuse of power which was explicitly rejected in the informed consent legislation (as early as 1986) passed to prevent such conduct. The belief that incompetence annuls this right cannot be justified by recourse to the argument that 'perhaps' the patient would have changed his or her mind.

If we have no direct knowledge of the patient's wishes, then we need to obtain consent by substitution before treating the incompetent patient; in other

words, we need to ask for the consent of somebody who can act as a surrogate, whether explicitly appointed or otherwise (a spouse, son, etc.) to interpret what the patient's life values were (and are). When this consent by substitution is withheld, then treatment should not be given. Treating people without exploring their values and seeking to respect them is, in the words of one American judge, to treat them like objects, and that is unacceptable.

If we cannot identify a patient's stated wishes or substitute these through somebody who is close to the patient, then we should act in 'the best interests' of the patient, but we should do this bearing in mind that this interest does not consist simply of adhering slavishly to the protocol for treating the patient's condition but rather in tailoring treatment to reflect the patient's circumstances.

Josep Ma. Busquets

Responsible for Bioethics for the Department of Health of the Government of Catalonia

I would like to mention a couple of issues which I think might be relevant. Firstly, we should recognize that we live in a society where, in general, we are very overprotective of young people. In my opinion, this overprotection does little to help minors deal with difficult situations, and to understand and manage contradictory behaviour. Nor have we been able to move beyond rhetoric about the sort of sexual education which should be provided in schools to actually delivering education which enables young people to acquire the maturity they need if they are to take decisions for themselves. In the adult world, it is almost as if death did not exist in our society, and the topic continues to be covered by a conspiracy of silence.

Modifying this situation is a long and complex job which clearly goes much further than simply legislating, and involves every layer of society: families, schools, the media, etc., but also health professionals. Health education should prepare the individual to recognize and accept risks, should help equip them with the knowledge and the judgement needed to deal with such risks, and should also enable them to cope with adverse situations.

Health professionals should include the need for patient support in their care planning. And this is particularly important when it is very likely that complex decisions will have to be taken in the near future (surgery, hospital admission, whether to continue or suspend treatment, etc.). In this context (and in others, too, of course) advance directives are very useful.

While criticisms have been voiced regarding the usefulness of advance directives, primarily when they have not been drawn up on the basis of an open dialogue which allows the patient's beliefs, values and fears to be explored, and in which specific procedures are explained, and as a consequence of which the content is too vague and of little help when taking decisions. But the solution is not to replace advance directives with some other instrument, but rather to use them as they were intended: as some-

thing to contribute towards decision-making, not as a defence of medical practice.

The use of advance directives to ensure the adequate planning of the care that the patient wishes to receive includes the expression of the individual's values, wishes, attitudes towards specific situations and instructions to be followed in these situations, but it also allows for the possibility of appointing somebody whom we trust to take these decisions on our behalf if we are no longer competent to do so for ourselves. Indeed, an advance directive may be limited to just this: the designation of an individual who we wish to talk on our behalf when we are no longer able to talk for ourselves. It may sometimes be necessary to assess the suitability of this representative when the decisions taken are clearly harmful to or against the best interests of the patient, but the health professional should always bear in mind that, irrespective of the closeness of the representative's relationship to the patient, this is the person in whom the patient has placed his or her trust.

The representative cannot be limited solely and exclusively to the contents of the document; indeed, it would render the representative redundant if he or she was not required to offer a judgement about the considerations to be taken into account. Where there is no document, we should follow what the law says with regard to representation, while taking account of the opinions of the person who has been most closely involved with the patient. This can, of course, give rise to confrontations between different relatives and friends and even between health professionals, and it may therefore be useful or even essential to consult a clinical ethics committee, which may act as a mediator, although we should also accept that sometimes such conflicts have to be resolved by the courts.

Far more needs to be done to explain the benefits of advance directives, and to improve their wording and application at all levels. We also need to study the possibility of using such instruments with patients who suffer from mental health problems, as is the case in other countries, and we should modify the law so that advance directives drawn up by minors are governed by the same criteria as those established in the Patient's Autonomy Act for informed consent, and we should obviously set the age for drawing up a fully effective advance directive at 16 years.

The criterion established in this Act is the one which should apply to informed consent granted by minors who wish to terminate a pregnancy, without the requirement to inform the parents from 16 years of age for competent minors, except where there is a serious risk to health, as stipulated in the Act. And this approach should also apply to situations in which a competent minor rejects a health professional's attempts to advise or persuade her to inform her parents with the aim of ensuring that she is properly supported.

Montse Busquets

Lecturer at the School of Nursing at the University of Barcelona

The need to combine scientific progress with recognition of the moral autonomy of people with health problems raises fresh challenges. We now find ourselves dealing with situations which we could not even have imagined in the past, in which we have to act independently. For this reason, ethics and the law establish guarantees to defend autonomy: consent and advance directives are two key instruments designed to ensure respect for the autonomy of individuals when taking decisions about their health problems. However, the capacity to consent and thus to act autonomously requires several conditions: the individual must be capable of understanding the clinical aspects of his health problem and how this affects his needs; he must be able to establish causal relationships between the proposed methods of diagnosis, treatment and care and their possible outcomes; and must be able to understand how these could affect him in the medium and long term. However, before reaching a decision the individual must also be able to imagine how he may feel about these decisions in the future. Of course, if this is to be possible then he must receive support so that he has all the information and knowledge he needs. This is one of the key roles of health professionals.

The capacity to take decisions is therefore quite complex and, while most people possess sufficient mental, cognitive and social abilities to take decisions in 'normal' daily life, doing so with regard to health problems is often much more difficult. This is why we need to remember that an individual may sometimes be unable to take decisions alone or by themselves, and may need somebody to help them or to represent their interests.

My contribution here will focus on analysing some of the situations in which consent by representation is used, normally granted by family members. The law enables the doctor to consider a person temporarily incompetent and to seek the consent of his relatives or those close to him. This is consent by representation. However, in clinical practice things are not as simple as the seminar presentations might suggest.

One of the big difficulties derives from problems of communication, comprehension and expression, which make it difficult to clearly identify the level of competence. For example, elderly people with hearing difficulties or with early cognition loss, disorientation, or people from different cultural backgrounds for whom our healthcare model is unfamiliar, may encounter serious difficulty in understanding and expressing themselves, and we may struggle to assess the scope of their autonomy. There is a danger of our succumbing to the temptation of treating these as situations of consent by representation from the outset. The lack of time and proximity, together with a paternalistic approach to care, may lead medical staff to seek consent from third parties, whether relatives or friends, instead of striving to establish an effective communication process. And this may lead us to be more concerned with the level of comprehension and competence of the patient than with helping him to be as competent as possible. For example, by focusing almost exclusively on what the patient is unable to understand, on his wrong answers, on what he seems not to comprehend, etc. However, if we reflect seriously on consent by representation, it becomes clear how we should proceed if we are cautiously convinced that the person really is incompetent. At the same time, the need for a representative can never replace the therapeutic relationship with the individual, nor can it become a reason for the health professional to cease to strive to facilitate the patient's competence. This means establishing effective, therapeutic communication, and creating a setting which is designed to help patients achieve the fullest possible competence. Communication which, at the same time, helps the professional to understand the human dimension of the person being cared for and treated.

Another problem arises when assessment of the level of competence is not ongoing and does not involve the whole care team. Primarily, this means involving both doctors and nurses, who are the staff responsible for care and treatment, but it also encompasses all who intervene in the care process at any moment.

