Monographs of the Víctor Grífols 05 Lucas Foundation

# Practical problems of informed consent

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#### **PROLOGUE**

The Víctor Grífols i Lucas Foundation organized this workshop on the challenge of implementing written informed consent in the awareness that, 15 years after the passing of Spain's General Health Act of 1986, the misunderstandings in this area persist and may even have grown. The issue of informed consent is at the heart of any bioethical analysis of our clinical practice, and understanding not just the theoretical need for such consent but the challenges and risks associated with it is essential if we are to avoid the shortcomings and abuses which may arise.

From a bioethical perspective, perhaps the first thing which we must understand is that informed consent is the reflection of a clinical relationship at a time of rapid and poorly understood change. The informed consent process, the documents associated with it, and the forms it takes reflect this complicated context. To argue that a written consent document of itself complicates the situation, as some doctors claim, is as absurd as the opposing belief that such documents can, in and of themselves, ensure a more respectful relationship. While these arguments take very different starting points (the former being based on rigid paternalism and the latter on an utterly unrealistic 'autonomism'), they share an unthinking, defensive use of informed consent documents which is nothing short of absurd.

This danger is clearly illustrated by the case studies presented by Pablo Simón at the start of the discussion session. These show very clearly how the misuse of informed consent documents helps create the fiction of a contractual medicine which merely compounds the shortcomings of a paternalistic clinical relationship by forcing patients to share responsibility for its failings. All of which avoids the key issue: the need for joint deliberation as the basis of shared decision-making. How, then, can we avoid negative uses of informed consent documents and instead use them as a means of achieving a genuinely informed consent which reflects the expectations of health service users? This is the key question, and to answer it we must improve our understanding of people's expectations, both of greater freedom and respect

in general when they are ill, and specifically with regard to how the informed consent process is conducted. Is there a need for further legislation to reinforce the obligation of health professionals to respect their patients' wishes, or would such moves have a negative impact and would it instead be preferable to wait for a new culture of doctor–patient relationships to develop over time?

Concerning as it does one of our most basic rights - that of personal autonomy - informed consent requires both the general backing which comes from legislation and the individualization which is necessary if we are to truly achieve our objectives. And the challenge of personalizing information is particularly difficult in the context of informed consent. It is not tenable to withhold information on the basis of a supposed 'therapeutic privilege', and nor is it right to impose unwanted information simply because this is what legislation prescribes. Many of the contributions to the discussion refer to this delicate balance, raising the question of whether, if the informed consent document records the patient's decision to accept or reject the proposed course of treatment, it should also record that the patient who has reached this decision is competent, has had access to the necessary information, and has made their choice freely, and in full understanding of the issues at hand. Should we accept consent documents which do not fully satisfy these criteria and which may not provide full legal protection, so long as they respect the wishes of the patient? Or does the threat of legal action faced by professionals justify the drafting of general documents which may contain more information than a specific patient may require? And would legislation requiring documents of this sort lead to the generalization of defensive practice?

These were some of the key questions which prompted the organization of this seminar. We addressed some of them in detail, while pressures of time meant that others were not even raised. It is to be hoped that the latter will provide the focus of other discussion days in the future.

It would be interesting to analyse the different positions in the discussion in the light of the daily experience of the speaker, whether doctor, nurse, philosopher, administrator or legal expert. This opportunity for sharing different perspectives was one of the most enriching aspects of the day. The seminar started with the presentation of abbreviated versions of two papers, the full versions of which had already been distributed to participants: a paper considering the ethical aspects of informed consent, by Pablo Simón, one of the leading theorists in this area; and a paper on the legal framework, by Carlos Romeo Casabona, Spain's leading authority on health law. Pablo Simón also illustrated his paper with a series of case studies to stimulate discussion.

The discussion session was structured around a series of guideline questions, moving from general to more specific issues, although participants were encouraged to diverge from these if there were other issues they wanted to raise. The transcription presented here was edited from a recording of the seminar proceedings.

Marc Antoni Broggi Member of the Board of Trustees of the Víctor Grífols i Lucas Foundation and the Catalan Society of Bioethics

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Informed consent: new approaches Pablo Simón Lorda It is ten years since informed consent was enshrined in Spanish law, and now is a good time to take stock and reflect upon both the positive and negative aspects of our experience to date. Only in this way can we better understand the future which awaits us. The first legal ruling to directly address the problem of informed consent was issued by the Supreme Court, in a civil action, on 23 April 1992, and ordered a number of surgeons to pay compensation of 30 million pesetas (180,000 euros) for damages arising from surgery for scoliosis on a minor, which left her paraplegic. According to this ruling, these surgeons had not advised the mother that the operation was not essential or necessary, nor did they explain other alternative treatments, or the risks of the operation. For this reason, the ruling argued, the surgeons personally assumed these risks because they had not obtained informed consent.

The Ruling related to events which had occurred in 1985, prior to the approval of Spain's General Health Act (LGS) and was therefore somewhat restricted in its legal ramifications. The Supreme Court Ruling which really recognized the application of the theory of informed consent in the health sector was issued exactly two years later, on 25 April 1994, in a vasectomy case in 1989, a ruling which went far further in jurisprudential terms and with which I am sure many of you are familiar.

It is important to note that, between 1986, when article 10 of the General Health Act established the right to informed consent in principle, and the 1992 Ruling, Spain's health professionals, professional associations and health institutions did nothing to embark upon the process of change which we now realize is so necessary. It is against this background that we need to summarize and review various aspects of the ethical and legal theory of informed consent, in an attempt to face the future with optimism.

### 1. The historical problem of informed consent

In my opinion, as I have made clear on numerous occasions, the problems of Spanish health professionals in understanding informed consent come, in

the first place, from their inability to understand that 'informed consent', is a sociopolitical or cultural issue, not just a medical one. Indeed, our problems arise from our resistance to accept that the doctor–patient relationship should include a notion of autonomy which had been developing over centuries in every other sphere of western society.

#### 1.1. A general introduction

As I have already described in detail elsewhere<sup>1</sup>, informed consent has its origins in a lengthy process of change to the basis of political power whereby, with the arrival of Modernity, we see the development of the concept of the rational, moral subject with the autonomy to govern his own life, and to choose his religious beliefs and political convictions. The most direct product of this change is undoubtedly the appearance of contractarianism, which traces its roots back to Hobbes' *Leviathan*, passing through Lock's *Second Treatise of Civil Government* and Rousseau's *Social Contract* to Kant's *Metaphysics of Morals*. Despite the many significant differences between these authors, the accumulated effect of their work was to make it impossible to defend the notion that political power derived from the direct designation of the monarch by divine will. Only the free, individual and, indeed, informed consent of citizens coming together to constitute a political society can provide legitimacy to the political forms of government.

This lengthy process of change, which departs from the pre-conventional forms of the moral justification of political power typical of pre-modern societies, proceeds by establishing the conventional forms inaugurated by Modern rationalism and culminates in the post-conventional morals of principles which appear in advanced capitalist societies to generate a means of legitimating properly established power. Sociopolitical relations are only morally just when they are based on the mutual recognition of the irrenounceable dignity, liberty, equality and communicative competence of those participating in or affected by them; sociopolitical relationships can no longer be based on an authority derived from the supposed superiority of

<sup>1.</sup> Simón P. El consentimiento informado. Madrid: Triacastela, 2000. pp. 25-118.

some citizens over others, but rather on agreements freely reached on the basis of the equality of all and following appropriate procedures.

The problem of integrating informed consent into medical practice reflects the medical sector's resistance to this radical change in what constitutes the basis of morally sound human relations. Instead, health relationships have historically adopted pre-conventional patterns, and this has persisted until the present day. The doctor, as the repository of practical and theoretical knowledge about the order of health and the disorder of illness, is the sole source of truth, goodness and beauty. The patient – ill, disordered, ignorant, immoral and offensive to the eye – has no option but to passively accept the instructions and orders of the doctor without question. Being a good patient means knowing how to submit, obey, and cooperate with the doctor in his fight against illness.

It is not easy to understand either how or why patients of the 18th and 19th centuries, increasingly conscious of their rights as citizens, passively tolerated this situation. Perhaps the simple fact of being ill, together with ignorance as to the causes of illness, have enabled this situation to persist for so long. In other words, while Modernism had established that the 'sick' condition of the social body, the *polis*, had its origin in how it was organized internally in accordance with a set of principles generated by society's members and which could therefore be changed in order to 'cure' the social body, in the case of physical illness, the process was not so clear. Disease seemed to come 'from outside', its origins lying in unknown causes and mysterious mechanisms, and only the privileged few – doctors – could provide more or less effective remedies. So, while the sources of the monarch's power were gradually questioned and displaced by the will of the people, the sources of the doctor's power remained intact.

It was not until the second half of the 19th century, with the beginnings of microbiology, that the mechanisms of some illnesses were laid bare, and given an objective description which was not dependent upon the wisdom of doctors<sup>2</sup>. This finally made it possible to judge the appropriateness of medical actions, and such actions could no longer be offered as absolute truths impervious to outside analysis, but became instead verifiable procedures open to ques-

tion by those affected, including patients. From the early 20th century onwards, the citizens of the United States, who had the most pronounced sense of their rights as citizens and of 'informed consent' in the sociopolitical sphere, now freed of the quasi-magical traditional explanations of illness began to tell their doctors that, in light of the fact that the actions of the latter were subject to objective analysis, they wished to be a part of any decisions about what was to be done with their ill bodies, with their lives, and with their health.

We know how North American doctors responded to such claims, and we also know how patients reacted to this refusal: they had recourse to the legal procedures established by modern societies to defend the rights of their citizens. Those citizens who reported their doctors to the courts sought to establish that their condition as patients did not erode, limit or undermine their rights as citizens. In other words, if a citizen has the right to participate actively in the political decisions which affect his or her social life, than that citizen has the same right to participate actively in health decisions which affect his or her physiological or bodily life. The history of informed consent, then, was born in the courts as a response to the resistance of doctors to the social and cultural changes which, since the 16th century, had completely transformed human relations, initially in the public sphere and now, gradually, in the private sphere too. The 'blame' for the legalization of informed consent lies not with unscrupulous patients in search of money (although these undoubtedly exist), or with judges in search of notoriety (who also exist). Instead, the fundamental responsibility lies with the conservatism of health professionals and the inflexibility of medical organizations. In this context, the reaction of health professionals in the United States, who take cover behind defensive medicine, is an error which can only aggravate the original problem, increasing distrust between patients and doctors and triggering yet more legal cases.

#### 1.2. The Spanish experience

The history of informed consent in Spain is very similar to its development in the USA, although there are also some differences. These relate primarily to the structure of the law and how this responds to demands from society. While in the United States citizens can effectively create law inductively by

<sup>2.</sup> For example, Louis Pasteur was not a doctor but a chemist.

means of legal rulings which set a common law precedent, in Spain judicial rulings only have a secondary role in generating law. Instead, legal rulings use a deductive procedure which analyses each case in light of the rules generated by the legislature. In order to make changes to the doctrine embodied by these rulings, it is necessary to make changes to the legislation or to the procedures by which this legislation is interpreted. The key issue in Spain is therefore not so much the issuing of legal rulings on informed consent as the question of when, how and why legislation is created permitting such rulings to be issued.

In my opinion, 1978 - the year in which the Spanish Constitution was approved – is the key date for the history of informed consent in our country. This event marks the end of the sociopolitical paternalism which had marked our history until that point, and the start of the era of citizenship and of sociopolitical informed consent. And the rest followed of its on accord. Let me explain myself. In the United States, effective recognition both of the rights of patients and of many other rights such as those of African Americans only occurs when social pressure generates changes to ethical and juridical perspectives in society, and judges recognize this in their rulings which then become law. By contrast, the process in Spain operates almost in reverse. This means that the legislature generates legal rules, either as a reflection of ideological convictions or as part of a parliamentary strategy or as a consequence of the consistent, gradual development of the law. However, it is often the case that such changes only reflect genuine social demands in an indirect, vague fashion, and are generally influenced by electoral considerations. As a result, direct social pressure on the legislature to introduce legislative changes is limited, while the internal dynamics of our institutions mean that it has little impact. One of the effects is that legislative change and social demands are often out of step, the one either running ahead of or lagging behind the other. It is my opinion that in the case of informed consent, article 10 of the General Health Act (LGS) of 1986 arrived before there was any social demand for it. And I also believe that the refusal of professional organizations and health institutions to respond reflects their conviction that this demand would never arise. And this is why I have said that we have lost six years which could have been used to transform our own paternalistic mentality, to prepare for change and embark upon a process of collective growth, in order to channel the demand which, sooner or letter, had to arise as a result of the social dynamic of an increasingly post-conventional modern society like 21st century Spain.

I say all of this because I still have my doubts as to whether health professionals have really learnt their lesson, despite the fact that there are two pieces of legislation which both extend and significantly improve upon article 10 of the LGS. I am referring to the Oviedo Convention, in force in Spain since 1 January 2000, and, above all, the White Paper 622/000007 presented to the Senate by *Entesa Catalana de Progrés* and *Convergència i Unió*, and designed to extend to the rest of Spain the rights possessed in Catalonia with regard to health, patient's autonomy and medical records. I am concerned that health professionals remain unable to understand that this legislation will require us to continue transforming health relations by making them more participatory, and more respectful of the moral autonomy of our patients. If this fails to happen then, once again, as citizens gain in maturity and seek to enjoy the rights offered by the law, they will demand them in court. And this would mean paying a very high price in a battle which has been lost before it even begins.

The reason why, in my opinion, health professionals have not yet grasped the profound cultural, sociological and moral implications of informed consent, and remain wedded instead to outdated, self-pitying notions is the result of various phenomena which I will analyse below, namely the following: the limited development of ethical doctrine on informed consent, the failure of the curriculum for medical students and trainee doctors to incorporate bioethics and the humanities in general, the design and use of written informed consent forms, and the public stance of doctors in some publications which are influential in the Spanish health sector.

### 2. The problem of the basis of informed consent

One of the key problems of the theory of informed consent in the USA has been the imbalance between the extensive legal basis (both legislation and

precedent) combined with a lack of sufficient consideration of the ethical basis, which provide the real foundation for what professionals do. I will therefore review some of the problems of the ethical basis of informed consent, the legal basis, and professional codes of ethics.

#### 2.1. The ethical basis

There has been relatively little work on the ethical basis of the theory of informed consent in North American bioethics, and in general this has been conducted within the framework of a principlism which simply identified informed consent with the principle of autonomy. As I have already performed an extensive review of the various proposals put forward in this regard, I will not repeat this here<sup>3</sup>. Instead, I will limit myself to summing up my own position.

#### 2.1.1. Diego Gracia's hierarchy of principles

As I am sure you are all aware, in my opinion, with regard to the development of bioethics, the most coherent framework for reaching moral decisions is the one proposed by Diego Gracia. This framework is inspired by the ideas of Xavier Zubiri, in which the apprehension of reality is a fundamental activity of sentient intelligence, permitting in turn the rational reconstruction of the process of moral decision-making and of moral knowledge in general. Sentient intelligence apprehends things as possessing a reality of their own and apprehends people as embodying a distinct mode of reality which is what makes them deserving of consideration and respect as moral subjects. This generates the canonical framework of morality, the formal system which reason must then provide with material content by means of moral outlines and normative proposals which are necessarily contingent, historical and relative.

Diego Gracia argues that the four principles of bioethics proposed by Beauchamp and Childress provide the best available moral outline for bioethics. His only modification to this model, apart from exploring in more detail the basis

for it (an area on which Beauchamp and Childress touch only in passing), is to propose a hierarchy which ascribes greater moral weight to the principles of non-maleficence and justice than to those of autonomy and beneficence. Gracia argues that the first two principles constitute level 1, an ethics of minima, while the remaining two principles constitute level 2, an ethics based on maxima. He argues that level 1 principles are *prima facie* more obligatory than level 2 principles because they reflect absolute duties which correlate to absolute rights in interpersonal relationships, and are recognized as such. By contrast, level 2 principles only reflect relative duties, which do not correlate to rights and which, therefore, belong to the sphere of pure morality, of pure excellence.