Continuous evaluation is necessary because otherwise a patient who at the beginning is unable to decide whether or not to receive a given treatment because he has been assessed as incompetent, or because he has great diffi-

culty making the choice and, either implicitly or explicitly, delegates the decision to a representative, may subsequently find himself deprived of his autonomy and decision-making powers throughout the entire process and in every aspect of his care. An individual's competence is not permanent and all-encompassing, and nor is incompetence. If decisions have been taken by a representative at the beginning, then we have to strive to reverse this state of affairs. If this is done, then the patient may be able to represent himself in the future. By doing this, we increase the individual's autonomy and reduce his dependence on others. This is why assessment of competence must be continuous and integrated into the healthcare setting. To achieve this, we need to be prepared to change the way in which we use representatives. And it will also help us to personalize care plans in accordance with the patient's wishes, beliefs and preferences, reflecting ethical criteria with regard to human rights and health.

The participation of the care team is essential when evaluating a person's competence, because the individual must be assessed in different situations and there must be a close, ongoing relationship. In this way, the assessment of all the health professionals involved in caring for the patient become an essential element of the medical decision as to whether consent by representation is required. Shared responsibility, as in any aspect of health care, is essential. And it is also vital if we are to establish effective communication with the patient, to understand his non-verbal communication, expressions, emotional states etc. which may indicate his wishes.

What we cannot do, when faced with difficult situations, is simply use consent by representation as a catch-all solution which deprives the individual of a basic right. However, ethical sensitivity can help us to act as mediators in difficult situations, such as those involving adolescents. Similarly, when the individual's decision puts him or her in conflict with the wishes of the family, we can help the individual to act independently even in an acute or crisis situation, we can try to help relatives consider whether their decisions are consistent with the patient's wishes, etc. We should also consider whether making the transition from consent by representation to informed consent should be treated as a criteria of quality care. Where this is not possible, we need to ensure that there is a real guarantee that the representative really reflects the desires of the person who is unable to express his wishes for himself.

Finally, we must consider whether modern ethical criteria necessitate changes to the information we need when looking after and caring for people with health problems. We need to know who their representatives are, who they wish to share decision-making with if they become unable to decide on their own, what role they wish their families to play, or whom to choose from within the nuclear family. It is important to address these issues throughout the care process, and not just when a critical situation requires urgent decision-making. In such situations, an advance directives document is extremely helpful, and we need to promote them, particularly in situations where the prognosis is predictable. Helping someone to look ahead, to consider their future and assess their wishes, preferences and beliefs can help us to anticipate situations and incapacity, and to offer them the opportunity of exercising their autonomy in advance. This should be included in their medical records in the same way that we would include details of who they want to share information about their health problems and progress with. This information helps us to treat and care for people as human beings, to understand the reality of their lives and to ensure that our professional practice is informed by respect for the patient's moral autonomy.

Final report

In today's seminar on "Consent by representation: a challenge for critical care medicine" we have benefited from two very different viewpoints which both have a vital contribution to make to this area: that of the law, and that of health professionals.

Following the opening words of Victoria Camps, Mirentxu Corcoy introduced the event by identifying the problem addressed in this seminar: the degree to which the concept of consent in the patients' rights legislation of 2002 detracts from the authority of 'consent by representation' in the event of conflicts of interest, and the extent to which this concept is distinct from the general principle of 'informed consent'. In particular, the situation of minors, incompetent patients, and patients in intensive care units were analysed.

A third issue concerns the efficacy of informed consent within the context of possible legal action. Mirentxu Corcoy argued that the way in which informed consent is normally obtained means it would usually struggle to meet the standards of legal evidence.

Jacobo Dopico began his presentation of the legal perspective by clarifying the terminology used in this area, before going on to address key issues such as medical treatment and informed consent by representation, and the opposition between heteronomy and autonomy which underpins this area.

After analysing the limitations of consequentialist and formal models, he argued that the current legal approach is based on a functional perspective: a competent individual is one who possesses natural competence to understand his or her situation, the medical treatment proposed and the attendant risks (*Gillick competence*).

The regulatory framework provided by art. 9.3 of the Patient's Autonomy Act 41/2002 starts from the premise of an 'age of medical majority' of 16, something which is extended to those who are younger but possess natural competence; adults who have not been incapacitated are competent to grant consent, except in those cases where, in the doctor's opinion, they are incapable of taking decisions, in which case consent must be granted by the patient's legal representative or, where none exists, by people linked to him by ties of family or friendship). Dopico then went on to consider the position of the doctor responsible for care in assessing such situations.

He also discussed the apparently paradoxical case of the 'incompetent competent' individual: that is, of someone who holds irrational beliefs, either for religious reasons or because he has renounced medical treatment in favour of pseudoscientific treatments which may indicate cognitive or educational deficits.

In his discussion of who should substitute the patient's wishes, Dopico analysed legislation at both the Spanish state and Catalan regional level, explaining that regional legislation gives priority to the partner, and then to the parents and children, among those who are defined legally as "people with family or *de facto* ties".

This brought us to the key question: what criteria should the substitute or representative use when reaching their decision? Art. 9.5 of the Patient's Autonomy Act employs vague concepts which often give rise to unresolvable conflicts of interest by failing to provide reasonable criteria with which to resolve many basic dilemmas, because they do not clearly identify the patient's best interests.

Dopico identified three possible decision criteria, and analysed the pros and cons of each: a. the subjective assessment of the substitute; b. substituted judgement (or surrogate decision-making) and; c. objective evaluation of the patient's best interest.

The first of these criteria was criticized for its lack of legitimacy. In the second, we considered the fact that there are at least two possibilities for substituting the judgement of somebody who cannot currently express their wishes: their assumed wishes, and an advance directive, which may be provided in writing or reported by the substitute. It was argued that the criterion of *substituted judgement* possessed certain advantages, while the concept of best interest was the easiest to measure objectively and thus the least controversial.

In practical terms, where a proposed treatment corresponds to the patient's best interest, the requirement of proof of the patient's wishes would appear

to be less onerous. Or, to put it another way, the further one deviates from standard medical practice, the more evidence there needs to be that this course really reflects the wishes of the person being substituted.

Particular attention was paid to the current issue of the granting of consent by minors, specifically in the context of termination of pregnancy. In this context, it was surprising to discover that the Patient's Autonomy Act has to be supplemented by the Legal Protection of Minors Act, which establishes, in art. 2, the need for interpretation to provide a wider scope for the wishes of the minor in the event of problems of interpretation.

Which criteria can a minor's representative use when the minor is aged below 16? We cannot simply appeal to the minor's wishes, although we must listen to his or her opinion of the proposed treatment. It seems that a minor aged between 16 and 18 cannot grant consent by representation: however, "in the case of very risky behaviour, in the doctor's judgement, the parents are informed and their opinion is taken into account when taking the relevant decision" (art. 9.3 of the Patient's Autonomy Act) which raises the problem of the legal status of this opinion.

In the case of unconscious minors, aged between 16 and 18, the lack of clarity of the law (which permits neither representation nor advance directives) means it is unclear what is to be done if the representative rejects medically indicated treatment.