However, Diego Gracia's model runs into trouble when we seek to apply it to the basis of the theory of informed consent. In the United States, as we have already seen, informed consent is based on the principle of autonomy, and Diego Gracia himself argues that the new model of the doctor–patient relationship associated with informed consent consists of correctly articulating the principles of autonomy and beneficence. However, the legal theory of informed consent does not see this as something optional, something which is dependent upon the level of expertise of the health professionals, typical of an ethics of maxima. Instead, legal theory sees informed consent as an absolute ethical, legal requirement, an ethics of minima which has been encoded historically as a legal rule, because failing to respect the autonomous decisions of individuals is to damage them on the moral plane and not to respect them as people, as moral subjects capable of taking their own decisions.

For this reason, echoing the criticisms voiced by Clouser and Gert with respect to the principlism of Beauchamp and Childress, and the doubts of Manuel Atienza and Adela Cortina with regard to Diego Gracia, I believe there is a need to modify the model proposed by Diego Gracia.

### 2.1.2. The principle of autonomy does not exist as such in the principlist model

It can be argued that in the pre-modern era there was only one basic moral principle, that of beneficence, underpinned at the meta-ethical level by natu-

<sup>3.</sup> Simón P. El consentimiento informado. Madrid: Triacastela, 2000. pp. 119-150.

ralism. To be beneficent was to do good, and this meant enabling every thing and every person to occupy its place in the order of nature. As Diego Gracia himself has clearly demonstrated, this notion of beneficence absorbed the principle of non-maleficence, as this simply consisted of the negative version of the principle of doing good<sup>4</sup>. It can also be argued that beneficence encompassed the principle of justice, because what was just was good, consisting as it did of everyone occupying his place in the natural order of the *polis*. This beneficence was necessarily paternalistic, given that the room for manoeuvre allowed for individual autonomy was almost non-existent in light of the notion of a natural, predetermined order. As a result, paternalistic beneficence was the principle which both embodied and superseded the three classical moral obligations set out by Ulpian in the Digest (3rd Century A.D.) as the basic legal precepts of *honeste vivere*, *alterum non laedere*, *suum cuique tribuere*: that is, beneficence, non-maleficence and justice.

I have argued, then, that the key achievement of Modernity was to conceptualize people as morally and intellectually autonomous beings, with a capacity for reasoning and decision-making, and the ability to choose their own values and to decide upon their own notions of well-being and happiness. This idea shattered the natural order, and the notion of a divinely ordered world was replaced by a belief that it was open and constantly changing. And, by the same token, the notion of people as autonomous beings also shattered the principle of paternalistic beneficence, breaking it down into three distinct concepts: the principles of non-maleficence, of justice and of beneficence, now clearly differentiated from each other.

In other words, what was involved was not so much the appearance of a new moral obligation, distinct from those discussed in the Digest, but rather a reinterpretation of these obligations in the light of the notion of the autonomy of individuals, which gave rise to their being clearly perceived as distinct moral obligations. However, in addition to creating this distinction, consideration of the autonomy of human beings led to an emphasis on two distinct aspects of our lives. One, the private sphere, where people decide upon their

own moral project of well-being and happiness, was defined by the principle of beneficence. While the other, the public sphere, is one in which autonomous people generate rules of respect and coexistence, governed by the principles of non-maleficence and justice. The first of these rules of coexistence and respect reflected the discovery of the principle of tolerance and, in particular, the right to respect for the autonomy of the individual. Respecting the autonomy of individuals, the autonomy to determine their own project of self-fulfilment or the autonomy to play an active role in the process of generating these rules thus became an absolute obligation which reflected the right of people to be respected.

Does this mean, then, that the 'principle of autonomy' should be assigned, without further ado, to level 1 of Diego Gracia's model? This is not the issue. The problem of the 'autonomy' of individuals is precisely that it has been defined as a principle, instead of being understood as a radical change of perspective with regard to the nature of human relations, which must shift from an asymmetrical relationship between beneficent actors and passive recipients, to a symmetrical relationship between autonomous moral subjects, with a duty of non-maleficence, beneficence and justice. Autonomy is, in reality, an attribute of individuals; it is the core of a specific, modern anthropology, just as adapting to the natural order is the core of a naturalistic anthropology. This notion of autonomy as an anthropological attribute gives rise to a specific vision of morality. According to the Kantian view, autonomy operates as an objective principle of action, as a moral law, and from this perspective we can say that it constitutes the centre of the canonical reference system for, as Adela Cortina argues, the capacity of rational beings to create universal laws which guide their empirical behaviour is the key to the notion of dignity<sup>5</sup>.

However, what we are really interested in is untangling whether the concept of autonomy contained in bioethics can be established as a subjective principle of action, as a maxim. In my opinion, within the moral framework of principlism, it is not, because its content belong to the moral conception of

<sup>4.</sup> Gracia D. (1990); 47-62.

<sup>5.</sup> Cortina A. (1993); 230 and ff.

the three classical moral obligations of the Digest, to the other three maxims or principles of bioethics. This modern vision states that what is new is the obligation to respect the autonomy of the individual to take decisions, which is an absolute obligation deriving from the principle of non-maleficence, because failure to do so would jeopardize the person's mental and physical well-being, and their moral life; disregarding a person's autonomous decisions is to injure one of their fundamental rights. It is precisely for this reason that the Law has gone to such lengths to protect it, and has considered injury to it as moral harm. Diego Gracia himself has argued, perhaps without realizing, that "if beneficence is in opposition to autonomy, then it is not beneficence but maleficence" 6.

This new perspective also provides a basis for a clearer understanding of the significance of the historical development of legal decisions in the United States. This history can be summarized as a gradual transformation of the concept of medical negligence to accommodate the obligations to inform and to request consent – from  $negligence_1$  to  $negligence_2$ . This transformation has arisen as a result of cases of battery in which the patient's right to self-determination is invoked. That is,  $negligence_1$  represents classic paternalistic beneficence which, under the impact of the notion of patients as autonomous beings, is forced to incorporate this concept as a new element of existing professional legal obligations, giving rise to  $negligence_2$ , in which such respect for autonomy represents both a moral and legal requirement upon all health professionals which is part of an absolute obligation of non-maleficence.

However, things don't stop there because, in addition to not harming people and, among other things, the obligation to respect the individual's autonomy, we also have the obligation to do good in so far as we are able. This is the principle of beneficence. And the best way of doing good is by enabling people as far as possible to pursue their own project of happiness. This is what we call, 'promoting the autonomy of the individual', taking every possible measure to enable them to reach their own decisions, decide upon their future, how they wish to live, etc. This is a relative rather than an absolute

obligation. Nobody can force another to promote the autonomy of others; we can only morally urge them to do so. There is therefore another element of the original 'principle of autonomy', which in reality constitutes the modern version of the maxim of beneficence.

If the maxim of autonomy can in reality be identified as the contents of the modern interpretation of the maxims of non-maleficence, justice and beneficence, how and why did the 'principle of autonomy' arise? The confusion arose, firstly, when the Belmont Report failed, as we have seen, to distinguish between non-maleficence and beneficence, and secondly, when it treated what was really an aspect of non-maleficence as a separate principle, which it defined as the 'principle of respect for persons', a name which in itself is quite appropriate, as it refers directly to the idea of non-maleficence. And the confusion became permanent when Beauchamp and Childress identified four separate principles. Why did this occur? Well, Clouser and Gert have identified the reasons very clearly. Because the main enemy to address was paternalism, this could only be done by countering it with a principle of equal moral weight. The only way to do this was by means of another moral principle, that of autonomy, backed as it was by the whole modern legal tradition which questioned the principles of natural law, the traditional basis of paternalistic beneficence. This is not a superfluous reason. It can be argued, then, that there are significant historical and pragmatic reasons for affirming the existence of a 'principle of autonomy'. However, as noted already, deeper consideration of its content has the effect of dissolving this principle.

But before moving on to the next point, there is one issue I would like to clarify. This criticism of the principle of autonomy is a criticism of the structure of a specific moral framework based on the four principles of bioethics: that is, the principlist framework of bioethics in general and, in particular, the one proposed by Diego Gracia. This is because the stability of this framework depends upon the suppression of the principle of autonomy, because the contents of this principle are actually attributes of the other three principles. Nobody is arguing that the principle of autonomy cannot exist as a stable, coherent maxim within an alternative moral framework to the one offered by principlist bioethics.

<sup>6.</sup> Gracia D. (1990); 80-81.

### 2.1.3. A new moral framework with two levels, three principles, laws, instructions and advice

The moral framework which I propose as an alternative to the one defended by Diego Gracia also contains two different levels, but just three principles, and must also take account of the standards which derive from these principles: laws, instructions and advice.

Level 1 consists of absolute duties, which relate to the rights recognized between individuals, and which nobody can violate without putting themselves on the margins of society. This is the level of minimal ethical guarantees which need to be encoded in law if they are to be effective. For this reason, we call them ethical-legal duties. However, this does not mean that Level 1 is identified solely with the Law. History shows that the ethical awareness of certain individuals or groups often runs ahead of the rest of society and, above all, of the legislative process, identifying certain ethical issues as minimum requirements before the rest of humanity has done so and enshrined them in law. The two principles which constitute this level are non-maleficence and justice, together with the rules which derive from them.

The modern vision of the principle of non-maleficence obliges us to describe it in the following way. "You should not do physical, mental or moral harm to others," or, to put it another way, "treat everyone with the same consideration and respect for their biological, psychological and moral life." This obligation to respect moral life gives rise to rules which oblige us to respect people's autonomous decisions. For its part, the principle of justice states: "You should treat everyone with the same consideration and respect in the social, political, economic and cultural order." This principle forms the basis for rules by which the sociopolitical structure and institutional framework facilitate universal access to public resources under conditions of fairness.

Level 2 consists of relative duties, which do not correspond to rights. These form part of the ethics of maxima, which are not enforceable but which are voluntarily accepted by moral individuals. They have no legal counterpart, and they are therefore purely moral duties. All these duties derive from a single principle: the principle of beneficence. The modern version of this

principle states, "Do good to others, while seeking to ensure that they are able to pursue their own autonomous project of happiness." The principle of beneficence gives rise to two types of standard: 'mandates' and 'advice'. Mandates specify obligations of beneficence which have been assumed publicly and voluntarily, and which others may therefore see as moral requirements. Advice is an obligation only in so far as an individual feels morally bound to provide it.

If we apply this model to the obligations of health professionals, we will find that, in addition to the general obligations of non-maleficence, beneficence and justice borne by any member of society, they also have special obligations of non-maleficence, beneficence and justice as professionals. And this duty to respect both their general and their professional obligations of non-maleficence and justice is morally and legally enforceable. Respect for the obligations of beneficence specific to their position as professionals – that is, those obligations set out in codes of professional ethics – can only be enforced morally through professional colleges. In principle, it is not possible to prosecute a health professional for failing to uphold his or her obligation of beneficence, in contrast with the obligations of non-maleficence and justice.

In this context, it is essential to explain how Professional Codes of Ethics should be understood. Professional Codes of Ethics are collections of professional standards of non-maleficence, justice and beneficence. The fact that they include obligations of non-maleficence and justice mean that they have great legal significance. They are not part of the law as such, but the legislation refers to them and they are frequently cited in legal rulings because they help to define the Level 1 obligations of health professionals, obligations which are often not clearly specified in the legislation itself. However, the legislation does not refer to the (regrettably small) part of the Professional Code of Ethics which establishes obligations of beneficence, because these obligations are solely moral in nature.

However, the degree of compliance with specific level 2 ethical obligations is an excellent measure of the moral quality of a profession. Excellence in this area is expressed primarily via attitudes and virtues, rather than through standards, but it is this which ultimately determines the ethical standing of

the profession. For this reason, it has been the touchstone of the medical profession for many centuries, and this is also why there is a strong current within North American bioethics which is seeking to revive the tradition of beneficence within medicine, rescuing it from the restrictive framework of paternalism<sup>7</sup>. While health professionals tend to think that merely by satisfying Level 1 – that is, the minimum principles of non-maleficence and justice – they are satisfying their moral obligations as professionals, in reality by taking this approach they transform themselves into salaried bureaucrats, the absolute antithesis of a professional with a vocation.

However, health professionals are not the only ones with moral obligations. Institutions - in our case, health organizations, and publicly funded ones in particular - also have them. It is therefore essential that we construct a comprehensive ethics for health organizations (Cortina, 1998). Institutional obligations of non-maleficence oblige them to be structured and to operate in such a way as to treat service users in a manner which respects their physical, psychological and moral order. The obligation of justice requires institutions to be structured and to operate in such a way as to guarantee fair access by users to available resources. A Rawlsian reading of these institutional obligations might identify the principles of non-maleficence and justice with the first and second principles of Rawls' theory (Rawls, 1996:328), and this argues that fair, just institutions are those which comply with their level 1 obligations8. In this way, it might be argued that the principle of non-maleficence when applied to institutions obliges them to guarantee to each citizen or service user a "right which is equivalent to to a model of equal basic rights and which is compatible with a similar model of universal freedoms". And the principle of justice would entail an obligation to ensure that any social and economic inequalities arising in the structure or operation of the institution satisfy two conditions: "that they be linked to positions open to all under conditions of fair equality of opportunity and, secondly, that any inequalities are to be of the greatest benefit to the least-advantaged members of society."

In addition to these level 1 obligations, institutions and organizations have obligations of beneficence. Just as we need to produce excellent professionals, we must nurture excellent health organizations, whose structure and way of operating help members of society to achieve their life plans, in so far as is possible. The challenge is to understand organizations as structures which support the social fabric of human communities, enabling the growth of the personal projects of happiness of each individual member of these communities<sup>9</sup>.

An interesting question with regard to the moral obligations of health organizations is the role played by the growing preoccupation with designing adequate accreditation systems for hospitals and health centres. As far as I can see, their role is very similar to that of Professional Codes of Ethics. So, if you look at the Accreditation Manual of the Joint Commission – to give the best known example – and turn to the chapter dedicated to institutional ethics<sup>10</sup>, what you find are sets of standards derived from the three principles of bioethics. Some of these are minimum standards, and failure to apply these would make it impossible to authorize the institution's operations – for example the accreditation standard which means that informed consent must be obtained for clinical trials. Others are maximal standards, which transmit an ideal of institutional excellence, such as that which evaluates "whether the hospital permits patients and their families to express their religious beliefs and cultural practices, so long as these do not prejudice others or interfere with their treatment."

#### 2.1.4. Level 1 and Level 2 Informed Consent

If the principle of autonomy does not exist, what then should be the basis of our moral obligation to obtain informed consent? I believe that the moral

Perhaps the two publications which best characterize this approach are by Pellegrino and Thomasma, and by Drane; the latter, influenced by the work of two Spanish authors, Jose Luis López Aranguren and Pedro Laín Entralgo. See Pellegrino ED, Thomasma DC. (1988) Drane JF. (1988).

<sup>8.</sup> This leaves open the problem of how to interpret the lexicographical order introduced by Rawls, which gives priority to the first principle (non-maleficence) over the second (justice). In general I would accept that this Rawlsian interpretation of level 1 institutional obligations constitutes a model requiring further elaboration and justification which goes beyond my scope here of outlining a general approach to the issues.

<sup>9.</sup> Cortina A. (1994); 82.

<sup>10.</sup> The Joint Commission on Accreditation of Healthcare Organizations (1996).

framework outlined in the section above fulfills this role perfectly. From this perspective, it can be argued that both professionals and health organizations have the obligation to obtain level 1 informed consent (IC 1) and level 2 informed consent (IC 2). Obtaining IC 1 is an absolute obligation, an ethical and legal obligation which corresponds to patients' right to respect for their autonomy. For professionals, the ethical basis for this is the principle of nonmaleficence, and failure to respect this may mean that the health professional is liable for civil damages or has committed a criminal offence. The elements of this obligation are therefore generally the same as those contained in the legal theory of informed consent, although they go further. Obtaining IC 1 therefore entails the doctor providing the patient with adequate information as defined legally, offering alternatives, suggesting the treatment recommended on the basis of best medical or scientific knowledge, allowing the patient to decide freely, and recording this in the medical records or in the written form. Failure to do so, where physical or moral harm arises, would mean the physician would bear subjective liability.