In the specific case of abortion, the contradictory wording of art. 9.4 of the Patient's Autonomy Act establishes that the voluntary termination of pregnancy should be governed, in general, by the age of majority or, where this exists, by special legislation. In the absence of special legislation, the Civil Code (art. 162.1) would not appear to grant powers of representation to the parents, while art. 2 of the Legal Protection of Minors Act allows us to conclude that the rule of natural competence could apply, because this is the one which ascribes the highest degree of decision-making competence to the minor. At the practical level, it would be difficult to justify imposing the wishes of the parents or a third party against the wishes of the minor, given the existence of a 'right of veto'.

With respect to legal reform in the area of abortion, Jacobo Dopico distinguished between legal discussion and discussion in the media, differentiating between the issue of consent (and who has the right to grant that consent) and the issue of informing the parents.

During the discussion, Marc Antoni Broggi asked about the possible benefit of identifying a surrogate decision-maker in the advance directives document. Jacobo Dopico suggested that this would be comparable to a living document or record of fundamental values. If we appoint somebody on the basis of these values, we are not so much appointing that person to decide but rather asking them to apply our values. In other words, it is an attempt to embody these life values in a single individual. In this regard, we saw that the appointment of a single person who is closely linked to the patient may also give rise to problems when the representative also suffers an accident. To address this issue, in the United States it is usual to appoint several people, or to employ complementary criteria. Another problem concerns how to assess the competence of the person appointed to take the decision by representation.

Pablo Hernando, psychologist, started by considering natural competence and criticized the inadequate legislation which exists in this regard in Spain compared, for example, to the English-speaking world, arguing for better regulation of this area. Regarding the Hannah Jones case, Jacobo Dopico asked what legal basis there might be for resolving this case given the doctors' opinion of the minor's maturity. Jacobo Dopico argued that the concepts used in theoretical discussion could also be applied in the legislation.

Victoria Camps, with reference to the issue of a minor's granting consent to abortion, pointed out the difficulty of distinguishing free consent, in the event of conflict, from the obligation to inform the parents. In his reply, Jacobo Dopico discussed the problem of sexual education and health decisions, and argued that legislation should provide for 'bypass' options, so that the decision is taken either by the family, or by the social services, or by a judge, or by doctors. In other words, although the social services would appear to have the task of resolving such problems, the related political controversy may be distorting the legal debate.

Gian Maria Nicastro explained the Italian debate around the issue of the value of an advance directives document drawn up before an illness has occurred and when the patient has therefore not been able to take its effects into consideration. In response to this, the Italian legislation provides for the expiry of advance directive documents and the need for the patient's wishes to be reconfirmed. In Spain, as Jacobo Dopico explained, we are currently at the stage of a theoretical debate which has not yet been given legal form. While, in his opinion, there would be no objection in principle to the need to update advance directives, this would also create the problem that these could cease to be valid if this had not happened. Mirentxu Corcoy suggested that, for the wishes expressed in such documents to be ratified legally, a sum of money must change hands, even if it is only symbolic. In this context, she backed the need for some kind of mechanism to facilitate the updating of advance directives.

Màrius Morlans introduced a new issue for consideration, that of decisions taken by mature individuals who, from a lay perspective, might be considered irrational. In his opinion, the only basis for understanding the nature of such decisions is by building close relationships with those concerned. Jacobo Dopico explained the need to distinguish between cases of irrational beliefs (which are objectively false) from those beliefs which are matters of conscience, religious freedom or similar factors.

Núria Terribas regretted the gap between theoretical-legal positions and practical problems, a contrast with an Anglo-Saxon model which is more concerned with the legal resolution of conflicts. More specifically, she questioned the necessity of having recourse to the Legal Protection of Minors Act to supplement art. 9.4. of the Patient's Autonomy Act, given her understanding that the general regulations on abortion are already applicable in this area.

In his reply, Jacobo Dopico outlined some of the problems faced when we seek to use legislation to regulate general situations. In this context, the Patient's Autonomy Act is, in essence, a law designed to regulate conflicts. And here Dopico drew a distinction between excessive legal interference, which is undesirable, and excessive legislation. With reference to the issue of abortion, both Jacobo Dopico and Mirentxu Corcoy gave their opinion that art. 417 bis CP 1973 is not conclusive, and Dopico explained that a pregnant woman, as a patient, has the competence to be listened to and, generally, to decide.

Leonor Ruiz, with regard to the mentally ill, discussed the position of involuntary psychiatric admissions who are not covered by the logic of consent by representation and fall into the category of 'competent/incompetent' patients. On a similar note, she raised the issue of involuntary outpatient treatment. With regard to abortion, she pointed out that there are also cases where the immediate family want to terminate the pregnancy while the minor wants to continue with it.

Margarita Boladeras, discussing the theoretical aspects, identified an issue which came out of the Italian experience: the importance of the intervention of the representative to safeguard the rights of those who are unable to decide for themselves.

Montse Busquets argued that, in contrast with the general view that the family acts as an obstacle to the doctor's attempts to ensure the patient's well-being, often it is the family which defends the patient's well-being in the face of those who advocate aggressive medical treatment. Jacobo Dopico agreed that families often act as a bulwark against medical action.

The second presentation, given by Emilia Civeira, was more concerned with the 'is-ought' aspect of informed consent, in a setting (internal medicine) where rapid decisions have to be taken regarding patients who are not even aware of the decision to be taken. As a result, there are cases where the patient is unable to decide, and some of the most important of these were addressed.

After describing these cases, she put forward a number of proposals designed to address the problems encountered in daily practice, including the following:

1. Hospital ethics committees should have a written report on the state of health and prospects for recovery of incompetent patients, enabling them to resolve cases of euthanasia and restrict the excessive application of futile medical treatment.

2. In the case of medically incapacitated patients (rapid loss of competence due to organic or functional causes) she argued for the need to distinguish between the different types of cases we may encounter (coma due to a range of causes; anxiety or family isolation, etc.) which raise problems for the compulsory application of informed consent in ICUs. Only as a result of a thorough analysis can medical staff reach a consensus in such cases, among other reasons because of the practical problems associated with our legal model.
3. In the case of patients who have recorded an advance directive, when this is of a generic type it is not always easy to identify the scope of their instructions with respect to the necessity of the specific medical treatment proposed and the risks associated with it. And this leads her to question the validity of living wills or the feasibility of acting by representation, apparently contrary to what has been agreed.
4. A number of actual cases raise the question of what enables somebody to grant consent on behalf of somebody else. This problem arises when several individuals meet the formal requirements for acting as representatives, giving rise to the question of legitimacy.
5. Another issue for discussion was the correct role of the intensive care doctor in the context of informed consent: how do they inform, and how much information should they provide? These questions are underpinned by a deeper problem, which concerns the legal nature of informed consent within the framework of rights and duties.
6. The doctor can decide without the consent of the patient in cases of 'therapeutic privilege', which applies to at least two situations: a) when the doctor believes that what he is proposing is essential, even when this is not accepted by the patient; b) situations of extreme emergency, which are covered by the legislation.
7. These groups of cases share a common element, which is not a lack of competence to take decisions but rather circumstances which mean there may be medical grounds for acting against the patient's wishes. This is the case of patients suffering from severe psychomotor agitation (under the effect of drugs, or due to respiratory insufficiency), when the patient refuses to be admitted to the ICU.

The main conclusions included the following key points: 1) the specific nature of intensive care medicine means that doctors often have to take decisions without informed consent; 2) the lack of specific legal regulation is a problem in this area.

In the debate following this presentation, Gian Maria Nicastro drew a contrast between abstract notions of informed consent and its application in practice. He argued that it would be better to talk of 'agreed consent', because the transfer of information should be part of a two-way communication process. The ethical concept of "therapeutic alliance between doctor and patient" could help us to understand what this means.