Health organizations also have to obtain IC 1 because of the principle of nonmaleficence, with the result that such institutions must be organized and must operate in such a way as to guarantee that users are freely able to exercise their basic freedoms and rights, one of which is precisely the right to informed consent. Failure to properly create or maintain these procedures, resulting in harm, would mean that the institution would bear objective liability, for which it could be legally prosecuted. Indeed, from the moral perspective, one could argue that it would thereby fail to satisfy the Rawlsian requirements of justice and fairness by failing to adequately guarantee application of the first principle of justice. This is important, because it is often argued that a fair health system is one which adequately, fairly distributes health resources (principle of justice). But this is to forget that to be truly fair in the Rawlsian sense it is also necessary to provide users with procedures by which to exercise their basic rights and liberties (principle of non-maleficence). For this reason, informed consent and, in general, the issue of the participation of users in the process of taking health decisions is not just the exclusive luxury of health systems in the developed world but rather a crucial aspect of any health system which aspires to fairness.

For its part, IC 2 relates to the establishment, by health professionals of a model of relationships which maximizes the active participation of patients in the decision-making process, which promotes communication, the free expression of fears and desires, the joint evaluation of alternatives, and the selection of that option which the patient understands as best fitting his or her own scale of values and life health project. To do this is a relative moral obligation, but one which health professionals are bound to perform precisely by virtue of their status as health professionals. It is a mandate. So long as a health professional complies with IC 1, he or she cannot be held legally responsible for failing to involve patients in the decision-making process, for failing to maximize the patient's autonomy, for not helping the patient to take good decisions, etc., although the professional can be held morally responsible for such failings. What we can say of such professionals is that the content of the clinical relationship is impoverished from a moral perspective, and that their behaviour is a long way from embodying excellence. The methods of obtaining informed consent advanced by defensive medicine completely ignore this approach and adhere, instead, to the requirements of IC 1, although at times they fail to satisfy even these. Clearly, it will not always be possible to obtain the fullest degree of IC 2, and often it is only possible to obtain IC 1, but none of this prevents the health professional from striving to achieve IC 2 in so far as is possible; it is precisely for this reason that it is a maximal obligation. By contrast, there can be no exceptions to the requirement to obtain IC 1, because this is a minimal obligation. Finally, there is also an institutional obligation with respect to IC 2. When health organizations strive to go beyond their obligations to ensure compliance with IC 1 and implement structures designed to enable health professionals to obtain IC 2, they are achieving organizational excellence.

### 2.1.5. Bioethics and informed consent: a cultural artefact of the ethical imperialism of the west?

Having set out the overall framework both for our general moral obligations and, in particular, for our obligations with respect to informed consent, I believe it is necessary to address a question which is often raised in debates

about ethical conflicts in medicine. Is bioethics, and in particular our understanding of autonomy and informed consent as part of its core values, a North American and western cultural artefact, a new form of paternalism and ethnocentric imperialism? And what of the differing moral sensibilities of communities within the same country or between different ones? Can we 'morally condemn' particular health practices in other countries, particularly in the Third World, just because they don't conform to our notions of morality? How does the moral life of a country incorporate 'moral strangers', those foreigners who do not share our moral wisdom but instead have their own wisdom? I am obviously not going to seek to resolve the eternal conflict between moral universalism and cultural ethical relativism or, to put it in more political terms, liberalism versus communitarianism. This is a complex issue and one which goes beyond my own expertise and powers of analysis. However, I will describe in broad terms my position, above all with respect to informed consent, because this issue has been raised forcefully in the bioethical literature in relation to a range of questions such as, for example, obtaining informed consent when performing clinical trials for therapies and vaccines against HIV in Africa.

I believe that the moral canon which establishes the irreducible dignity of each and every individual whom we consider moral beings is something which is no longer questioned by anybody, irrespective of how we have arrived at this morality. I therefore believe that this statement constitutes a radical transhistorical and transcultural truth which nobody can seriously question without putting themselves on the margin of rational life and the human community. It is quite another matter to determine which members of the human species do or do not belong to the category of moral beings, a thorny issue which I will not consider here because it is of little direct relevance to my purpose.

But I believe it is possible to go beyond the formal canon and argue that there is a sufficiently broad global intersubjective consensus with respect to the consensual truth of some of the material content which derives from this moral canon, and this, as Victoria Camps argues, independently of whether or not we agree upon the correct way to establish such a consensus<sup>11</sup>. I refer specifically to what we call Human Rights, both first and second generation,

11. Camps V. Paradojas del individualismo. Barcelona: Crítica, 1999 2.p.52

which could be understood as rules derived from the principles of non-maleficence and of justice, respectively.

For this reason, like Ernesto Garzón Valdés, I believe that the identification between cultural diversity and moral wealth is a new naturalistic fallacy. Not all cultural forms of life have the same moral value, nor do all deserve to be conserved and protected from moral evolution<sup>12</sup>. Community identities and their cultural practices may be judged morally, both internally and externally, on the basis of the degree to which they comply with these agreed, minimum moral principles and standards. I don't believe this is an ethnocentric or imperialist position but rather, plainly and simply, a post-conventional one. If we refuse to accept this then we have no arguments to question the practice of clitoral ablation in some African cultures, infanticide or the abandonment of female children in China, the treatment of women by the Taliban, suttee or the burning of widows in India, the rejection of wives in Pakistan, the death penalty in the USA, ETA terrorism in Spain, or sharia law in Muslim countries. The problem of radical cultural relativism is that it entails a moral relativism which leaves us defenceless against violence. A quite separate issue is whether there is agreement as to how these cultural or political communities should be pressurized into changing this behaviour, facilitating moral growth and advancing in our respect for universally agreed minimum moral content.

I believe that informed consent should also be considered in this manner. The ethical-legal requirement to obtain level 1 informed consent and the moral aspiration to obtain level 2 informed consent are sufficiently well rooted in the theory which defines the moral identify of the professions and of health institutions as to be considered a universal requirement which is integral to their practice, derived from the conviction that human beings, including those who are sick, enjoy as a matter of principle sufficient moral autonomy to take their own decisions. I therefore believe that no health professional or health institution in any country of the world can consider performing treatment or research without taking into serious consideration the requirement for informed consent in both senses. We can argue as to the specific forms in

Garzón Valdés E. Cinco confusiones acerca de la relevancia moral de la diversidad cultural. Claves de Razón Práctica 1997; 10–23.

which it is applied and how the decision-making process should be conducted in light of the cultural peculiarities and values prevalent in each country and each community, and we should strive to harmonize informed consent with these. But applying it in one way or another is not up for question.

And this brings us to the practical problems encountered when doing so. For example, the provisions of the Israeli Patient Rights Act (1996), which on the one hand reinforces the liberal model of informed consent so long as the patient accepts the proposed treatment, while limiting it in the event of a competent patient rejecting a treatment which, in the opinion of the health professional, is necessary to preserve the patient's life<sup>13</sup>,<sup>14</sup>. Or the controversial Japanese law which establishes that patients who wish to receive detailed information from their doctors must pay for it<sup>15</sup>.

And this also applies to internal differences within a given society or group, whether they be socioeconomic, educational or generational differences. Clearly, each of these population groups develops value systems which at times differ widely from one another. But I do not believe this means that any of these groups should be systematically excluded from the general dynamic of informed consent, even if it must of course be adapted to each group and, ultimately, to each individual. Recognition of differences and, in so far as is possible, respect for them, should not be equated with the abdication of accepted interpersonal moral obligations.

#### 2.2. The legal basis

Although Carlos Romeo will address legal issues in his presentation, there are a few legal issues which particularly concern me, perhaps because I have not understood them properly. I will start with two of them, before addressing some others later.

#### 2.2.1. Is informed consent a 'highly personal act'?

It is common, in discussions of informed consent, for legal experts to affirm that consent is a highly personal act of patients, seeking thereby to place it on a pedestal, safe from critical analysis. Unless I am mistaken, in Spanish civil law, it is a fundamental characteristic of highly personal acts that nobody can perform them on behalf of the individual: that is, either the individual himself performs them, or they are not performed. In other words, they are beyond the scope of institutions such as guardianship, parental authority, tutorship, etc. <sup>16</sup>. However, it could be argued that there are three further characteristics which should be added to this. One is that they concern acts which involve, and may therefore either benefit or harm, the legal properties or fundamental rights of the individual. The second is that, for such acts to be performed, the principal must demonstrate sufficient mental aptitude, wisdom, maturity or capacity to govern himself; that is, he must have *de facto* capacity. And the third, obviously, is that the actor must be recognized as possessing legal capacity to perform them<sup>17</sup>.

The law establishes the figure of highly personal acts and the requirements which these must satisfy. It may also restrict their performance by specific individuals, but in this case it must do so expressly, by legal ruling for example. The most classical instances of highly personal acts are entering into marriage, making a will, and recognizing a child out of wedlock<sup>18</sup>. But there are others, such as suffrage.

<sup>13.</sup> Gross ML. Autonomy and Paternalism in Communitarian Society: Patient Rights in Israel. *Hastings Cent Rep* 1999; 29 (4): 13–20.

<sup>14.</sup> Glick SM. Unlimited Human Autonomy: A cultural bias? New Engl J Med 1997; 336 (13) 954–956.

<sup>15.</sup> Akabayashi A, Fetters M. Paying for informed consent. J Med Ethics 2000; 26:212-214.

<sup>16.</sup> According to O'Callaghan:

<sup>&</sup>quot;Certain acts are highly personal and may only be performed by the principal himself; that is, either individual performs them or they are not performed at all. In these acts, if the principal is incapacitated, he may perform such acts if, despite this incapacitation, he possesses natural mental competence to do so. In no event may the legal representative (parent or tutor) perform the act in the name of the incapacitated party."

See O'Callaghan Muñoz X.(s.f.); 231. Also O'Callaghan Muñoz X. (1986).

<sup>17.</sup> We will return to the concepts of *de facto* and legal capacity and the problems associated with them below.

<sup>18.</sup> See O'Callaghan Muñoz X. (1986); 14-15.

It is worth asking whether informed consent should be deemed to constitute a highly personal act. It would appear to comply perfectly with the second of the typical characteristics of such types of act, given that in the act of consenting to a given diagnostic or therapeutic intervention, the patient brings into play his or her right to life, to health, and to physical integrity and freedom, all of which are fundamental, personal goods and rights. The same occurs with the other criteria when the individual has sufficient legal and *de facto* capacity to perform it. When this occurs, consent may not be granted by another person in place of the patient; the patient may not be substituted and this is a highly personal act.

However, the situation is quite different when the individual lacks either legal or *de facto* capacity. Here, informed consent diverges from the category of 'highly personal acts' because, unlike these, the patient may be substituted by a representative. As Bacigalupo explains, "the possibility of substituting the consent of a legal representative for that of an incompetent individual is a general principle of Spanish law" And this leaves us with the question of whether or not informed consent for medical intervention constitutes a 'highly personal act' in the same sense as getting married or voting.

#### 2.2.2. The problem of tacit and assumed consent

Another point frequently made in discussions of informed consent is that there is no need for so much fuss because when patients voluntarily see the doctor they are already giving their tacit or assumed consent to medical intervention, and even more so when, in response to being told of the proposed course of action, the patient simply asks when and where it is to be performed. I have my doubts as to the validity of these arguments.

To start with, I agree with Llamas Pombo when he argues that voluntarily attending the doctor and thereby consenting to enter into a contractual relationship does not necessarily imply giving one's consent to the physician then intervening upon the patient's body as he or she sees fit:

19 Bacigalupo E. (1989/1990).

"There is a difference between consent understood as an element of a private legal agreement and as an expression of free acceptance by the patient of medical intervention on his or her body. For this reason, when talking of 'medical consent' or 'the patient's consent', we must be very clear as to what we are referring to, because this distinction, apparently so clear at first sight, gives rise to more than a few misunderstandings when we come to analyse the medical relationship from a legal perspective. So, for example, when we are talking of contractual consent the requirement for the patient to have reached the age of legal majority is clear, while for clinical consent this requirement is perhaps not so clear. In the first instance, the patient's wishes relate to the creation of a contract, from which derives the other party's obligation to provide care and the patient's obligation to pay any fees. In the second instance, the patient only wishes to enable the doctor to perform certain acts which affect his or her body and physical integrity.

Often, however, both wishes are expressed jointly without the patient consciously distinguishing one from the other or even realizing that consent to medical intervention is a separate element within the dynamic created by the consent to the creation of a contractual relationship."<sup>20</sup>

Secondly, the normal use of the term 'assumed consent' is not, in my understanding, quite accurate from a legal perspective. Unless I am mistaken, the theory of assumed consent was developed primarily by German legal specialists, and in particular by Edmundo Mezger<sup>21</sup>. Assumed consent is applied in

Llamas Pombo E.(1988); 152–153. Ataz López takes a similar view, although less clearly defined. See Ataz López J. (1985); 63.

<sup>21.</sup> In his classic Tratado de Derecho Penal he writes the following:

<sup>&</sup>quot;I. It is not in contradiction with legal principles when the possessor of the legal good which is threatened by implication consents effectively to the action. This is because consent alone is not able to satisfy in full the practical needs of the interested party. In fact, it is not uncommon for consent to be absent and that the urgent and pressing needs of the injured party nevertheless require action to be taken. Some examples from the literature may help to clarify the issue: a person enters his neighbour's house while the neighbour is away in order to repair a broken water pipe, or to open a letter addressed to his friend but concerning an urgent issue which must be resolved immediately; an individual kills another person's dog to put it out of its misery after it has been run over by a

those situations in which it is possible to deduce that an absent or incompetent individual, affected by the action in question, would have consented to its being performed had or she been present or competent to decide and familiar with the circumstances<sup>22</sup>. I therefore do not think it is appropriate to use this term to refer to situations in which patients, who are physically present and legally competent, reluctantly accede to the performance of specific medical actions.

This leaves us with tacit consent. To put it bluntly, I do not believe this exists. There is no consent without prior information. So what should patients be

tram, or finishes off an injured deer on another person's hunting estate with the intention of handing it over to the owner of the estate; a person injures another in the process of saving him from certain death from drowning; the doctor operates on the unconscious victim of a car accident, or extends the scope of an operation which is already under way on an anaesthetized patient; or, when talking to a patient who suffers from heart problems, does not talk about the dangers of the surgery the patient is about to undergo. In all these cases, real consent is absent. And, despite this, it is indisputable that consent would have been granted had the supposed injured party been aware of the situation and able to do so. There is no doubt that, in such cases, just as in those where there is effective consent, it is not possible to talk of behaviour which is illegal or punishable. What is at issue is simply what this conclusion is based on and to what degree the justification extends to cases which are less clear.

II. The illegality disappears in cases of this sort in light of the notion of assumed consent. Assumed consent requires a judgement of objective probability by the court to the effect that the injured party, had he or she been in full knowledge of the situation, would have consented to the action. This leads to the following conclusion: that legitimation of the action on the basis of consent occurs not only in the event of actual consent, granted when the injured party's wishes concur with the actions taken, but also when the evidence shows that the injured party would have consented to the action had he or she been fully aware of the situation. The issue, then – and I must stress this – is not to determine what the supposed injured party ought to have done in the situation, but rather how he or she really would have behaved (as far as can be predicted) in accordance with his or her personal wishes.

This so-called assumed consent therefore represents a valid substitute for real consent."

See Mezger E. *Tratado de Derecho Penal*. Tomo I. Madrid: Ed. Revista de Derecho Privado, 1955; 430 432.

22. López Barja de Quiroga J. El consentimiento y la esterilización de los incapaces. *Cuadernos de Política Criminal* 1991; 44: 311–348.

informed about? I believe that for consent to be valid the patient must be explicitly informed about the various aspects of the proposed intervention, and that it is a professional obligation to offer such information. The patient may then say, "Okay doctor, thanks for offering, but I prefer you not to tell me anything because I trust you; go ahead with the test," in which case the patient is freely exercising his or her autonomy, and granting a consent which is valid, voluntary and, if you wish, explicitly ignorant, but not tacit.

#### 2.3. The problem of (POOR) professional ethics

Unfortunately there is little to be said on this issue. The current Code of Professional Ethics for Doctors in Spain – with the exception of Catalonia, where doctors have had their own code since 1997 – is the one approved at the Assembly of the College of Doctors on 25 September 1999. Questions relating to informed consent are addressed in section 2 of article 9 and in the six sections of article 10. Here, the issue of informed consent is treated in a scanty, confused and at times rather paternalistic manner. One might have hoped that on the eve of the new millennium the guardians of medical ethics in this country would have shown a better understanding of the society they are meant to serve. This is why I stated at the start that this was one of the issues which inclined me to believe that the medical profession has not yet changed its mindset. I should say that the Catalan code is quite different and, while it could be improved and expanded in many aspects, it is a clearly modern text.