With regard to the content of the information, Italian case law establishes the obligatory content for this to be deemed effective: the potential risks and side effects and their likelihood must be identified, and information must be provided about any structural factors which increase the risks associated with treatment. He also noted how, since the start of 2009, there appears to have been a trend in case law towards the notion that only express refusal to undergo treatment can prevent a doctor from acting.

Ramón Bayés focused on the issue of advance directives and their changeability. In his opinion, this is not just an issue of solving problems, but of identifying the correct strategy for dealing with such situations. This means that only when the wishes have been expressed at that moment and repeatedly can we consider them to be relevant for the purposes of making decisions, because life is in constant flux and there is therefore no guarantee that consent still exists. As a result, he argued that we are still at the stage of improving our understanding of the problem, without yet solving it. Finally, he argued that the two-stage activity of 'informing and deciding' also requires doctors to listen.

Joan Escoter noted that some problems could be relieved by addressing anxiety, with the help of a psychiatrist.

Montse Busquets, reflecting on some of the cases identified, warned that at times we are not actually dealing with problems of consent: this is the case where there are difficulties of communication between doctor and patient,

where there are problems linked to administrative (and care) management, or related to the need to support the patient's decision-making, among others. In other words, there is sometimes a tendency to see management problems as problems of consent.

Marc Antoni Broggi argued that we are striving to move from a period of strict paternalism to a situation where patients defend their rights. Informed consent should be seen as an opportunity to say no, but we must also accept that patients may refuse treatment for trivial reasons. This means that recommended medical treatment should be seen as a proposal, as an offer of help which the patient can accept or reject. The seriousness of the patient's condition cannot, therefore, provide the basis of the decision. We have to accept the patient's decision to take no action, even if it is not a position we share. We must ensure the rational nature of the decision-making process, so long as it is based on reasonable arguments. And for this reason therapeutic privilege is not a basis for going against the patient's wishes or acting without his consent, but is instead a way of hiding (all or part of) the information on therapeutic grounds.

Following on from this intervention, Mirentxu Corcoy, taking the example of transitory mental disturbance, questioned whether in extreme situations competence to grant consent exists, given the anxiety which radical medical treatment may provoke. Jacobo Dopico insisted on the need to make a functional and situational assessment of competence, and argued that the doctor should be responsible for deciding as to the patient's capacity and competence in these extreme situations.

Josep Maria Busquets commented on the apparent difference between the logic followed in the Mediterranean and English-speaking worlds in discussion of this issue in the legal and professional spheres, and even among ordinary people. The concept of advance directives is difficult to embed in societies where people are reluctant to plan ahead. For this reason, he argued that health professionals most raise awareness of this issue and drive it forward. And advance directives should not be seen as a static element.

Núria Terribas, with reference to advance directives, stressed the opportunity for anticipating issues, working in the context of the patient and his family to avoid foreseeable difficulties. While she accepted the changing nature of directives, she also argued that patients may be clear about certain actions and beliefs, and these give the document its legitimacy. And she noted her disagreement about the content of the information provided, arguing that it is not acceptable to conceal information from somebody whose life expectancy is limited, and that health professionals need to be aware that such information cannot be hidden. She ended her contribution by regretting the lack of basic training for health professionals in concepts such as informed consent, how to handle situations of grief and conflict, how to communicate difficult information, etc.

Finally, Margarita Boladeras reflected on some of the terminological problems which may hinder debate, and Josep M.ª Grau highlighted the difficulty, in some situations, of identifying the doctor responsible for coordinating information and health care.

In the afternoon discussion session, Pablo Hernando again raised the criteria which have typically been applied to consent by representation, and drew attention to the differences between the Spanish system and American case law, which is the product of long-running social debate. With reference to Jacobo Dopico's contribution, he questioned the 'abstract' notion of medically indicated treatment, because any such indication should take into account the patient's values. And in a more critical tone, he questioned whether therapeutic privilege could really exist.

Clara Llubià pointed out that we assume that doctors have the communication skills needed to articulate informed consent, when this not always the case. She argued that we do not need to teach skills as a means of solving conflicts, but rather of understanding them better.

Blanca Mendoza again raised the question of natural competence to act in relationship to the type of health professional who should make the assessment, particularly when we consider the vulnerability of the patient and the unequal nature of the doctor-patient relationship. Regarding parental

involvement in cases of abortion involving minors, she suggested that instead of starting from the question of the maturity of the minor as compared to the maturity of her parents, the real question is whether the issue is one which affects the minor so directly and personally as to make the involvement of a third person unacceptable: who should have the last word? She argued that this should be the minor, with support, if necessary, to resolve conflicts. She also raised the issue of newborn infants suffering from severe medical conditions, where the parents wished to keep them alive despite the apparent lack of any medical justification for this approach; and she considered some other examples of medical treatment which, while questionable from a strictly medical perspective, possess a certain utilitarian logic at the heart of which lies the same issue: are the parents entitled to decide as to the best interests of the minor?

Màrius Morlans focused on a number of issues: 1) trusting the doctor's ability to decide on the patient's competence, which is the basis of the clinical relationship - society needs to value the idea of the responsible doctor; 2) representation in difficult cases, starting from recognition of the following principles: the family are not representatives; at a practical level, we need to identify a principal contact person, who is usually also the patient's main carer; institutions should adopt this criterion as a way of facilitating the work of the health professional; 3) consent in ICUs has its own special peculiarities, but this does not mean we need to document every individual action; ethics committees should help ensure consistency and prevent arbitrariness, although they also need to become more credible by ensuring, among other things, that they are more accessible.

Leonor Ruiz Sicilia pointed to the specific issue of those suffering from mental illness who she termed the 'incompetent-competent', for whom the only solution involves the legal system. We need to make people aware that the mentally ill are thus deprived of any representative other than a judge. She also criticized the error of reducing the question of informed consent to the signature of a form. This may be due to concerns about safety, and the solution would appear to lie in establishing a two-way relationship based on trust, of which information is a necessary part.

Núria Terribas reported on the efforts of institutions to review the status of patients who had been hospitalized involuntarily, and to reassess their competence. She considered the dual concept 'capacity–competence' which can confuse medical discussion: the issue of whether someone possesses legal capacity is separate from the issue of competence which lies at the heart of today's seminar. She also criticized the notion of therapeutic privilege, particularly with regard to decisions by minors, when we should really be seeking to support and accompany the minor. Related to this, she described some of the practical problems which arise when a minor says she does not wish to be accompanied by family members or others, and requests complete confidentiality; and she also referred to the problem of conflict between parents.

Josep Mª Grau raised two points. The first concerned the use of vague legal concepts, while the second concerned the legal problem of identifying the doctor responsible for providing care.

José Luis Goñi pointed out the patient's position of inequality (and need) with respect to the doctor, before focusing on the constitutional aspect of the conflict. There are just a few Constitutional Court Rulings (in particular, Ruling 154/2002) which address this issue, and their conclusions are somewhat contradictory. In its first ruling in this area, the Constitutional Court gave precedence to ideological (if not religious) freedom with regard to parental refusal to authorize a blood transfusion. However, the Constitutional Court has also argued that the refusal of Spain's Social Security system to pay for alternative treatment in such situations is not subject to the individual's right to religious freedom. As a result, the Constitutional Court has not followed a clear line of argument.

With regard to the issue of authorized family members, he raised doubts as to who is best placed to fill this role.

A new topic of discussion concerned the question of how to address data protection: if the doctor provides information against the patient's wishes, then he may be breaching the latter's basic rights. In this regard, Spain's Data Protection Agency concluded (in a report issued in 2004) that minors aged 14 years or over are entitled to exercise their right to access their data on their

own behalf, and that nobody may substitute them in this right; however, in a subsequent report (issued in 2008), it allowed the release of medical data to those exercising parental authority. It is unclear whether the second ruling supplements or replaces the original opinion.

Joan Escoter explained that, in his opinion, there are three distinct cases of informed consent: a. acute, b. chronic, and c. sub-acute (individuals who are competent for some issues but not for others). He argued that the same solution should be applied to chronic and sub-acute cases. He questioned the validity of consent in acute cases, and insisted on the concept of 'adaptive disorder', which must be evaluated and would help to understand those situations where the patient gives an unexpected response. And he also suggested that consent by representation is used in admissions both of elderly patients and of young women for the termination of pregnancy.

Montse Busquets agreed with much of what had already been said. However, she argued for the need to improve an information process which should be based around the two-way transfer of information. In this respect, information provided by a social worker or nurse (with the necessary limitations) can make a major contribution to the process. She ended her contribution by arguing for new research into what service users and patients want.

Josep Ma. Busquets argued that an overprotective society such as our own does not help young people to mature, and this overprotection is sometimes also promoted by the health system. Health professionals should therefore explain the limits of care. And on the same lines he argued that the maturity of children, accepted as valid in some areas, such also be extended to issues such as those under discussion here. Finally, he suggested that primary care health professionals be included in any discussion.

According to Marc Antoni Broggi, we have to start from the understanding that when a person is incompetent to decide, this does not mean that he has no rights but rather that he is unable to exercise them. We need to strive to ensure that the exercise of the patient's autonomy is not restricted by the patient's inability to express it. We need to accept the patient's decisions, help patients to be independent, and try to restore their autonomy if they have lost it. Health professionals should seek to engage in dialogue before situations of incompetence arise, and they need resources to enable them to identify such situations and respond to them. The patient's best interest does not always consist of curing his illness, and this is why a personal definition of best interest should always take priority over a standard one.

Margarita Boladeras wondered how we could involve health professionals in establishing universally accepted criteria for action. She argued that we need to strive to establish protocols in this area, and in this regard Emilia Civeira highlighted the need to address this from a bioethical perspective. In the general discussion, it was noted that protocols of this sort are already viewed as quality indicators in some countries.

Ramón Bayés stressed the need to distinguish between situations where there is time for decision-making, and others where time is at a premium. In the latter case, while we need background information, he argued that we should not automatically base our assessment exclusively on an advance directives document, which should instead be just one element of any assessment. He also argued that internal medicine specialists should identify in advance what information they require about patients, so that this could be provided in a straightforward manner upon admission. This would allow doctors to identify the representative (and a substitute, where applicable) and would provide basic indicators of the needs and wishes to be taken into account in treatment and in the decision-making process.

To summarize, today's workshop combined analysis and debate designed to contribute to a shared objective: that of pooling information and proposals with regard to consent by representation, combining a theoretical perspective with an awareness of the practical requirements of both patients and health professionals. It is only by understanding the true scale of the problem and its different aspects that we will be able to offer better solutions.

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Conclusions

The efficacy of the consent granted by the holder of a fundamental right should be absolute in every sense, both with regard to the option of renouncing this fundamental right, and with respect to the decision about how this right is to be exercised. This principle would appear to be beyond dispute, given that the Constitution establishes with absolute clarity that life, health, liberty, security, privacy and dignity are fundamental individual rights which should be protected by the state and public bodies. In other words, the Constitution does not grant the State the right to protect these fundamental individual rights but rather a duty, and it should therefore be understood that this duty of protection does not exist when the holder of the right does not wish to exercise it and instead renounces it. This configuration of the fundamental rights exclusively as a duty on the part of the authorities to protect the individual's fundamental rights, without implying any further rights over them, is what determines the fact that the owner of the right is the only person who has the competence to decide how and in what form this right is to be exercised. This is because what is being protected is not life itself but rather the individual's interest in it, as a result of which, if this interest ceases to exist then the State's duty to protect it automatically disappears. This is particularly important with regard to problems relating to euthanasia, the concept of a 'dignified death', and the efficacy of consent to medical-surgical treatment, and it is this last issue which was the focus of this seminar.

Although the Constitution establishes fundamental legal entitlements as a right rather than as a duty, the efficacy of consent with regard to these rights and the degree to which individuals may dispose of basic legal rights such as the right to life and health have traditionally been debated within the context of criminal law. In general, the starting point for this discussion is the belief that the right to life and health cannot be disposed of, an argument which is based on the fact that crimes against life and health are legislated for in the Criminal Code. In the previous version of the Criminal Code, it seemed clear that consent in this area lacked efficacy or had only very limited efficacy, with regard to the legal right to life, given that not just incitement and material assistance to suicide were punished, but that this prohibition also extended to mere complicity, while there was no reference whatsoever to the problems of homicide by consent in cases of euthanasia. The Criminal Code of 1995 appears to grant greater efficacy to consent, not just because it no longer penalizes mere complicity in suicide, but also because it makes reference for the first time to homicide by request, in which case the penalties are significantly lower and where, moreover, one has to consider whether the act being punished may be covered by a duty of cooperation. With regard to the protection to health under criminal law, the changes to the Criminal Code of 1995 with respect to the efficacy of consent are similar to the provisions made regarding the protection of of life, with a shift from viewing the right to health as not being disposable at all in the previous legislation, to one where the current Code provides for a reduction of the penalties in the event that the injured party has freely granted his or her consent.

The relative efficacy of consent with regard to the right to dispose of life and health has, traditionally, been based on a view that these fundamental rights contain a supraindividual component which imposes an obligation upon the State to protect them, even against the will of their holder. However, this explanation lacks any basis if these rights are held by the individual, as a result of which the constitutional duty of the State to protect them ceases as soon as the holder of the right declines this protection. The absence of any legal basis for claims to a supraindividual component of certain personal legal rights can also be deduced by the fact that, in the absence of any constitutional basis whatsoever, this supraindividual component is only ascribed to the rights to life and health, while all other rights are considered to be eligible to be disposed of by their holder, without any valid reasons being offered for this differential treatment.

If the absolute or relative prohibition on disposing of the right to life or health cannot be based on the Constitution, then the reason why the Criminal Code limits the efficacy of consent with regard to the capacity to dispose of these legal rights can be found in the persistence of ethical, or rather religious, values in the legal sphere, or on politico-criminological reasoning based on the difficulty of proving that the consent of the holder of the right was freely granted and issued in a valid manner, especially when the right being disposed of is the right to life. The problems of proving that consent has been granted freely and without interference could explain why criminal

law starts from an assumption of the absence of free consent and, as a result, it punishes the participants, although with more lenient sentences. This position, which is the only possible reading of the law as it is, given the regulation of consent with regard to life and health in the Criminal Code, should be reconsidered from the perspective of what the law ought to be, and grant efficacy to consent even when in such cases this requires clear evidence of the freely granted consent of the holder of the right and one starts from an assumption of the absence of consent. A different problem concerns the possibility of transferring the freedom to dispose of one's life or health to others, which is the issue underlying the legislation on injury, suicide and euthanasia in the Criminal Code, as a result of which it is only these other participants who are punished. Although this is not the place to enter into this debate, I would like to note that the atypical behaviour of the participants stems from the fact that it is the holder of the right who effectively exercises competence over his own death, and therefore the owner of the right should be considered to be responsible.