With respect to the Code of Professional Ethics of Spanish Nurses, I have recognized elsewhere that it contains an impressive number of articles establishing the obligation of nurses to conduct and participate in informed consent processes<sup>23</sup>. However, the wording, layout and order of the articles make it difficult to gain a clear idea of the ethical obligations of nurses. As a result, it urgently requires comprehensive revision.

All that remains, finally, is for me to express the hope that professional ethics in Spain is gradually transformed into a reflection upon our ethical obliga-

Simón Lorda P, Barrio Cantalejo IM. El consentimiento informado en enfermería: Un modelo integral. JANO 1995; XLVIII (1117): 911–921.

tions as professionals, with more explicit, well grounded and detailed content than the sparse and somewhat rigid system of rules which constitutes our current Codes, enabling these to be replaced by practical handbooks of ethical excellence of the quality of the one produced by the American College of Physicians<sup>24</sup>.

## 3. Does informed consent really constitute a new model for the doctor-patient relationship?

I owe this question to Javier Júdez, secretary of the Institute of Bioethics at the Health Sciences Foundation, and his negative response, which I echo, is the starting point for this section. In fact, for a long time I argued that informed consent constituted a new model for the doctor–patient relationship. However, I now believe that this way of putting things tends to confuse our moral obligations when requesting informed consent with the manner in which this actually occurs within the context of a relationship which should be both human and professional at the same time. That is to say, there are quite different ways of meeting the moral obligations with respect to information, consent and patient participation in decision-making in general. Sometimes this is because our understanding of these moral obligations differs radically from one case to another. And at other times, even when the basic assumptions are very similar, they give rise to different models of the clinical relationship.

### 3.1. Ezekiel and Linda Emanuel: four models of the doctor-patient relationship

The history of medical literature on the doctor-patient relationship has been marked by a succession of major contributions which have served to synthe-

24. American College of Physicians. Ethics Manual. Ann Intern Med 1998; 128:576-594.

size and stimulate debate about the appropriateness of different models of the doctor–patient relationship. As a minimum, one might recall the article by Szasz and Hollander in 1956 or by Mark Siegler in 1982<sup>25</sup> <sup>26</sup>. I believe that at present the 1992 article by Linda and Ezequiel Emanuel<sup>27</sup> – recently translated into Spanish<sup>28</sup> – is the one which continues to best describe the current state of the debate, even more than subsequent valuable contributions such as Quill and Brody, 1996<sup>29</sup>.

Emanuel and Emanuel argue that modern medicine draws on four paradigms or ideal models of the doctor–patient relationship, which they term paternalistic, informative, interpretative and deliberative. Each of these embodies a different way of expressing the moral idea of informed consent. In this regard, there is a qualitative leap between the paternalistic model and the other three.

According to the classic paternalistic model, as we already know, patients should only be given information and asked for consent when this is essential to optimize the patient's collaboration with the health procedures which the doctor, in his technical and moral wisdom, considers necessary to ensure the health of the patient, as this is defined by the doctor. This model is incapable of incorporating the anthropological shift of modernity towards moral autonomy. Despite what the authors of the article say, I do not believe there is any place for this model in contemporary medical relationships. At this point, someone usually asks, "Not even if the patient wants it?" However, this question is logically contradictory, because if the patient voluntarily – either explicitly or implicitly – states his or her wish to be treated 'paternalistically'

Szasz TS, Hollender MH. The basic models of the doctor-patient relationship. Arc Intern Med 1956; 97:585–592.

Siegler M. The physician – patient accommodation: A central event in clinical medicine. *Arch Intern Med* 1982; 142:1899–1902.

Emanuel EJ, Emanuel L. Four models of the physician – patient relationship. JAMA 267:2221–6.

<sup>28.</sup> Couceiro A. Bioética para clínicos. Madrid: Triacastela, 1999; pp. 109–126

<sup>29.</sup> Quill TE, Brody H. Physicians' recommendations and patient autonomy: finding a balance between physician power and patient choice. *Ann Intern Med* 1996; 125:763–9.

this of itself makes it impossible to apply the paternalistic model as it is set out by the authors. In my opinion, the frequent claim that the paternalistic model remains applicable derives more from a rejection of other models which radically embody the concept of the patient's moral autonomy and which are frequently what springs to mind when the term 'informed consent' is mentioned – in particular, what Emanuel and Emanuel call the informative model – than from a genuine conviction of the need to restore paternalism. In other words, it is a reactive rather than a truly proactive claim.

At the same time, it should be clear to anyone with a modicum of awareness that the informative model does not adequately reflect the moral and human complexity of the encounter between health professional and patient. Indeed, I believe that it is more of a theoretical construct than a tangible reality; nobody goes to the doctor with absolute clarity about their own values and with no desire whatsoever to hear the doctor's opinion as to what should be done. And, in the unlikely event of a patient seeking to apply this model to an encounter with a doctor or nurse, I am not at all clear that it would be morally acceptable for the health professional to acquiesce. Far worse, in my view, is the fact that health professionals themselves, in a paradoxical intensification of defensive medicine, have at times shifted towards this model, reasoning that, "if the patient is the one who decides, then I know what I'm going to do; when a patient comes to see me, I'm going to explain the alternatives so that he can tell me what he wants us to do, and that's what we'll do." All that this radicalization of 'the right to be left alone' achieves, in my humble opinion, is to abandon the patient and to undermine the moral mission of the health profession, which is to procure people's health on the basis of respect for their beliefs and ideals. When a health professional adopts this approach, it is a negation of his moral duty.

The real choice with regard to the doctor–patient relationship, therefore, is between the interpretative and the deliberative models. I believe that both satisfy the moral requirements of informed consent. The fundamental difference between them lies in the degree of moral leadership exercised by the doctor through the use of persuasion. However, in contrast with the authors of the article, I do not believe that the best model is what they call the delib-

erative one. Rather, it is my opinion that one or the other should be applied in light of actual circumstances. Indeed, I would add that the deliberative model, if it is not managed properly, may spill over into paternalism while the interpretative model provides better safeguards against this danger. I believe that these are the models explored in a recent study published in the British Medical Journal, which asked patients whether they preferred a more directive style ('paternalistic') or a more participatory one, and concluded that patients did not have a clear preference for either but that, instead, the doctor should choose one or other in light of the interpersonal context<sup>30</sup>. But what concerns me here is whether the term *deliberative model* is the right one. I believe not. In my opinion, both models address moral consideration of what should be considered and done in deliberative terms, and this in my opinion is currently the most fruitful model of moral analysis. But that is a matter for the following section.

#### 3.2. Deliberation: articulating ends and means

In the above sections, we have discussed in some detail the problems of principlism, starting from the assumption that the best ethical analysis of moral conflicts in medicine is one which is based on the founding principles of bioethics. In practice, this assumption often leads to an excessive simplification of the conflict in principlist terms, and to the error of thinking that simply by classifying something as 'non-maleficent', 'unfair' or 'non-beneficent' this automatically (mathematically) solves the moral conflict, and allows the course of action to be determined in a straightforward manner. This position, unfortunately adopted by many bioethicists, could not be more mistaken.

In this respect, I believe that we need to reclaim the deliberative procedure as the best way of exploring what is to be done in any given situation. In this, once again, I follow Diego Gracia<sup>31</sup>, although I have also been influenced by

<sup>30.</sup> McKinstry B. Do patients wish to be involved in decision making in the consultation? A cross sectional survey with video vignettes. *Br Med J* 2000; 321:867–871.

<sup>31.</sup> Gracia D. La deliberación moral: el método de la ética clínica. Med Clin (Barc) 2000.

the deliberative and participatory democracy of authors as diverse as Amy Gutman, Charles Taylor and Michael Walzer, and by what we might call the deliberative political constructivism of Rawls' 'political liberalism', together with the proposals of European discursive ethics along the lines of Apel, Habermas and Adela Cortina. Together, these give rise to a deliberative procedure which, starting from Aristotle's posing of the question in Book III of Nicomachean Ethics, insists on the modern necessity of recognizing all participants in practical discourses as valid contributors. Deliberating means, therefore, engaging in dialogue in the context of recognizing the equality of all before all, with the purpose of considering the possible courses of action in light of the principles or values in play, taking into account the possible consequences of each course of action and being aware of the circumstances of each specific case being deliberated upon in order to choose that course of action which brings us closest to achieving the desired aim. Deliberation has classically been the axiomatic procedure of clinical practice, and it should also be so in ethics, even once we assimilate the postulates of Modernity, such as respecting decisions made by those whom they affect.

The essence of the deliberative process lies in the correct articulation of ends and means, because "things being as they are, and man being as he is, one should in everything search not for what is absolutely best but for what is the best possible given the circumstances" 32. But, as Pierre Aubenque argues, anyone who hopes to find in Book III of *Nicomachean Ethics* any statement as to the effective manner in which to do this (that is, who hopes to find there a psychology of deliberation) will encounter only frustration, because Aristotle dedicates most of his time to discussing the subject of such deliberation, and who engages in it, but not the procedure – how one deliberates. And what Aristotle says is that deliberation is an investigation of things which are not necessary, that is which could be done in one or several ways, and that a prudent man deliberates well. And he also says, as Pierre Aubenque reminds us, that "deliberation with oneself is nothing other than an internalized form of shared deliberation, just as it was practised, if not in the Assembly of the people, then at least in the Council of men of experience," that is, the 'pru-

32. Aubenque P. La prudencia en Aristóteles. Barcelona: Crítica, 1999. pp. 123 and ff.

dent men' of Athenian democracy. However, Aristotle was not against the participation of the common people in practical, deliberative discourses; to reach judgement on simple issues which affect the group, it was not necessary to be wise, but only to be 'cultivated'.

To summarize, I believe that the interpretative and deliberative models set out by Emanuel and Emanuel satisfy the deliberative procedure and incorporate the moral requirements with regard to informed consent raised by the anthropological shift of Modernity. However, I also believe that the deliberative procedure raises a problem which remains unresolved. In the Aristotelian deliberative model, deliberation focuses on how to ensure that the means fit the ends: in other words, it focuses on the means, because the ends are already given. However, in medical ethics the aims of medicine are not so clear. Indeed, an article by the highly regarded North American bioethicist Robert M. Veatch, entitled "Abandoning Informed Consent", reveals precisely this frustration with the lack of clarity of the aims of medicine<sup>33</sup>. Veatch argues that informed consent is impossible because it is impossible for the doctor to really identify the values of the patients he is treating, and argues that this would only be possible in moral communities where doctors and patients shared 'deep values' which oriented their decisions. As I see it, the problem is not one of 'values', but rather of the goals of health activities. That is, the interpretative and deliberative models of Emanuel and Emanuel may encounter the problem that the disagreement relates not to the core values of the patient and the decision to which these lead, but rather to the purposes of medical activity and the role of the doctor. This is why it is essential to consider the issue of the goals of medicine in more depth. The project which was pioneered by the Hastings Center Report in the early 1990s is a good starting point<sup>34</sup>, but further progress can only be made if we bring together health professionals, citizens and governments in a global discussion with bioethics at its core<sup>35</sup>.

<sup>33.</sup> Veatch RM. Abandoning Informed Consent. Hastings Cent Rep 1995; 25(2): 5-12.

<sup>34.</sup> The Hastings Center. The goals of medicine. Hastings Cent Rep 1996; 26(6): Sup.

Gracia D. "Los fines de la medicina en el umbral del siglo XXI." In: Sarabia J, ed. La bioética, horizonte de posibilidades. Madrid: Asociación de Bioética Fundamental y Clínica,2000. pp. 55–68.

### 3.3. Nurses and families: neglected by the theory of informed consent

In this section, I would like to raise two problems which, I believe, have been neglected by the theory of informed consent due to its focus on a model of the health relationship which derives from the highly individualistic culture of the United States, causing it to see the problem exclusively in terms of the doctor on the one hand and the patient on the other. However, this does not actually reflect reality in the USA, and far less so in Spain. In fact, the health relationship is a complex one involving many participants. Even if only the doctor and the patient are physically present in the consulting room, the relationship may also involve the health organization and pharmaceutical companies, together with others who are more intimately involved and may even be physically present. I will consider two members of this latter group: the family and nurses. And below I will briefly consider some others, such as students and interns.

When I talk of the problematic (not the negative) role of the family in health relations, I am not referring to the intervention of relatives in the event of a patient being incompetent. (Such decision-making by representation constitutes a separate area, and one which is complex in its own right.) But what I am talking about here is the fact that competent patients are also affected by the decisions of others. The ties of mutual moral responsibility which exist within the nuclear family and, above all, in family units as extended as those which in a Mediterranean society such as Spain affirm the right of relatives to have some sort of participation in the decision-making process. This is clear, above all in those decisions which seriously affect the patient's life expectancy or quality of life, among other reasons because families continue to bear the greatest burden of caring for patients.

The problem revolves around how and to what degree the family should be enabled to participate in decision-making. If such conditions are not imposed, then the patient's autonomy and privacy are at risk. On the other hand, if the family are excluded then both the patient and the family may have the sensation that the patient has been 'kidnapped' by the doctor. Per-

haps the only solution is to make cautious but clear efforts to build a relationship first with the patient and then with the family, in accordance with the patient's wishes, with the aim of negotiating and deliberating upon this issue. In any event, this is a complex area for which I can offer no fixed formulae.

The issue of nursing strikes me as being similarly complicated. This is particularly the case of primary care nursing, because this enjoys a far higher degree of professional autonomy than hospital nursing. Following the model proposed by Carpenito, nursing consists of two functions: independent and interdependent. The independent functions are those which constitute the core activities of nursing, for which it is directly responsible. By contrast, interdependent functions are those in which nursing performs task in cooperation with other health professionals, with whom it shares responsibility<sup>36</sup>. In accordance with his commitment to promoting the professional identity of nursing, Carpenito does not mention the dependent functions which once constituted the bulk of nursing activity, in which nurses were limited to following the instructions of other professionals - doctors in particular - neither initiating nor taking responsibility for what they did, but simply obeying the law of due obedience. I am not sure that this picture is quite accurate, and suspect that such dependent functions continue to exist. Perhaps what happens is that within the interdependent functions there is a wide range of situations in which the nurse's level of initiative and responsibility varies.

We can now address the role of informed consent in nursing activity. The attention it receives in the Professional Code of Ethics of nurses makes it clear that it does indeed have a role, although the Code itself, which is confused and old-fashioned, is of little help in identifying exactly what this role is. It seems clear that, when performing independent functions, nurses bear the responsibility for incorporating consent into what they do. For example, curing straightforward bedsores is an independent function which the nurse can only perform under the aegis of informed consent. The real problem, then, lies in the interdependent functions. Here, the problem is knowing whether the nurse's responsibility is limited to her own actions or whether

<sup>36.</sup> Carpenito LJ. Diagnóstico de enfermería. Madrid: Interamericana, 1991.

she also has responsibilities with regard to the process as a whole. This is open to debate.

### 4. The problem of information: 'what', 'how much' and 'who'

The issue of information has historically focused on debates around informed consent, to such a degree that this has often been the sole topic of discussion. Here I will focus on some aspects of information which, in my opinion, continue to be problematic. These concern the long-standing questions as to 'what', 'how much' and 'who'.

#### 4.1. What?

I will only refer here to two issues which particularly concern me. The first of these relates to section 10.4 of Spain's General Health Act. This states that the patient has the right "to be notified if any prognosis, diagnosis and therapeutic procedures applied may be used as part of a teaching or research project which, in no event, may pose an additional risk to his or her health," and that, "in any event the prior written authorization of the patient and its acceptance by the doctor and the management of the relevant health centre will be required." Almost everyone who reads this section of article 10 notices the phrase 'research project', which immediately refers them to the specific legislation in this area, which regulates the issue of informed consent in some detail and therefore does not pose any problems. But I do find a problem, and this is with the phrase 'teaching project'. How should this be understood? In my opinion, this phrase refers to the participation of students and interns, who are doctors acting as specialists, but who do not have a qualification in caring for patients. And the question under discussion is not whether students and, above all, interns, may take an active role in the process of obtaining informed consent from patients - to which I would argue that the answer is no in the case of the former and yes in the case of the letter, depending on their level of qualification, as Juan Antonio Garrido explained very clearly some time ago<sup>37</sup>. The problem, rather, is whether or not the institution, the student, the intern or the teachers are obliged to inform patients of this fact. And the second problem, which derives from this, is whether health service users may therefore reject this participation and request that they only be attended by staff who are fully qualified for this purpose.