The fact that the limited efficacy of consent with respect to life and health is based on politico-criminological arguments and not on an evaluation of any supraindividual component of these individual rights which, as we have said, has no constitutional basis but rather, exclusively, a religious or ethical one, better explains the impunity of the holder of the right in crimes against life and against health, in so far as, where consent is granted, the holder of the right should also be considered to be a participant. Explanations designed to justify the impunity of the holder of the right on politico-criminological grounds, or on the basis of the existence of a principle of absolution, lack foundation; the notion that the holder of the right is covered by a principle of absolution has no basis in law. With respect to the politico-criminological reasoning which seeks to justify impunity on the basis of the absence of the need for any punishment, either because the holder of the right has already died, making it impossible to impose a punishment, or if the holder of the right has not died, in which case imposing such punishment on somebody who wishes to die would have no general or specific deterrent effect, the same can be said; if the right to life and health really contained a supraindividual element, then the greatest requirement for punishment would apply to the holder of the right, who would be the one who had most directly damaged this aspect of it. Therefore, if we discard such religious or ethical assessments and, as a result, discard the supraindividual component of the right to life and health, we must conclude that these legal rights, like any other individual legal right, may be disposed of by their holder and, what is more, that only the holder has the capacity to dispose of them and that it is he who can decide upon the form and manner in which he wishes to exercise this possession. This is the only approach which allows us to really respect another right, one which in theory is granted the highest regard but which often, in practice, lacks content: the right to liberty. The right to liberty can only be exercised effectively when the holder of this right is able to exercise all of his legal rights and specifically the rights to life and to health.

This conclusion directly affects the problems relating to the efficacy of consent with respect to medical-surgical treatment, both concerning the right to life and the right to health. With regard to the right to life, if this right pertains exclusively to its holder, then one must consider whether exercising it in full requires us to speak of a right to die or, rather, the absence of a duty to live, particularly when the holder seeks also to exercise the right to dignity, and remaining alive would entail a clear attack on this dignity. Respect for the right to health, for the dignity of the individual and, in particular, for his liberty means that the holder of this right should be the one who defines for himself what constitutes health, together with the best way to exercise his freedom of personal development; as a result, any unwanted external intervention designed to improve his health in the purely objective sense of extending his life is prohibited. Extending somebody's life is only legitimate if the holder of the right to life gives his free and valid consent for this purpose. This attitude towards the right to dispose of the individual rights to life and health has significant implications for problems relating to the separate issue of euthanasia, and for the limits on medical-surgical intervention, which is precisely the issue under discussion today.

Before we can consider the efficacy of any consent granted, we must discuss the nature of this consent. If the decision by the holder of an individual right to dispose of it is to be effective, his consent must be granted freely and in a

valid form. However, the freedom and validity of the consent raise problems in three areas. Firstly, the decision to dispose of the right to one's own life, in addition to the theoretical objections raised by those who argue that suicide is never free, also poses practical problems which are difficult to resolve because by definition the holder of the right cannot give evidence as to the validity of the consent. The challenge of proving freedom of consent in these cases means that the legislator must take special care when legislating with regard to suicide and euthanasia; however, as I have argued, this does not mean that it is valid to assume the absence of consent. This problem also applies, although to a lesser degree and for other reasons, with regard to the right to dispose of one's health, particularly due to the problems associated with the fact that the validity of any consent depends upon the information available to the holder of the right with regard to the actions to which that consent relates. Thirdly, there is the question of how we establish whether a person has the competence to grant consent to exercise his fundamental legal rights. The problem comes into even sharper focus with regard to the efficacy of consent granted by minors, incompetent adults and those who are classified as 'incompetent-competent' individuals, because they base their decisions on beliefs which the majority of us deem irrational. A simplistic approach might lead us to argue that competence to grant consent should be subject to the rules of Civil Law. However, when such fundamental individual rights as the right to life, to health and to privacy are at stake, the solution is not so straightforward. Minors and incompetent individuals are human beings and, as such, they should be allowed to exercise their rights in so far as we can ascertain their natural competence to consent. With regard to the rationality or irrationality of 'incompetent-competent' individuals, we must distinguish between those who base their decisions on religious beliefs, and those who look for answers in pseudo-scientific treatments, which may indicate a cognitive deficit. In the first case, what is at stake is the right to ideological freedom, and we must therefore start by considering the rationality of the decision from the perspective of the patient's beliefs. However, we must also accept that there will be situations in which certain beliefs will strike the majority as both irrational and, in many cases, contrary to fundamental rights endorsed in international agreements. In this event, it might be considered to be an instance of irrationality. Who is entitled to assess the competence to consent and the rationality of the decision? Spanish legislation does not specify criteria about how to determine natural competence, although criteria have been discussed at the theoretical level which could be implemented in law.

Natural competence is the determining criterion with respect to the efficacy of consent by minors, an issue which is of particular relevance given the current draft legislation on abortion. The law which regulates the rights of minors, Act 1/1995, of 15 January 1996, on the Legal Protection of Minors, establishes a set of age limits with respect to the degree to which the minor's wishes must be taken into account: these are 12, 14, 16 and 18 years. In general, the choice is between formal competence to consent, on the basis of the age of majority, and natural decision-making competence. In these circumstances, the natural decision-making competence must be analysed in the light of the rights over which the minor is exercising authority and the future consequences of the decision for the minor. In this regard, art. 162. 2. 1º of the Civil Code, referring to the rights of the individual, is clear as to the efficacy of consent on the basis of the maturity of the individual. The provisions of art. 9.3.c) take as their starting point the fact that consent must be granted by the minor wherever this is possible, and limits consent by representation to cases in which the "minor is neither intellectually or emotionally capable of understanding the scope of the treatment". The law goes further, and states that even in this event, the opinion of minors aged 12 years or over must be taken into account. The efficacy of any consent granted by a minor aged 16 or over, with respect to medical-surgical treatment, is conditioned by the fact that it relates to the rights to life and health, both of which are individual rights which cannot be freely disposed of even by adults. In this regard, Act 41/2002, in the final part of art. 9.3.c), limits the efficacy of the consent of the mature minor, even when the minor has been emancipated, when the treatment is of considerable risk, and establishes that the parents must be informed. Once again, the legislation rather than providing a solution, poses a problem, because it only states that the parents should be informed without establishing the importance to be assigned to the opinions either of the minor or of the parents. Again, I believe there is a need for more

specific guidelines to ensure that health professionals are properly protected. And I also believe that ethics committees should help resolve any conflicts.