The second question, which is to a large degree an extension of the first one, concerns whether the patient may demand that the professional or the institution provide information regarding the limitations and skills of the professionals responsible for providing care in order, on the basis of this, to accept or reject the participation of these professionals or, even, to request transfer to another care centre. Or, to state this as a negative, can an institution conceal information about the effectiveness of the care it provides, or about the specific personal circumstances of the professionals working for it? Specifically, in our public health system, does the patient have the right to be informed of the surgical infection data for the hospital and for each health professional in order to be able to decide freely where to be operated upon and by whom? What obligations do health institutions have with respect to patients and professionals, where there are issues of alcoholism, drug addiction or being HIV positive? Do patients have the right to this kind of information, and how can this be combined with the need to protection the right to privacy of the health professional? These are not merely hypothetical or theoretical questions: I am sure that everyone present will be familiar with real cases where these issues have arisen. Possible solutions have been the subject of frequent debate in the bioethics literature, but we still have no definitive answers. But in a public system such as the one in Spain, these problems are particularly acute as a result of the very real challenge of choosing where to be treated.

#### 4.2. How much?

The question as to how much information should be provided regarding the risks associated with any intervention is another long-standing question

<sup>37.</sup> Garrido San Juan JA. Formación en comunicación y consentimiento informado en nuestro sistema de residencia. ¿Qué información puede y debe dar un residente? *Med Clin* (Barc) 1998; 111:739–41.

which has historically had a decisive influence on the history of the legal theory of informed consent in the USA. As we have already seen, in the USA, of the three legal tests historically applied, the one which continues to carry greatest weight is that of the reasonable doctor, far more so than the standard of the reasonable individual or a subjective standard. In Spain, the concept of the reasonable doctor has also tended to be the legal standard by which information is judged, with respect to the concept of typical risk. However, there have already been some rulings which appear to be shifting towards a more subjective test, where what is important is identifying whether or not the information would have affected the patient's decision.

But what really concerns me in this section is the role played by the health professional when he or she has not determined the quantity and quality of the information but this has, instead, been brought by the patient. I am referring in particular to two eventualities. The first of these is the information available in drug leaflets, and the second is information which patients obtain from the internet and which may be of a low standard or of a very high standard, for example online versions of articles in journals such as the *Annals of Internal Medicine*, specifically adapted for patients. In both situations, the doctor is more of a moderator and interpreter of information rather than its provider, and this brings with it new ethical and legal challenges which we will need to address.

#### 4.3. Who?

Another long-standing problem concerns the question of who should provide the information and request consent. In this regard, there are two aspects which merit some consideration. One is the discussion as to whether the responsibility of informing the patient lies with the person who indicates the treatment or the person who performs it. And another concerns the role of nurses.

The General Health Act does not address these questions directly. Section 7 of article 10 states that the patient has the right to be assigned a doctor "of whose name he will be informed", and who will be his "principal point of

contact with the care team," but does not state that this individual will bear all the responsibility with regard to information. In the Catalan health legislation, by contrast, article 2.3. reads as follows:

"It is the duty of the doctor responsible for the patient to ensure compliance with the right to information. Those care professionals involved in caring for the patient or applying a specific technique or procedure must also assume responsibility for the information process."

This article is somewhat confusing. It starts by stating that the obligation to inform lies primarily with the doctor responsible for the patient, but goes on to say that others – doctors, nurses, technicians etc. – also have responsibilities, although these are not specified. At the same time, in practice it may be difficult to determine who the doctor responsible for the patient is, particularly in complex clinical situations where multidisciplinary intervention is required. Indeed, it is sometimes difficult to determine this where there is a change of care level from primary to specialized care.

In any event, it strikes me that the polemic as to who should accept the responsibility occurs because we continue to see informed consent in terms of conventional morality. We can only move beyond this if health professionals understand that informed consent is inherent to their professional practice, based on the principles of non-maleficence and beneficence. At the same time, we need to organize so that we provide the same information in a coordinated, cooperative manner. The only way of doing this is by achieving genuine team working, an area where practice and theory remain out of step.

### 5. Capacity and the problems associated with it

I have always argued that the really thorny issue of informed consent is not that of information but that of capacity. There are, I believe, at least three controversial questions which must be discussed. And I will leave a fourth, even more controversial issue – that of minors – for later.

#### 5.1. The terminological problem

In my opinion, one of the sources of difficulties with the issue of the capacity of patients lies in the lack of clarity of the Law in this regard. In the first place, there is the vast number of terms used in the legislation to describe this situation. The latest addition, in the Catalan legislation, is the term *competencia* (competence) and its derivatives competent, incompetent etc. But more problematic, in my opinion, is the conceptual issue. Jurists are reluctant to recognize that the real problem in healthcare relates to natural or *de facto* capacity, rather than legal or *de jure* capacity. The issue, therefore, is whether this particular patient, here and now, is capable of taking this particular health decision, and this is a *de facto* question. This is the reality we need to address, and which conditions the response to the questions as to how we do this and who is responsible for it.

### 5.2. Who should determine the competence of patients?

When jurists fail to recognize the problem of competence as a *de facto* problem and remain wedded to the concept of legal capacity, it is hardly surprising that they should respond by saying that this is the exclusive competence of judges. But the notion that every time a patient's competence is questioned in a health centre we have to call a judge should alarm both those working in the health sector and the judges themselves. This is why I believe it is essential to clarify the fact that we are talking fundamentally of *de facto* incompetence and that doctors (and nurses?) can and should determine whether or not this competence exists. When this incompetence is established, two groups of problems arise: the first concern the ethical and legal issues relating to representation, and the second concern the question of when and how this declaration of *de facto* incompetence should reach the courts.

#### 5.3. Criteria, standards and protocols

In this regard, I will simply mention that I believe that establishing criteria, standards and protocols for the evaluation of *de facto* competence is an absolute priority in Spain. Historically, doctors have evaluated this competence

using intuitive (and often highly effective) procedures. But I believe that the complexity of modern care requires the standardization of these procedures using objective measures. And this despite recognizing that, at bottom, the assessment of capacity contains a very important value element and is, in the final instance, a pragmatic judgement. Which of course is why accurate, automatic procedures to evaluate the capacity of individuals do not exist.

### 6. Truth and lies in objections to informed consent

The theory of informed consent has many proponents, but it also has many critics, both in the USA and in Spain. We will look, then, at some of the objections which have been raised to informed consent, both from a theoretical perspective and, above all, from a practical one. These objections are often expressed in the form of phrases which are little more than clichés among health professionals. We will look at seven of the most representative of these, and will briefly analyse to what degree, if at all, they are justified.

#### 6.1. Intolerable interference

"The theory of informed consent constitutes intolerable interference by society and, above all, by legislators and judges, in professional medical activity, because it places upon doctors obligations which go beyond their professional duties, which consist solely in striving to ensure the health and protect the lives of their patients."

This objection is one with which we are familiar. It is usually formulated by health professionals who continue to believe, as did Marañón, that the liberal professions should be responsible for defining all of their moral obligations, and that nobody else should interfere in this process, defining it as an internal matter for the profession itself. Society as a whole, and therefore legislators and judges, have no right whatsoever to become involved in defining the duties of doctors. If applied rigorously, this thesis leads to the conclu-

sion, fiercely defended by Marañón, that doctors are bound by ethical duties but not by legal ones. Although many doctors who find themselves in agreement with the phrase at the start would baulk at this conclusion, it is in fact implicit in it.

The philosophical current which underlies this notion of interference is paternalistic beneficence. However, as we have already seen, Modernity introduced the idea that human beings are autonomous and society has since sought to construct mechanisms which ensure that this autonomy is respected in all spheres of life. Modern law has been one of these mechanisms, and has therefore taken upon itself the task of establishing that the professional duties of doctors must be founded upon this basis. This is indeed the origin of the theory of informed consent in the USA, in Spain and in any other country whose sociopolitical structure is based on modern, liberal-democratic principles. In summary, then, professionals who make statements like the one above still have a lot of thinking to do about the content and origin of the ethical principles which inform their professional morality.

### 6.2. When patients reject information and participation

"The theory of informed consent is based on an erroneous premise, because patients do not wish to be informed and nor do they wish to participate in the decision-making process."

This is an important objection and the North American literature on informed consent has addressed it, and studied whether it is actually correct, although perhaps not in the necessary detail. One of the first authors to study this question was Ralph Alfidi. The two studies he published<sup>38</sup> are intriguing because, according to Meisel and Roth, the results they produce are contradictory<sup>39</sup>. According to these authors, this is due to the different methodologies used in the two studies. In Alfidi's first study, the vast majority of patients appreciated

being informed about potential complications of angiography, while in the second study, 176 of 275 patients interviewed said they did not want to be informed about any potential complications associated with X-rays using contrast media. By contrast, in the most recent study, by Winfield, Friedland et al., 95% of the 787 patients surveyed preferred to have been informed about the risks of these X-ray procedures with contrast media<sup>40</sup>. A study employing far greater methodological consistency, designed by Ruth Faden et al. to explore the wishes of patients with epilepsy or the parents of children with epilepsy with regard to information about the side effects of drugs and alternative treatments revealed, however, that the demand for information was far greater than the amount of information usually provided<sup>41</sup>. Overall, it can be argued that empirical studies tend to show that North American patients want more information than they are actually given, rather than the opposite.

In any event, these wishes for information appear to depend on a number of factors. One is the type of illness. According to Lidz, Meisel, Osterweiss et al., one of the factors which determine both the wish for information and the participation of patients in decision-making is whether the illness is acute or chronic<sup>42</sup>. Patients with acute conditions appear to be more likely to take a passive, detached attitude to treatment decisions. By contrast, patients with chronic conditions tend to be more active and more interested in receiving information and participating in decisions. According to these authors, these differences clearly reflect different ways of adjusting their lives to the reality of illness. People with acute illnesses tend to assume the role of 'patient' more readily, and to give the doctor control of their bodies. In exchange, they hope that the doctor will return them to health, thereby enabling them to resume their former life. However, patients with chronic conditions, who cannot aspire to this kind of rapid recovery, resist such a move because this would mean ceding control over their body and their autonomy for lengthy periods of their existence<sup>43</sup>.

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<sup>38.</sup> Alfidi RJ. (1971). Alfidi RJ. (1975).

<sup>39.</sup> Meisel A, Roth L. (1981).

<sup>40.</sup> Spring DB, Winfield AC, Friedland GW. (1988).

<sup>41.</sup> Faden RR, Becker C, Lewis C, Freeman J, Faden AI. (1981).

<sup>42.</sup> Lidz CW, Meisel A, Osterweiss M, Holden JL, Marx JH, Munetz MR. (1983).

<sup>43.</sup> In this respect, it is interesting to note the study by Strull, Lo and Charles of 210 patients diagnosed with AHT, designed to identify how much information they wished to receive

Another factor which has a very significant influence on whether or not the patient will demand information and ask to participate is his or her sociocultural context. This sociocultural context will have a decisive influence both on how the illness is perceived and on the patient's understanding of him or herself as an autonomous being or not. The patient's perception of the illness, and whether or not he or she comes from a cultural universe which offers explanations of illness which differ from those provided by the western technical-scientific model, is very important for the patient to decide which type of information he or she wishes and the level of participation in treatment<sup>44</sup>. Indeed, if the patient's health decisions are condition by other factors or values than scientific medical information, then this information may even be superfluous<sup>45</sup>.

regarding their illness and treatment, and how the decision-making process developed. 41% of patients would have preferred more information than was provided, 53% received "the right amount", and only one patient wanted less. Similarly, 55% of patients preferred a "fairly detailed" or "very detailed" discussion of treatment. However, a significant percentage of these patients preferred to leave decision-making in the hands of the doctor. See Strull WM, Lo B, Charles G. (1984).

- 44. According to Gillick, in the USA, models to explain illness and health which differ from the western one are very common, and failure by doctors to identify these is one of the causes of failure in the therapeutic relationship. See Gillick MR. (1986).
- 45. In this regard, the study by Christensen Szalanski et al. is very revealing. This examined the criteria used by paediatricians and obstetricians when deciding how much information to give to parents regarding the risks of circumcision, and compared the effects of partial and full disclosure. The study hypothesis was that increasing the amount of information about potential complications associated with circumcision would increase parent satisfaction with the doctor's care and would reduce the percentage choosing to have their sons circumcised. The results completely contradicted this hypothesis. Neither full or partial disclosure of information, nor the manner in which it was transmitted (orally or with written support) modified circumcision rates. Indeed, if after full disclosure the doctor urged parents to assess the risks and benefits of the procedure, all this achieved was to increase anxiety and discomfort, and generate hostility towards the doctor, without modifying the decision taken. This was due to the fact that parents taking the decision to have their sons circumcised did so more on the basis of considerations of family tradition or religious beliefs than on the basis of medical data, and all the provision of such data achieved was to make decisionmaking more difficult. See Christensen Szalanski JJJ, Boyce WT, Harrell H, Gardner MM. (1987).

Whether decisions are taken individually or communally in the patient's cultural model also has a major influence; in the first case, the demand for information and participation is greater, while in the second it is the family or the community which takes precedence. In this respect, it is interesting to note the differences of attitude found by a study comparing different North American cultural communities (of European, Korean, Mexican and African origin)<sup>46</sup>.

Obviously there are other factors, such as age and education, which influence the demand for information and participation in decision-making<sup>47</sup>. But it is important to note that demands for information and participation do not necessarily go hand in hand. In fact, the former appear to be far more frequent than the latter. According to Lidz, Meisel et al., the patients in the study gave four different reasons for wanting more information<sup>48</sup>: to be able to follow doctors' instructions more closely, as a demonstration of courtesy and respect towards them by the doctor, to enable them to exercise their right of veto and, finally, to be able to participate in the decision-making process. Furthermore, only 10% of patients interviewed in the study gave this reason.

In any event, it is clear that, at least in the North American context, a high proportion of patients want to receive information and some also want to participate in the decision-making process. Furthermore, society has decided that offering this option is part of showing respect for people and therefore constitutes a moral obligation. As a result, even if the proportion of patients wishing information and to participate in decision-making were low, this option should continue to be offered because it represents a moral obligation which exists regardless of the empirical wishes of specific patients. Obviously we need to ensure that those patients who do not wish to accept this offer of information and participation are free to reject it.

<sup>46.</sup> European and Afroamerican communities share an autonomous decision-making model; Mexican American and Korean American communities are community and family-based. See Blackhall LJ, Murphy ST, Frank G, Michel V, Azen S. (1995).

<sup>47.</sup> With regard to age, and older patients being more passive than younger ones, see for example Cassileth BR, Zupkis RV, Sutton Smith K, March V. (1980).

<sup>48.</sup> Lidz CW, Meisel A, Osterweis M, Holden JL, Marx JH, Munetz MR. (1983).

And what is to be said of the Spanish situation? Firstly, that there are no studies indicating what level of information and participation patients require, apart from the occasional general sociological survey. This is therefore a field where further research is required. Secondly, that it seems likely that attitudes will generally be slightly more reticent with regard to information and participation than in the United States, although there will almost certainly be significant generational differences. In any event, Spain's Mediterranean cultural context, which tends to favour paternalism over individual autonomy, will undoubtedly have an impact in this regard. Thirdly, despite the above, it is also clear that Spanish society as a whole views as a moral and legal obligation the need to offer information, request consent and facilitate the participation in the care process of those patients who so wish.

#### 6.3. Inadequate understanding

"What the theory of informed consent proposes is pointless, because the reality is that patients do not understand the information they receive, because it is too complex and too difficult for them to evaluate and analyse it."

Eric Cassell identified this, in the first edition of the *Encyclopedia of Bioethics*, as "the obstacle to informed consent most frequently cited in clinical settings"<sup>49</sup>. As early as 1972 Ingelfinger, in a famous editorial in the *New England Journal of Medicine*, cited this argument to question the theory of informed consent in research settings<sup>50</sup>.

The first challenge faced by this claim is to provide empirical evidence to back it up. In Spain, we are not aware of any studies of this issue. However, there are several in the North American literature. The first problem faced by this type of research is that there are no clear criteria for defining which variables to use in order to analyse the complex psychological phenomenon which we call 'comprehension'. Back in 1981 Meisel and Roth noted that the first problem faced by empirical studies of comprehension was the lack of

homogeneity in this regard<sup>51</sup>. Many studies of 'comprehension' analyse it by considering 'recall'. According to this approach, the level of a patient's comprehension of the information provided by the doctor can be estimated by analysing what the patient recalls of the information and of the informed consent process in general. Studies conducted on the basis of this hypothesis have concluded that the level of comprehension of information was disappointingly law, because they found that patients recalled almost nothing of what they were told, irrespective of the time lapse between information and interview<sup>52</sup>. However, the identification of 'comprehension' with 'recall' is problematic. Just because, shortly after receiving it, a person forgets complex information provided to enable him to take a decision, it does not necessarily follow that at the time of receiving the information he did not understand it. Forgetting is a psychologically normal process, above all when it involves complicated information which is only used at a particular point in time and will not be used again by the individual concerned. Nor is it possible to establish safe inferences about 'comprehension' by analysing the 'retention' of information (that is, by analysing short-term memory one or two hours after the information has been provided) because forgetting immediately may also be normal. However, it is true that other studies using more complex variables to measure comprehension, where the information itself is less complex and is provided in a much more careful and structured manner, have also found serious deficits in the comprehension of information<sup>53</sup>.

<sup>51.</sup> Meisel A, Roth L. (1981).

<sup>52.</sup> The classic studies of this sort are Robinson G, Merav A (1976). Byrne DJ, Napier A, Cuschieri A. (1988). Morgan LW, Schwab IR. (1986). In the research sphere, see the studies by Woodward WE. (1979). Bergler JH, Pennington AC, Metcalfe M, Freis ED. (1980).

<sup>53.</sup> One of these classic studies was conducted by McCollum and Schwartz in 1969 at the Center for Clinical Research at Yale University. In it, the authors interviewed 140 mothers of children with very rare diseases who were about to be admitted to the Center for the aetiological, physiopathological and therapeutic investigation of their conditions. After a meticulous information process in which different people explained how the Center worked and the purpose of admitting the child, 44% of mothers showed themselves to be incapable of understanding that the purpose of admission was not so much therapeutic as for research purposes, and that there was no guarantee that their child could be cured. McCollum AT, Schwartz AH. (1969). See also the review of similar studies conducted by Wallace LM. (1986).

<sup>49.</sup> Cassell E. (1978).

<sup>50.</sup> Ingelfinger FJ. (1972).

In any event, the fact that empirical studies show that patients do not understand information fully is not an objection to the theory of informed consent. It may simply show that the manner in which doctors transmit information to patients does not facilitate its comprehension. The problem, then, lies not so much with patients as with doctors, and these studies should encourage us to reflect upon the factors which limit comprehension and to search for new ways of transmitting information with greater clarity. As we have already noted, the need to obtain informed consent is a duty of health professionals, correlating in large measure to a right of patients as established by society, and health professionals therefore have the obligation to provide all the means at their disposal to ensure that this right is respected. And furthermore, because this right also corresponds to the moral duty of beneficence, it constitutes a stronger requirement than a simple ethical-legal obligation.

#### 6.4. The anxiety generated

"The theory of informed consent is morally questionable because it generates unnecessary anxiety for patients."

This is another of the classic arguments of critics of the theory of informed consent. In 1979 Loftus and Fries, in an article published in *Science* and to which we referred in section 1, strongly defended this position, with reference to research activities<sup>54</sup>. Although their position was hotly contested<sup>55</sup>, many North American doctors agreed with them at the time, and may continue to do so today<sup>56</sup>.

However, empirical studies in this area do not confirm this position, suggesting that it is based more on prejudice and ideology<sup>57</sup>. Studies are now also being undertaken into this issue in Spain. None of these found that information increased anxiety – measured using objective tests – but instead identified increased satisfaction of health service users, higher levels of knowledge and, even, reduced anxiety<sup>58</sup>. And even were anxiety to be increased, this would not necessarily be such a problem. Many of the important events in our lives cause anxiety, but we do not therefore argue that it would be better not to know what they involve or what consequences they might have (for example, getting married, applying for a loan, sitting an exam, or performing surgery).

#### 6.5. Side effects

"The theory of informed consent is morally questionable because all it achieves is to cause patients to suffer more discomfort and side effects than when they do not receive information."

This objection is very similar to the previous one. Some North American doctors raised it to question the theory of informed consent<sup>59</sup>. In addition, some studies in the research sector have shown that the appearance of mild, subjective side effects was more frequent when information was given about them than not, and that this endangered some classic procedures such as

<sup>54.</sup> Loftus EF, Fries JF. (1979).

<sup>55.</sup> Marcus R, Kuclick B, Bercovith S. (1979).

<sup>56.</sup> In a study on obtaining informed consent for studies with intravenous contrast medium by US radiologists, 83% of those surveyed estimated that informed consent increased anxiety on the part of the patient, and 40% of those who do not obtain consent give this as the second most important reason for their position (the most important is the assumed low risk of the procedure). See Spring DB, Akin JR, Margulis AR. (1984).

<sup>57.</sup> In the study cited above, by Spring, Winfield, Friedland et al., only 23% of the 902 patients interviewed said they felt more anxious after being informed of the risks of the radiology procedures they were about to undergo. Spring DB, Winfield AC, Friedland GW. (1988); 1243–1245. Of more interest are those studies which seek to conduct objective measurement of anxiety pre- and post-information, using instruments such as the STAI (Spielberger State Trait Anxiety Inventory). For example, Christopherson B, Pfeiffer C.(1980). Inglis S, Farnill D. (1993). Older and methodologically more questionable studies, but still of interest are Langer EJ, Janis IL, Wolfer JA. (1975). Lankton JW, Batchelder BM, Ominsky AJ. (1977).

<sup>58.</sup> Moix J, López E,Otero J, Quintana C, Ribera C,Saad I, Gil A. (1995). Hernando Robles P, Ponts Torrents X, Falcó Torrents J. (In print).

<sup>59.</sup> Katz RL. (1977).

placebo controls<sup>60</sup>. However, other studies did not confirm this hypothesis at all<sup>61</sup>.

Of course, it is possible that certain patients become hyper-aware of complications as a result of receiving information, but these are unusual cases, because otherwise the studies of anxiety noted above would not produce the results they appear to. Therefore, the fact that occasionally, in individual patients, information may cause psychogenic side effects does not provide any basis for questioning the theory of informed consent. And such a reaction may anyway indicate the possible incapacity of the patient or trial participant.

#### 6.6. Increased rejection of health care

"The theory of informed consent is morally questionable because it increases the frequency with which patients reject diagnostic and therapeutic procedures suggested by doctors, and endangers their life and health."

Once again, it must be said that empirical studies into the effects of information on patients in North America do not support such claims<sup>62</sup>. I am not

aware of any literature on this issue in Spain. In any event, it is necessary to reflect upon what this means. Even were an increase in the rejection of treatment to be demonstrated, this would not invalidate the theory of informed consent from a moral perspective, if we accept the moral perspective of modernity, which is based on the defence of individual autonomy. And this is because the only thing that a hypothetical increase in rejection of treatment would demonstrate would be that patients' opinions had not previously been taken into account or that their consent had not been genuinely informed and that the decision to accept the procedure did not accurately reflect their wishes and values.

#### 6.7. The time consumed

"The theory of informed consent is impractical because it takes up an enormous amount of health professionals' time, and this is not viable for a health system which aims to be effective and efficient."

This is a commonly heard objection among Spanish health professionals. It may be frequent among North American doctors, but there is almost no literature about it<sup>63</sup>. The first thing to be said is that, given the fact that informed consent is recognized as a fundamental right, health administrations must structure their activities in such a way as to ensure respect for it, in so far as is possible. It is the duty of health managers to reconcile the efficacy and efficiency of the system with respect for patients' rights. Health planning must, then, take into account the fact that time and space are necessary if health professionals are to be able to conduct informed consent processes in a satisfactory manner. The obligation to obtain informed consent derives from the principles of non-maleficence and justice, and failure to satisfy it leaves administrations in a position of objective liability.

Edlund MJ, Craig TJ, Richardson MA (1985). Myers MG, Cairns JA, Singer J. (1987). Dahan R, Caulin C, Figea L, Kanis JA, Caulin F, Segrestaa JM. (1986).

<sup>61.</sup> In the study by Spring, Akin and Margulis noted above, 82% of radiologists interviewed believed that anxiety made a significant contribution to mild reactions to contrast fluid, and 37% went so far as to state that information also influenced serious reactions. However, in the review of two million radiology interventions with intravenous contrast fluid performed during 1982 no significant differences were found in the appearance of reactions to contrast fluid between patients who had been informed of them and those who had not. See Spring DB, Akin JR, Margulis AR. (1984); 609–613.

<sup>62.</sup> In the first study by Alfidi (1971) only 4 of the 232 patients studied rejected the procedure after having been fully informed of potential complications. In Alfidi's second study (1975) only 1 of 275 patients rejected radiological procedure as a result of receiving information. In another study, cited earlier, by Morgan and Schwab, none of the 50 patients given detailed information about cataract surgery rejected the operation. For their part, the surveys conducted by the President's Commission produce very similar results: only 5% of the 288 individuals interviewed had rejected treatment as a result of information contained in the

consent form. See Alfidi RJ. (1971); 1325–1329. Alfidi RJ. (1975); 231–234. Morgan LW, Schwab IR. (1986); 42–45. Louis Harris & Associates. (1982).

<sup>63.</sup> See for example references to this issue in Arnold RM, Lidz CW. (1995).

However, even if the administration fails to fulfil its obligations in this regard, this does not exonerate doctors from fulfilling theirs. The obligation to obtain informed consent derives from the duties of non-maleficence and beneficence. This means that health professionals have a legal and moral obligation to optimize their team so as to satisfy the requirement of informed consent in so far as is possible. Furthermore, professionals also have an absolute moral obligation to dedicate as much time as possible to their patients, to discuss whatever health concerns they may have, so long as this does not mean neglecting their other obligations. Such attention is an essential part of caring for the patient's health.

#### 7. The curse of forms and signatures

I do not intend to dedicate too much time to this issue, despite the fact that written informed consent forms have reached an almost suffocating level in Spain. However, I do wish to analyse who bears the main responsibility for this situation. The finger tends to be pointed at two parties. The first, perhaps inevitably, is legislation and the judges. But the second is the health authorities. Because the Spanish health service, at both national and regional level, as part of its contract with hospitals, began to demand indicators of the level of introduction of informed consent forms, the administration is also seen as being responsible for creating this situation.

I have to say that I think this somewhat misses the point. In my opinion, the main reason why we have entered the jungle of consent forms, and why we continue to stumble around inside it with no sight of an exit, lies with health professionals and their organizations, which have still not really thought about the moral requirement of informed consent in post-conventional terms. Instead of doing this, professional associations have responded by hiring legal practices to draw up their 'informed consent documents', the design and contents of which are enough to make the reader's hair stand on end.

Our problems with forms lie not with the law, nor with the judges, nor with the health authorities. They lie with ourselves.

### 8. Look to the future: post-conventional growth for people in learning organizations

I have almost finished. The purpose of this paper has been to open up debate about issues of the theory of informed consent which require further consideration. I have therefore chosen to end by referring to an idea put forward by Josep M. Lozano, teacher at the ESADE and author of a fascinating book entitled *Ética y empresa* (Ethics and business)<sup>64</sup>. I believe that the future of bioethics, and the future of informed consent, depends upon integrating our moral growth as people and professionals, within dynamic, living organizational structures which both allow us to learn and also learn themselves. This means we must transfer reflection upon informed consent from the individual field to the field of the ethics of health organizations. Only if we begin to understand our moral obligations and our moral growth, within this collective context, can we advance towards greater respect for patients as people. The alternative is to remain trapped by the constraints of defensive medicine, or to practise the most extreme form of pre-conventional paternalism.

<sup>64.</sup> Lozano JM. Ética y empresa. Madrid: Trotta, 1999.

Informed consent in the doctor-patient relationship: legal aspects

Carlos María Romeo Casabona

#### 1. Concept, nature and effects of consent

Consent as a legal concept draws on a long tradition, and is fundamentally the reflection of the wishes and freely given agreement of parties to a relationship, and thus expresses individual autonomy in private legal relationships in general and in contracts in particular<sup>1</sup>. At the same time, the consent of the interested party is a condition of the legitimacy of the action of a third party in so far as this action may affect the former's legal entitlements such as the right to bodily integrity and health, freedom of movement and the right to form and express his wishes<sup>2</sup>.

In the health sector, because the actions of health professionals may affect the physical and moral integrity and individual self-determination of the patient or service user<sup>3</sup>, together with other rights (such as freedom of movement, freedom of belief or conscience, and the right to equality before the law)<sup>4</sup>, this consent constitutes the manifestation of a fundamental right which must therefore be respected and protected as such<sup>5</sup>. As a result, consent in the health sector is not simply a component of a legal contract in the sense of Civil Law, because it does not refer to the establishment, suppression or creation of rights or obligations between the parties to a legal relationship<sup>6</sup>, nor

1. See José M. Fernández Hierro, *Sistema de responsabilidad médica*, 3rd ed., Pub. Comares, Granada, 2000, p. 138.

is it necessarily linked to medical or surgical treatment<sup>7</sup>. At present, it can be understood primarily as a subjective right which is connected to various fundamental rights and which thus confers legitimacy upon the medical act in light of any legal manifestations this may have (either civil or criminal). In principle, a similar status could be attributed to the patient's other rights.

We can therefore state that information and informed consent are legal obligations which respect the autonomy and self-determination of patients, whose fundamental and civil rights are unaltered by any restrictions on the individual's situation as a result of illness. This is without prejudice to the fact that in extreme situations the individual's capacity to form and express his wishes may be significantly reduced and a third party (e.g., the patient's legal representatives), may be called upon to grant consent.

At the same time, the decision of the patient to submit to treatment or diagnostic tests does not in any way imply that these will be successful and have a favourable impact on the patient's health but rather, to the contrary, that the patient accepts any foreseeable risks to his life and health. And this is abundant reason why such a major decision must necessarily be taken freely by the person involved. Furthermore, the doctor cannot assume sole responsibility for his actions but must share it with the patient, informing the patient of the potential risks, asking him about whether he is prepared to accept these risks and thus the intervention itself. The issue with regard to consent is, then, what the patient is consenting to. The answer is that, in addition to consenting to the medical intervention itself, and its diagnostic, preventive or therapeutic aims, the patient is also consenting to the unavoidable risk of harm.

Medical professionals have for some years been aware of the need to have the consent of the patient or the patient's representative. This interest – and

<sup>2.</sup> Carlos María Romeo Casabona, El Médico y el Derecho Penal. I. La actividad curativa, Bosch, Casa Ed., Barcelona, 1981, pp. 141 and ff. and 285 and ff.

Health service users are not necessarily suffering from illness: e.g., donors of gametes, blood or other tissues or organs, or a health person who voluntarily participates in clinical research.

<sup>4.</sup> However, it is not possible here to specify which rights are actually affected or how these relate to each other, as this depends on each specific situation.

<sup>5.</sup> This was recognized explicitly by the Supreme Court in its ruling of 12 January 2001, f.j. no. 1.

<sup>6.</sup> The meaning of consent in the health sector does not derive from the legal structure and the requirements of contracts, but it nevertheless shares certain features in common. Throughout this paper I will be exploring some of these similarities and differences.

See, Romeo Casabona, El Médico y el Derecho Penal. I. La actividad curativa, op cit, pp. 273
and ff. Also, in this respect, Ricardo De Lorenzo y Montero / Javier Sánchez Caro, "El consentimiento informado", in Responsabilidad Legal de Profesional Sanitario, Asociación
Española de Derecho Sanitario, Madrid, 2000, pp. 64 and ff.

<sup>8.</sup> Engisch, K. "Arzt und Patient in der Sicht des Strafrechts" in *Universitas*, 5, 1965, p. 471; Romeo Casabona, *El Médico y el Derecho Penal. I. La actividad curativa*, op cit p. 311.

concern – has been reflected in a number of studies of informed consent with regard to a variety of common care practices such as surgery and others in which a degree of risk is involved. These studies have generated specific and by and large useful informed consent protocols which provide guidelines about how to transmit information to the patient prior to obtaining consent in the most common situations.