The limits with regard to the efficacy of the consent of a minor to exercise his or her individual rights derive from the guiding principle of "the minor's best interests". This clause is analogous to the stipulations of the Patient's Rights Act. With regard to minors, this principle is established in the United Nations Convention on the Rights of the Child of 1989 and in Basic Law 1/1996, on the Legal Protection of Minors. From this legislation it is clear that both public and private bodies must always give prime consideration to the child's best interest, and this includes recognizing his competence to decide even if he has not yet reached the age of majority. The alternative is to evaluate the nature of the consent granted by a minor, taking as one's starting assumption that the minor lacks competence, and ensuring that the minor is acting freely and really possesses the natural competence to decide. In this assessment of the competence of the minor to decide, it is necessary, given the guiding principle of ensuring the minor's best interest, to evaluate the consequences for the minor of granting consent. Spanish Constitutional Court Ruling of 24 February 1994, with respect to the alleged unconstitutionality of the rule of the Private Insurance Legislation Act preventing parents from taking out a life insurance policy for their children aged below 12 years, should be interpreted in this context. The ruling confirmed the constitutionality of this law on the basis that if it discriminated against anyone it was the beneficiaries of the insurance policy rather than the minors themselves, and that this reflected the legal aim of protecting children by obliging their parents to take special care in looking after them. The ruling is therefore consistent with the criteria established in the United Nations Convention on the Rights of the Child, of 20 November 1989 (RCL 1990/2712), which states, in art. 19, that: "*States Parties shall take all appropriate legislative, administrative, social and educational measures to protect the child from all forms of physical or mental violence, injury or abuse, neglect or negligent treatment ...*" We must therefore conclude that the general principle of natural competence to decide applies with regard to the exercise of the individual rights of minors, irrespective of whether or not they have been emancipated. This agrees with the provisions of art. 2, of the Legal Protection of Minors Act which establishes the need for interpretation to provide a wider scope for the wishes of the minor in the event of doubt. This legislation should supplement the Patient's Rights Act.

However, the situation is very confused with regard to minors aged between 16 and 18 years because, despite the fact that 16 is the age of majority for health issues, art. 9.3 of the Patient's Rights Act establishes that in the event of high risk treatments, as assessed by the doctor, the parents should be informed. But the Act does not establish the legal status of any opinion expressed by the parents or the efficacy this should be accorded. Despite this lack of clarity, the fact that 16 to 18 year-olds are deemed to have attained the age of majority for health issues means that the decision of the parents cannot be decisive for medical treatment; in the specific case of termination of pregnancy, this is despite the fact that art. 9.4 of the Patient's Right Act establishes that the age of majority will be governed by general legislation in this area. As a consequence, we must consider art. 162.1 of the Civil Code and art. 2 of the Legal Protection of Minors Act, which allows us to conclude that the rule of natural competence could apply, because this is the one which ascribes the highest degree of decision-making competence to the minor. From this perspective, it is difficult to justify imposing the wishes of the parents or a third party against the wishes of the minor. The reference made in art. 9.4 of the Patient's Rights Act to special legislation would refer to the proposal contained in the Draft Legislation on Abortion, which on this issue has generated a public debate which bears little relationship to real problems. In this regard, it should be clearly stated that if information is ultimately provided to the parents, this is done under the provisions of art. 9.2 of the Patient's Rights Act where it refers to "high risk courses of action" and the solution applied is the one described above: that providing information does not equate to attributing to the parents the power to grant consent by representation. The information must be provided for the purpose of enabling the parents to understand the situation and discuss with their child what action is in her best interest. Although the solution adopted is the same for high risk situations and pregnancy, in the latter case the minor may not have told her parents about her pregnancy because of their religious or ideological beliefs. In such cases, intervention by the parents may constitute intolerable psycho-

logical pressure on somebody who, due to her situation, is particularly vulnerable. With regard to minors who are less than 16 years old, the situation is even more confused, because although in principle consent is granted by the parents, in the event of conflict this should be resolved by referring to legislation establishing the protocol to be followed governing the intervention of health professionals and the family, together with the courts, the social services and the ethics committee.

With some modifications, all of the comments regarding minors also apply to incompetent individuals and 'incompetent-competent' ones. The problem arises when the patient rejects a treatment identified in the care protocol as being the most appropriate. Of course, the possibility of rejecting treatment is a logical consequence of the patient's right to choose. A patient may refuse to receive treatment when, in light of the options available, he does not wish to be treated. The doctor is not under an obligation to apply alternative treatments if he is convinced that these do not represent an effective response to the illness, but nor can he force the patient to accept that treatment which he, personally, deems the most appropriate. In these cases, in the public health context, the law states that the patient should apply for voluntary discharge. Should the doctor's refusal to apply the treatment chosen by the patient have no rational basis, notwithstanding any administrative penalties which may be imposed upon him, his conduct may also leave him open to criminal prosecution for neglect, in the event of injury or death which could have been prevented by application of the patient's preferred treatment. The problem here is analogous to the one which arises regarding the validity of the consent of minors, and of incompetent or 'incompetent-competent' individuals. We need therefore to identify when the doctor has rational grounds for refusing to apply the patient's chosen treatment, together with the related question of the scope and limits of conscientious objection in doctors, a problem which goes well beyond the bounds of this publication.

The situation is more complex when refusal of treatment comes from the family: that is, when we are dealing with consent by representation. In these cases, the problem lies in the efficacy of consent by representation when the health professional considers the relatives' decision to be contrary to the patient's interests or when there is no consensus among family members as to which decision to adopt. In both cases, we need legislation to establish how to resolve the conflict. The Patient's Rights Act proposes a limit on the efficacy of consent by representation, by favouring the patient and respecting his dignity without establishing how these criteria should be evaluated or by whom. One of the conclusions we arrived at in this Seminar was that there is a need to develop regulation in this area, something which I believe needs to be done by hospital ethics committees. Where the decision contradicts the one taken by the family or there is a need to decide which family member is the 'representative', the ethics committee must be granted competencies in this area, derived from specific legislation. In situations where there is no family consensus, some Spanish regions distinguish between those who are defined legally as "people with family or *de facto* ties", giving priority to the partner, and then to the parents and children. Where the partner is given priority, this must be defined as referring to the current partner, whether common law or by marriage. However, this order of priority can only be indicative because, in any specific case, the ethics committee should have responsibility for deciding which family member is the representative.

When the family take irrational decisions or where there are disagreements between family members, it is not clear which criteria to apply in order to reach a solution. The law has developed three possible decision criteria: a) the subjective assessment of the substitute; b) surrogate decision-making, and; c) objective evaluation of the patient's best interest. The first of these is open to criticism because it lacks legitimacy in the context of consent by representation, and the representative is not the holder of the right to which the decision relates (the life or health of the patient). With respect to the second, there are at least two possibilities for substituting the judgement of somebody who cannot currently express their wishes: the assumed wishes, and an advance directive, which may be provided in writing or reported by the substitute. The criterion of *substituted judgement* possesses certain advantages, while the principle of best interest is the easiest to measure objectively and thus the least controversial. In practical terms, where a proposed treatment corresponds to the patient's best interest, the requirement of proof of the patient's wishes would appear to be less onerous. However, the more best

interest deviates from standard medical practice, the more evidence there needs to be that this course really reflects the wishes of the person being substituted. The aim, then, is to find a way of combining substituted judgement with the patient's best interest. We cannot define this best interest exclusively in terms of best medical practice, particularly where this would have the result of prolonging life at any cost.

The legislation on consent by representation, as set out in the Patient's Rights Act, makes no reference whatsoever to the advance directives document regulated in the same piece of legislation (admittedly with serious shortcomings). Despite failing to make any explicit reference to advance directives documents, a systematic interpretation of the law would have to conclude, in legal terms, that such documents represent direct consent rather than consent by representation. However, if such documents are to be effective in practice, they need to be made directly and rapidly accessible to health professionals, for example, by being included in patient's electronic health files together with other data from their medical records. We also need to create mechanisms for validating and updating the document to reflect the shifting realities of people's lives and health and changes to their condition, with the result that documents which have not been updated, while remaining valid, would be of more limited efficacy. Where there is a diagnosis of serious illness, and particularly where this is degenerative, the health professional, as part of the process of providing information prior to obtaining consent, should also inform about the existence of these documents, what they mean, and their efficacy. With regard to the content, rather than specifying in detail what one does and does not want, it is better to appoint a representative who shares the values of the person drawing up the document. The result is that the representative, rather than taking a decision himself, seeks to apply the values of the person being represented. From a practical perspective, it is advisable to appoint two representatives, particularly as it is possible that, in the event of an accident, both the person drawing up the document and the representative are victims.