However, the intensification of this concern has been reflected with phrases such as "I do informed consent, too!" which, while reflecting an acceptance of the obligation to obtain consent, also betray a degree of misunderstanding as to its real meaning. To start with, it is not simply one more legislative imposition or a result of the "bioethical" impregnation of everything medical, designed to add one more item to the already excessive list of doctors' obligations. On the contrary, it is a guarantee for patients, a requirement if they are to exercise their autonomy in an area of their personal life which is often of great importance for themselves and their families.

Nor is it correct to assume that the health professional is the main or sole partner in the informed consent process. Rather, this is a process whose legal significance is expressed at a number of different stages of the process, and which culminates in the statement (or successive statements) of his wishes by the patient or the patient's representative, where this is provided for by the legislation. In other words, the doctor offers information and the patient receives it, and on the basis of this and other personal factors the patient decides whether or not to grant his consent to surgery or diagnostic, curative or preventive treatment. As a result, "informed consent" is really something which the patient does, aided by the doctor. At the same time, the phrase mentioned above ignores or undervalues other types of information which are not directly linked to the patient's consent, but which are nevertheless legally significant, as we shall see below.

Finally, in addition to the frequent failure to understand the true importance of information in the relationship between doctor and patient, and between the patient and the nursing staff, the information process is sometimes seen as nothing more than the transfer of responsibility to the patient, and while there is an element of truth in this, as we noted above, this approach betrays a purely formal understanding of this obligation, a deviation from its real objective and, more worrying still, an expression of defensive medicine. As we know, transferring the weight of responsibility to the patient or, to put it more accurately, transferring the risk for the medical action to which the information relates, only has legal effect for the purposes established, and in no degree covers negligence on the part of the professional. In this event, responsibility continues to be that of the doctor.

Consent is not restricted to satisfying a legal requirement in order to legitimate the medical act, but should rather be seen as a starting point for the achievement of other equally important objectives, such as ensuring the maintenance of a relationship of trust between the health professional and the patient and, finally, contributing to an improved quality of care.

### 2. Information and consent: a new model of the doctor-patient relationship

### 2.1. The origin of informed consent as a core component of patients' rights

Just like other patients' rights, informed consent has its origins in a range of different phenomena<sup>10</sup>. Firstly, greater vigilance and recognition of citizens' rights in general and patients' rights in particular. And secondly, a change in the health model, with a shift from individualized to coordinated treatment in health centres and hospitals, involving a number of health professionals from a range of specialist areas and with varying levels of expertise, together with the availability of more sophisticated resources. Finally, another expla-

Carlos María Romeo Casabona (Ed.) and others, "Presentación. La práctica de la información clínica", in *Información y documentación clínica*. Su tratamiento jurisprudencial, Ministerio de Sanidad y Consumo, Madrid, 2000, pp.11 and ff.

<sup>10.</sup> Carlos María Romeo Casabona, "Configuración sistemática de los derechos de los pacientes en el ámbito del Derecho español", in *Jornadas sobre los derechos del paciente*, Insalud, Madrid, 1991, pp.171 and ff.

nation lies in the change in how health care was accessed as it became a universal social right, at least in most European countries<sup>11</sup>.

The first thing one notices when studying the question of patient rights, and within these the right to consent, is the reason for establishing them as such. Apart from the Nuremberg Code of 1947, which, as we shall see below, provides an important precedent in this area, charters of the rights and duties of patients were drawn up in a number of developed countries around 30 years ago, although it should also be noted that these were often declarations of principles or expressions of moral intentions, rather than genuine, subjective rights which could be demanded of others.

The first text of this sort is probably the Declaration of Patient Rights, presented in 1972 by the American Hospital Association<sup>12</sup>. This Declaration recommended that the approximately 7000 member hospitals adopt its twelve points or a similar declaration, with the aim of contributing to "better patient care and increased satisfaction for patient, doctor and the hospital organization."<sup>13</sup> Although this represented a major step, at least symbolically, in placing the patient centre stage of decision-making with regard to his illness, the Declaration was subject to severe criticisms, for limiting itself to stating the obvious fact that, ultimately, hospitals are subject to the same standards in interpersonal relations and the prevention of aggression and harm as any other institution or member of society; or that some of the eventualities to which it referred would, in any other contractual relationship, be covered in more detail<sup>14</sup>.

In any event, this new trend drew on very important precedents in the form of international concern with human rights in general, as expressed in the Uni-

versal Declaration of Human Rights in 1948, reflected in various international conventions and in the domestic legislation of some States, above all in constitutions drawn up subsequent to this date; and in the Nuremberg Code which, although it was restricted to establishing ethical principles regarding experimentation with human beings, constitutes the core of this new perspective of individual respect for people undergoing medical treatment for research purposes and in particular recognition of the right to free self-determination.

Other precedents include documents published by international bodies, such as the Lisbon Declaration on the rights of the Patient, adopted by the 34th World Medical Assembly (Lisbon, September-October 1981); the Charter of the Hospital Patient, approved by the Plenary Assembly of the Hospital Committee of the European Economic Community (May 1979); Resolution 613 (1976) and Recommendation 779 (1976), of the Parliamentary Assembly of the Council of Europe, regarding the rights of the sick and dying; and the Recommendation (1980) of the Committee of Ministers of this body, regarding the participation of patients in their treatment. In addition to these initiatives, a wide range of international institutions have pronounced upon more specific aspects which in one way or another affect patients or those affected by medical action (such as experimentation on healthy people). From a legal perspective, one can cite the Patients' Bill of Rights of the State of Minnesota, passed into law by the chamber of representatives of that state, which strengthens the influence of the Declaration of the American Hospital Association; together with Decree 74/27, of 14 January 1974, in France, containing the Charter of Rights and Obligations of Patients<sup>15</sup>. From an international legal perspective, the first important recognition of the need for consent in the medical setting, although it does not refer to practices directly related to treatment, is the International Covenant on Civil and Political Rights of 1966<sup>16</sup>, which states that, "No one shall be subjected to torture or to

<sup>11.</sup> In other developed countries this access was made possible as a result of economic progress.

<sup>12.</sup> In, fact, the declarations of rights of the Beth Israel Hospital, in Boston, and the Martin Luther King-Health Center, in New York City, are earlier.

A Patient's Bill of Rights, 1972, Preamble. See full text in Tom L. Beauchamp/ LeRoy Walters (eds.), Contemporary Issues in Bioethics, 2nd. ed., Wadsworth Publishing Company, Belmont, 1982, pp.127 and ff.

<sup>14.</sup> See, in this regard, Willard Gaylin, "The Patient's Bill of Rights", in *Contemporary Issues in Bioethics*, op. cit., pp. 128 and f.

<sup>15.</sup> See Ignacio Gonzalez Riesgo, "La Carta de Derechos y Deberes de los Pacientes", in *Jornadas sobre Humanización de la Atención sanitaria en la red asistencial del INSALUD*, Instituto Nacional de la Salud, Ministerio de Sanidad y Consumo, Madrid,1985, p. 36.

<sup>16.</sup> Spain ratified this Convention on 27 April 1977, and it forms part of the country's domestic legislation (art. 96.1 of the Spanish Constitution).

cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." (art. 7).

The Convention on Human Rights and Biomedicine (CHRBM) of the Council of Europe of 1997 is the culmination of this new awareness and, for this reason, is without doubt the most important legal instrument of the twentieth century with respect to the individual rights which may be affected by modern medicine and biology. Because of the impact this has had on Spanish law, I will describe some of its provisions which are most directly related to patient consent.

In community law, the Charter of Fundamental Rights of the European Union contains a small but significant core of citizens' rights with respect to medicine and biology<sup>17</sup>, and in particular "the free and informed consent of the person concerned, according to the procedures laid down by law," (art. 3: 2). While it is true that this Charter does not yet constitute an obligatory part of the laws of EU States, it is nonetheless significant that this right has been explicitly recognized in a document which may very well become statutory in the near future.

With respect to Spanish law, the origins of the recognition of informed consent in the health sphere as part of the rights of patients and service users can be traced to various documents. Of these, we should first mention a Royal Decree of 1978, which contained as an Annex a list of patients' rights, including consent, although this list never came into force because the Decree was declared null for procedural reasons<sup>18</sup>. Some years later (1984), the Spanish Health Service approved a "Humanization Plan" which included a charter of patient rights, although this was advisory rather than statutory. It was not until the passing of the General Health Act <sup>19</sup> that, at the urging of the Ombudsman, a list of the rights of users of public health services and, in some

17. Approved, 28 September 2000.

cases, private ones too, was included, and this is legally binding and remains in force today. As we will see below, this legislation also establishes consent as one of the key patient rights. Recently, a cross-party group in Spain's upper house proposed legislation on "the rights to information about health and patient's autonomy, and medical records," which, if approved, would provide specific, detailed coverage of the key issues related to informed consent<sup>20</sup>.

In all the above documents the informed consent of the patient constitutes one of the key rights, and is always expressly recognized as such.

# 2.2. Legal situation of consent in Spanish law: general legislation

Today it is beyond dispute that the patient has the right to decide upon treatment, and this implies the need for the patient to grant consent (either directly or, if he is not in a position to do so for himself, then through a legal substitute) after receiving the necessary information, and to refuse to do so if he deems this to reflect his interests. This statement has a broad basis in the Spanish Constitution (arts. 10.1, 15, 17), and therefore little further explanation is required.

For its part, the General Health Act reflects this dual right in three key stipulations. In accordance with these, the patient or service user has the right, in the first place, to be given or for his friends and family to receive, comprehensive, ongoing information, orally and in writing, about the health process, including diagnosis, prognosis and treatment alternatives (art. 10, no. 5). And secondly, the right to choose freely between the options offered by the doctor responsible for treatment, with the prior written consent of the service user being necessary before treatment (art. 10, no. 6), without prejudice to certain exceptions: a) when non-intervention represents a risk to public health; b) when the patient does not have the capacity to take decisions, in which case

<sup>18.</sup> Supreme Court ruling (Court 4) of 29 April 1982 and 10 December 1982, consisting, in essence, of the absence of compulsory ruling from Council of State.

<sup>19.</sup> Act 14/1986, of 25 April.

<sup>20.</sup> BOCG, Senate, Series III, no. 11,1 March 2001, pp. 1 and ff.. See also, "Documento final del Grupo de Expertos en Información y Documentación Clínica", Ministry of Health and the Consumer, Madrid, 1998, on which this proposition appears to be based.

the right corresponds to the patient's family or those close to him; and c) when urgency does not permit delay because it may give rise to irreversible injury or there is a risk of death. And, finally, the patient may refuse treatment, in which case he must request voluntary discharge (art. 10, no. 9).

Other rights which incorporate the preferences of patients include the following: the authorization of the patient is required when the patient is to undergo a procedure which may be used as part of a teaching or research project (art. 10.4); the right to choose the doctor and other qualified health staff in accordance with the conditions established, in a public health centre (if the centre is a private one then the patient has an extensive right to choose) (art. 10.13).

The CHRBM also constitutes a source of legislation in this area, having been incorporated into Spanish domestic legislation with effect from 1 January 2000<sup>21</sup>. The CHRBM devotes particular attention to the consent of the interested party, considering a wide range of personal situations (competent adult, minor, mentally ill or incompetent to grant consent), to the purpose for which consent is required (for diagnosis or treatment, for clinical research, and for the live donation of organs for transplant) and to the combination of both. For the present, I will restrict myself to discussing the general system established with respect to consent, before comparing this with the provisions established earlier by the General Health Act in this regard, in order to construct a general picture of the current legal position with regard to informed consent in Spanish law:

"An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks." (art. 5)<sup>22</sup>.

Given its status as an international treaty, the CHRBM takes precedence over previous legislation, including the General Health Act (art. 96 of the Spanish Constitution); "No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others" (art. 26 CHRBM)<sup>23</sup>, and "None of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention." (art. 27 CHRBM).

#### 2.3. The system in Spain's autonomous regions

Some autonomous regions have established their own legal system with respect to the rights of patients and users of the public health system, including the question of consent together with other issues linked to it, such as medical records, which record information which is of relevance to the patient's decision.

In the first place, it is important to note the Decree incorporating the Charter of rights and duties of patients and users of Osakidetza (the Health Service), of 1989 (art. 1), of the Autonomous Region of the Basque Country. At the same time, it is also interesting to note that this region was the first to regulate the administrative system for medical records, which was subsequently revised and extended<sup>24</sup>. This legislation regulates informed consent and voluntary discharge forms, which are included in the medical records (art. 6).

<sup>21.</sup> The Convention was signed by Spain at Oviedo, on 4 April 1997, ratified by the Spanish Parliament on 23 July 1999, and published in the Official State Gazette (BOE) on 20 October 1999. Rectification of errors published in the BOE on 11 November 1999.

<sup>22.</sup> With regard to other issues, see arts. 6 (protection of the incompetent), 7 (protection of people suffering from mental disorder), 8 (emergency situations), 9 (wishes stated in advance), 16 and

<sup>17 (</sup>protection of people who agree to participate in research) and 19 and 20 (consent for the extraction of organs and tissue from live donors for the purpose of transplant).

<sup>23.</sup> Notwithstanding, the CHRBM itself allows for certain restrictions, although in no case may these affect any of the provisions of the Convention itself. See art. 26.

<sup>24.</sup> See Decree 272/1986, regulating the use of medical records in hospitals of the Autonomous Region of the Basque Country, and Decree 45/1998, of 17 March, establishing the content and regulating the assessment, maintenance and deletion of documents by the Register of Clinical Activities of the Hospital Emergency Services and Hospital Medical Records, respectively.

Catalonia recently introduced legislation regarding the patient's rights to information, autonomy and medical records which, as a result, directly affects the issues under discussion here<sup>25</sup>. This identifies as one of the purposes of the law, "determining the right of the patient to information regarding his health and to reach autonomous decisions" (art. 1). Subsequent legislation regulates the formulation and scope of the patient's right to information, the right to privacy and informed consent (arts. 2 to 8), in addition to the medical records (arts. 9 to 14). Other regions have adopted similar initiatives (e.g., Galicia, Andalucía, Aragón and Extremadura), in particular with the aim of developing what have come to be known as "advance directives".

## 2.4. Jurisprudence and informed consent: an overview<sup>26</sup>

The information which flooded into Spanish hospitals also flooded out, and with only the shortest of intervals, but this time in the direction of the law courts, in the form of conflicts with health staff or the institutions employing them. We must go back to the 1950s for the first legal case, although it is hard not to conclude that it was provoked by the defence, which in a criminal case claimed as justification the legitimate exercise of his profession by a doctor (a surgeon who was found guilty of negligence for the unplanned amputation, without consent, explanation or any subsequent justification, of the patient's penis, after he had been admitted for operation on a hernia of the groin), and although the Supreme Court ruled on the issue, the case was an isolated one<sup>27</sup>.

The 1990s is rich in examples in this area, and has given rise to the legal framework of liability arising from non-compliance or incomplete compliance with the obligation to inform, whether or not linked to consent. To this end, our courts have had almost no earlier rulings to build upon and only the scantiest of legal studies.

The number of rulings issued during the last decade is vast, when compared with previous periods, during which almost no precedents were established with respect to the issue of liability as related to information and informed consent<sup>28</sup>. This is not the moment to attempt to identify a sociological explanation for this change. What is clear is that these cases have reached the courts of justice as a consequence of claims presented by those affected or their families, and it is also clear that these have at times been successful in basing their claim of liability on a more flexible notion of the concept of harm and its connection – through a relationship of causality, either real or hypothetical in the event of acts of omission – with information which is non-existent or defective, starting from the inarguable fact that the duty to inform exists as a general principle, even if it is subject to certain qualifications and conditions.

However, the legal approach to information and consent are far from being free of controversy. In particular, it is not easy to endorse the enormous disparity in the levels of financial compensation awarded for broadly similar events. Although this is based on the indisputable assumption that in real life no two situations are identical and, as a result, nor can be the financial valuation placed upon them, this cannot justify undermining the principle of equality or effective legal protection nor, of course, of proportionality. It is also hard – especially for the layperson – to understand the disparity of criteria when deciding upon guilt or innocence in apparently similar cases but which are resolved differently by different branches of the law (e.g., civil and criminal). In general, the latter is more rigorous in its assessment of the

Law 21/2000, of 21 December, on the rights to health-related information, patient's autonomy and clinical records.