From another perspective, the need for rapid access to medical records is an essential tool for health professionals acting in an emergency, and particularly for those working in intensive care units. Hospital ethics committees should therefore have a written report on the state of health and prospects for recovery of incompetent patients, enabling them to resolve cases of euthanasia and restrict the excessive application of futile medical treatment. ICUs are also where the most complicated situations arise with regard to obtaining informed consent, given that the incompetence of the patient may be due to the anxiety caused by the situation in which he finds himself. In response to demands by some intensive care specialists to suspend the need to obtain consent in this context, we need to develop mechanisms which enable them to perform their job without renouncing the right of the patient to decide about his health. This right is sometimes violated on the grounds of what health professionals term 'therapeutic privilege', provided for in the Patient's Rights Act to enable action without consent in an emergency. However, this course of action is only permitted when it is genuinely impossible to obtain consent and so long as there is no advance directives document which establishes the guidelines to be followed. One conclusion we might reach on the basis of the specific problems faced in ICUs is the need to implement specific legislation and to establish protocols in all hospitals with ICUs. Given that a recurrent problem concerns situations of temporary incompetence, doctors - working with psychiatric specialists if necessary - should decide upon the capacity and competence of patients in these extreme situations.

If decision-making by ethics committees is to be effective, in addition to possessing the necessary legal powers for this end, we need legislation establishing how patients should be informed of this situation and which of the health professionals caring for the patient should provide the information. Proposals designed to make ethics committees more effective need to be combined with improved organization of these bodies and greater professionalization so that, together with their increased responsibilities, they would be able to act more quickly. With this improved structure, enhanced powers and greater accessibility, their function would not be limited to issuing non-binding opinions in the event of ethical conflicts, and they could instead mediate in cases of consent by representation and situations where competence is temporarily restricted. Specific provision should be made for them to have decision-making capacity with regard to immature minors and, partic-

ularly, newborn infants, at one extreme, and those suffering from senile dementia or in a persistent vegetative coma, at the other, in addition to deciding as to the possible irrationality of decisions. Intervention by the courts should be a last resort, in the cases of the mentally ill and, where necessary, immature minors and newborn infants, where the ethics committee disagrees with the decision of the patient's representative.

In any event, both the intervention of the ethics committee and the decision of the court should be based on the information that health professionals provide about the case. The existing competence of the courts with regard to the mentally ill should, by contrast, be limited, as the court cannot be the patient's sole representative and we need to establish a procedure whereby the decision both of the patient's representative and, in particular, of the health professionals, is given due weight. In the case of degenerative illnesses, as we have mentioned, when health professionals give information they should also cover the advisability of drawing up an advance directives document which would be binding upon health professionals where it is based on an accurate understanding of the development of the disease and its consequences.

We need to distinguish between different situations, such as those of individuals in a persistent vegetative state, newborn infants with severe birth defects, and patients with terminal illnesses for whom medical treatment may be futile and can even constitute a form of medical torment. In such cases it is essential that we have medical protocols which, as far as possible, standardize when, from a purely scientific viewpoint and on the basis of current knowledge, medical treatment ceases to have any efficacy. In this regard, we should remember the precedent in Spain's Organ Transplant Act which, on the basis of carefully considered scientific opinion, establishes the concept of legal death when a series of criteria are met. Analogous legislation could be passed for the situations mentioned above, without the need in these cases to have recourse to consent by representation.

Mirentxu Corcoy Bidasolo
Professor of Criminal Law at the University of Barcelona

List of invited specialists

- Ramón Bayés, Professor of Basic Psychology at the Autonomous University of Barcelona
- Margarita Boladeras, Professor of Moral Philosophy at the University of Barcelona
- Marc Antoni Broggi, President of the Bioethics Committee of Catalonia and Vice-president of the Víctor Grífols i Lucas Foundation
- Josep Ma. Busquets, Responsible for Bioethics for the Department of Health of the Government of Catalonia
- Montse Busquets, Lecturer at the School of Nursing at the University of Barcelona
- Victoria Camps, President of the Víctor Grífols i Lucas Foundation
- Emilia Civeira, Intensive Care Doctor at the Hospital Clínico, Zaragoza
- Mirentxu Corcoy, Professor of Criminal Law at the University of Barcelona
- Jacobo Dopico, Lecturer in Criminal Law at the Carlos III University of Madrid
- Joan Escoter, Psychiatrist at the Hospital de Meritxell, Andorra
- José Ignacio Gallego, Professor of Criminal Law at the University of Barcelona
- José Luis Goñi, Professor of Employment Law at the Universidad Pública de Navarra
- Josep Ma. Grau, Lawyer with the Legal Department at the Hospital Sant Joan de Reus, Tarragona
- Pablo Hernando, Head of Department and Chair of the Clinical Ethics Committee, Corporació Sanitària Parc Taulí of Sabadell
- Clara Llubià, Doctor with the Anaesthesiology and Reanimation Service of the Trias i Pujol Hospital in Badalona
- Blanca Mendoza, Professor of Criminal Law at the Autonomous University of Madrid
- Màrius Morlans, Doctor with the Hemodialysis Service at the Vall d'Hebron Hospital, Barcelona
- Gian Maria Nicastro, Lawyer, Turin
- Leonor Ruiz Sicilia, Psychiatrist at the Hospital Clínico Virgen de la Victoria, Malaga
- Núria Terribas, Director of the Borja Institute for Bioethics

Publications

Bioethics monographs:

25. *La ética, esencia de la comunicación científica y médica (Ethics: an essential element of scientific and medical communication)*
24. *Maleficence in prevention programmes*
23. *Ethics and clinical research*
22. *Consent by representation*
21. *Ethics in care services for people with severe mental disability*
20. *Ethical challenges of e-health*
19. *The person as the subject of medicine*
18. *Waiting lists: can we improve them?*
17. *Individual Good and Common Good in Bioethics*
16. *Autonomy and Dependency in Old Age*
15. *Informed consent and cultural diversity*
14. *Addressing the problem of patient competency*
13. *Health information and the active participation of users*
12. *The management of nursing care*
11. *Los fines de la medicina* (Spanish translation of *The goals of medicine)*
10. *Corresponsabilidad empresarial en el desarrollo sostenible (Corporate responsibility in sustainable development)*
9. *Ethics and sedation at the close of life*
8. *Uso racional de los medicamentos. Aspectos éticos. (The rational use of medication. Ethical aspects)*
7. *The management of medical errors*
6. *The ethics of medical communication*
5. *Practical problems of informed consent*
4. *Predictive medicine and discrimination*
3. *The pharmaceutical industry and medical progress*
2. *Ethical and scientific standards in research*
1. *Freedom and Health*

Reports:

4. *Las prestaciones privadas en las organizaciones sanitarias públicas (Private services in public health organizations)*
3. *Therapeutic Cloning: scientific, legal and ethical perspectives*
2. *An ethical framework for cooperation between companies and research centres*
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