<sup>26.</sup> For a full review of the jurisprudence in this area, see ROMEO CASABONA (Ed.) et al., Información y documentación clínica. Su tratamiento jurisprudencial, op. cit., pp. 23 and ff. See, also, De Lorenzo and Montero / Sánchez Caro, El consentimiento informado, op. cit., pp. 94 and ff.

<sup>27.</sup> Supreme Court Ruling (2nd, Criminal) of 10 March 1959. See below for other interesting aspects of this ruling (extension of treatment without consent).

<sup>28.</sup> With respect to this abundance of decisions of the courts of justice at every level, see Romeo Casabona (Ed.) et al., *Información y documentación clínica*. Su tratamiento jurisprudencial, op. cit.; and De Lorenzo and Montero / Sánchez Caro, El consentimiento informado, op. cit.

legal basis of any sentence, probably because this has more severe consequences<sup>29</sup>.

Without prejudice to the above, recent jurisprudence reveals significant efforts to reorganize and systematize this area, and to identify the legal significance of each of the issues involved. As a result, there are abundant references to the content of the information, with particular emphasis on information about risks and how this is transmitted; with regard to the person responsible for informing; with regard to the recipient of the information, in particular in the case of minors or the incompetent; of the relevance of the medical records in regard to the information test; regarding the characteristics of the information in special cases, etc. I will discuss all of this below. However, most of the rulings relate to the patient's consent and the function of information – in general, the absence thereof. But there are also some decisions which raise the question of liability for information about treatment options.

One of the areas where there is the greatest controversy and disagreement, and at times misunderstanding, regards information about the risks of treatment or intervention. It is clearly one of the most complex areas, and one in which it is very difficult to identify reasonable guidelines. So, what are known as 'typical' and minimal risks (and their counterpart, 'atypical' or infrequent risks) are usually measured by incidence rates, as established by scientific publications. We need to accept that the rate on its own should not necessarily be used as the determining factor in establishing the obligation to inform about these risks, as these may also need to be modulated by other factors such as the seriousness of any negative outcome, the degree of urgency of the intervention for the patient's health, the existence of alternative, lower-risk approaches and the efficacy and convenience of these for the patient, etc.<sup>30</sup> The combination of these criteria may justify the obligation to

inform about more remote but nonetheless real risks, such as occurs with risks associated with cosmetic surgery or sterilization, in this case regarding the possibility of pregnancy despite the operation (e.g., during a period immediately following surgery or due to the reopening of the vas deferens), given that the purpose of the intervention is precisely to prevent this, while it may not be necessary to inform about other, more uncertain risks associated with treatment of a patient suffering from a secondary tumour.

Sometimes the jurisprudence draws conceptual distinctions which remain valid, so long as they are applied sensitively. This is the case, for example, when some interventions (both therapeutic and not) are compared to a contract the subject of which is the final product or result. While it may be true that this is indeed the purpose of the intervention, just as in other interventions where the obligation is held to relate to the means employed and the result cannot always be guaranteed, the analysis revolves around the diligence of the health professional. And it is precisely with respect to such uncertainty that information must be provided, and where the intervention is for non-therapeutic purposes then the information regarding the risks referred to earlier must be even more exhaustive.

In other cases, one encounters classifications based on outdated, academic terminology which bears little relation to the matters at hand. This is the case with phrases such as 'voluntary medicine', which allude to interventions which are not strictly speaking part of care or treatment (e.g., cosmetic surgery)<sup>31</sup>. In fact, all medicine is 'voluntary', with the exceptions provided for by the law, and only a masochist would expressly hope for a negative outcome. Perhaps terms such as 'curative' (including diagnostic and preventive measures) and 'non-curative' or, if one prefers, 'therapeutic' and 'non-therapeutic' are less catchy but better reflect a duality which is useful from a

<sup>29.</sup> Curiously, until the late 1980s, the opposite was the case: the civil courts were more likely than the criminal courts to absolve defendants or hand down light sentences in cases of malpractice. See, in this regard, Carlos María Romeo Casabona, "La imprudencia jurídicopenal. Especial consideración del delito imprudente en la actividad médica", in *Anales de la Facultad de Derecho de la Universidad de La Laguna*, no. 11, 1991, pp.127 and ff.

See Supreme Court Ruling (1st, Civil) of 31 July 1996, Provincial Court Ruling of Barcelona (Civil) 28 April 1999, and Provincial Court Ruling of Valladolid (Civil) 19 April 1997, fin-

ding against the defendant. By contrast, the following rulings found the defendant innocent despite failure to inform about minimum risks: Supreme Court Ruling (Criminal) 3 October 1997, Supreme Court Ruling of Galicia (Administrative Disputes) of 8 June 1995, and Provincial Court Ruling of Soria (Civil) of 12 December 1994.

See, for example, Supreme Court Ruling (Civil) 25 April 1995, 11 February 1997, Provincial Court Ruling of Oviedo (Civil) 28 November 1995.

legal perspective, despite the fact that in some situations the line is not absolutely clear (for example, in the case of plastic surgery after an accident).

Another much used expression in some Spanish courts is *lex artis ad hoc*. This is intended to denote the idea that professional skills (*lex artis*, without any modifying phrases) must be assessed in the light of the circumstances of each specific case<sup>32</sup>. But this is already the case, given that the notion of professional skill implies the choice and application of method or procedure and this, by definition, means that this skill must be specifically adapted to the patient's actual condition, that it must be modulated to take into account the medical basis for the intervention or measure being adopted. The expression *lex artis ad hoc* therefore, is not only obscure but tautological<sup>33</sup>.

Rulings regarding medical records stress both their role in the doctor-patient relationship and, above all, their importance as evidence. Against the widespread fear that medical records would be used by the courts to find against doctor, the reality has been the opposite, with such records providing the basis for doctors being absolved, when the records proved that the health professional had complied with the obligation to inform<sup>34</sup>. However, it is important to bear in mind that the courts have tended to link the burden of proof to the seriousness of the charges being laid: the health professional is the one who must demonstrate that he has satisfied his obligation to inform and he or the health centre must, where necessary, submit the medical records<sup>35</sup>; in the event

that these do not exist, this is an indicator of a lack of professional rigour and, therefore, is in the first instance a basis for finding against the professional<sup>36</sup>. Given the dependency, in this case, of the patient on the health professional's good faith during the period when the medical records are drawn up (that is, during treatment and convalescence) and of the guarantees of safekeeping by the health centre, alteration of the records or the creation of 'parallel' records may give rise to administrative or even criminal liability.

I will discuss other, more specific conflicts below, in the context of the problems which these raise.

# 3. Patient information and consent: the multiple functions of health information

Addressing the issue of consent necessarily entails considering the question of information in the context of the doctor-patient relationship. Patient information has only recently become a major element of health practice<sup>37</sup>. This does not mean that patients were not informed in the past, but rather that providing information was not perceived by health professionals to be an obligation but rather as something discretionary, dependent, among other factors, on the presumed receptiveness of the patient. The General Health Act confirmed this obligation, which had already been identified by specialists in health law on the basis of more general legal principles.

Although information is normally seen as part of the process by which the patient grants consent, it comes in a variety of forms and serves a range of purposes. From a legal perspective, it is possible to distinguish three classes of information, which differ fundamentally in their respective purposes: a) information as the purpose of the medical act; b) information as part of treatment (therapeutic information); and, c) information as the basis for consent.

<sup>32.</sup> For the concept of *lex artis* see Romeo Casabona, *El Médico y el Derecho Penal. I. La actividad curativa*, op. cit. pp. 159 and ff.; Agustín Jorge Barreiro, *La imprudencia punible en la actividad médico-quirúrgica*, Tecnos, Madrid, 1990.

<sup>33.</sup> For examples of the use of this revealing 'discovery'; see Supreme Court Ruling 28 June 1997, 2 October 1997, 13 April 1999 (all, of course, by the Civil Chamber).

<sup>34.</sup> Absolutory sentences include: Supreme Court Ruling (Civil) 12 July 1994, 31 January 1996, 23 September 1996, 27 June 1997.

<sup>35.</sup> The following rulings reflect this judicial tendency towards the reversal of the burden of evidence: Supreme Court Rulings (Civil) 25 April 1994, 2 December 1996, 16 October 1998, 19 April 1999, 29 June 1999, 7 March 2000, 12 January 2001. However, there are also a number of recent rulings which reject this reversal: Supreme Court Rulings (Civil) 2 February 1993, 31 July 1996, 23 September 1996, 16 December 1997, 28 December 1998, 19 April 1999.

<sup>36.</sup> See Supreme Court Ruling (Civil) 2 December 1996.

<sup>37.</sup> Romeo Casabona (Ed.) et al., La práctica de la información clínica, op. cit., pp. 11 and ff.

Before we analyse the variety of purposes served by health information, it is important to note that it is recognized in a number of the provisions of the General Health Act<sup>38</sup>. This is implicit in art. 10 point 5, where the information referred to is not seen solely as a prior condition to the patient's choice of treatment and granting of consent but also entails the right to know about the state of his health and how this is progressing, and to receive therapeutic information. And these characteristics of health information are also recognized by the law when it establishes the right of health service users to receive a certificate accrediting the state of their health, when this is required by law (art. 10, no. 8), when it establishes the right of the patient to receive the hospital discharge report at the end of a hospital stay (art. 10, no. 11), and when it stipulates that medical records be made available to the patient (art. 61).

## 3.1. Information as the purpose of the medical act

Let us start by considering those cases in which information is the direct and immediate purpose of the patient or health service user's decision to consult a doctor. This usually occurs when the health service user (who is not necessarily ill) needs the information for a specific purpose, such as taking private or legal decisions unrelated to treatment (e.g., whether to accept a job offer, get married or take out an insurance policy, or how to act if one has a contagious disease). In this case, the medical act ends with the transmission of the information requested. This group would also include routine regular examinations, whether individual or collective, both voluntary and in order to satisfy legal or regulatory requirements, and also covering systematic checks to identify occupational illness, and consultations in response to symptomatic evidence of a suspected or unknown condition.

In sum, in these cases the health professional is being asked for diagnostic information – if possible, pre-symptomatic – with regard to the health of the service user at a particular point in time, accompanied, where relevant, by a prognosis. In other words, the information is the expected outcome of the

medical interaction. The conjectural nature of any diagnosis means that the information so provided may not turn out to be accurate, and this must be reflected in the standards by which professional performance is judged. Failure to provide this sort of information may give rise to civil or contractual liability on the part of the doctor, or civil or criminal liability for negligence, in the event that damages to the patient arise; and, in both cases, the health authorities may bear employer's liability if the staff responsible are employed by them.

## 3.2. Information as part of treatment: therapeutic information

The group of cases refers to information which the doctor must supply to the patient so that the latter is aware of his situation and how his illness is progressing, in order to adapt his lifestyle to it, or when, more specifically, the patient needs to cooperate with treatment: medication or other products or treatment (need for prescription, dosage, side effects, contraindications, consequences of failure to complete treatment or poor compliance), handling of instruments or devices (self-treatment in patient's home, etc., with support from technician if required), lifestyle (e.g., type of food, avoiding physical exertion, performing risky activities, etc.). In summary, information in this case requires the active involvement of the patient with his illness and its treatment, and must therefore be ongoing and primarily verbal.

This type of information has been called 'therapeutic information', forming as it does part of the treatment and therefore part of the practical skill of the doctor or, to put it this in more precise legal terms, of the duties of care and diligence incumbent upon all health professionals. It is by proper compliance with these duties that doctors safeguard themselves against criminal or civil liability for recklessness or negligence<sup>39</sup>. In this way, information performs a

<sup>38.</sup> Something similar is the case with regard to the CHRBM, and in particular its arts. 10.2 and 5.

<sup>39.</sup> Rulings in this area include: Supreme Court Ruling (Administrative disputes) 22 November 1991 (failing to advise of precautions following vaccination and of incompatibilities between medication), Supreme Court (Civil) 5 February 1999 (failing to advise of how to care for a wound which became gangrenous).

vital function; one which may receive little recognition in the law but which, nonetheless, has far-reaching legal implications. Such information plays an essential role in therapeutic activity; explanation of the guidelines to be followed by the patient, as noted earlier, is a type of therapeutic information which the doctor cannot neglect without simultaneously violating the duties inherent to his activities and potentially finding himself legally liable<sup>40</sup>.

Attention has also been drawn to the major role of this type of information in supporting health policy in the area of preventive medicine; it provides a conduit for treatment in the sense of contributing to an early resolution of problems and promoting a lifestyle which responds to the early diagnosis or preventive action, with the result that information becomes an additional medical teaching instrument which motivates the patient to adopt the recommended course of action<sup>41</sup>.

# 3.3. Information as a basis or requirement for consent

Finally, we must consider the information which patients need in order to grant their consent to an intervention (whether diagnostic, preventive or curative) or treatment. The basis for this is that legally valid consent can only exist if it is granted by the subject under certain conditions and in the absence of coercion.

We should not forget that it is consent which confers legitimacy upon any interventions which the health professional seeks to perform, so long as these are medically indicated. For this reason, this type of information does not, in itself, form part of the skill of the medical professional (or *lex artis*)<sup>42</sup>, except

in so far as it overlaps fully or in part with any of the functions discussed above. However, failure to provide this information or providing it incorrectly (insufficient or inaccurate information) may give rise to the civil liability of the professional or the objective liability, as employer, of the health authority. We will consider this below.

# 4. The specific requirements of informed consent

I have stated on several occasions that the consent of the patient or of the person who must grant it on his behalf is necessary for any intervention, whether diagnostic or consisting of clinical or surgical treatment. But this consent must also satisfy a series of requirements if it is to be valid. These include the need for it to be free and conscious (a characteristic which, incidentally, is not violated by the patient renouncing the information and nonetheless granting his consent). In addition, the information must be free of errors as regards the formation or expression of the wishes, something which is only possible if the consent itself is free of error and based on a clear understanding of the scope of the act or acts to which consent is granted; nor may there be coercion or any other procedure to obtain the subject's consent other than as the free and conscious expression of his wishes.

The requirements which the patient's consent must satisfy can be grouped as follows: a) prior to the statement of consent, both general (e.g., those affecting the patient's competence to grant consent) and specific (information about the diagnostic, curative or other type of intervention designed to ensure that the patient's wishes are not formed on the basis of misrepresentation and error); b) concomitant to the statement of wishes and scope of the consent (purpose, manner and time); and c) subsequent to the statement (but prior to completion of the act to which consent refers: rectification and cancellation).

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<sup>40.</sup> Romeo Casabona, *El Médico y el Derecho Penal. I. La actividad curativa*, op cit, pp. 252 and f. and 329.

<sup>41.</sup> Romeo Casabona, El Médico y el Derecho Penal. I. La actividad curativa, op. cit., p. 329.

<sup>42.</sup> Jurisprudence has not understood it in this way (in my opinion, incorrectly). See Supreme Court Ruling (1st, Civil) of 24 May 1995: "... through his omission he ignored the obligation placed upon him by *lex artis* in this specific area by failing to obtain the patient's consent...", something which is not an obstacle to a claim for civil liability, on the basis mentioned in the

text. This opinion appears to be shared by De Lorenzo and Montero / Sánchez Caro, *El consentimiento informado*, op. cit., p. 67 (see, however, n. 9).

#### 4.1. The subjects of consent

The subject of the consent process is, firstly, the person who must grant the consent: that is, the patient. When the patient is not in a position to do so, and only then, may another person grant it in his stead. The doctor and other health professionals are mere recipients of the consent<sup>43</sup>. However, their involvement does not end here, because the consent of the patient is of vital importance to health professionals, providing, as it does, the basis of the legitimacy of any action they perform; in this sense, they are also the targets of the consent.

#### 4.1.1. The competent adult patient<sup>44</sup>

The patient is necessarily the one who has to grant his consent to treatment, a personal decision which derives from the right of autonomy or self-determination, and reflects the nature of the legal rights involved and the fact that these are held exclusively by the patient. As a result, once the decision has been made it is not necessary to ensure the agreement of other parties<sup>45</sup>.

As a result, adult patients or health service users with full competence to grant their consent are covered by the general rules in this area. These rules focus on ensuring that the person's wishes have been freely formed and stated, on the basis of adequate knowledge of what the procedure involves, and that the information process itself has been free from errors or coercion.

Of course, for this consent to be valid, the patient must be aware of and understand the scope of his decision, and for this to be the case it is first necessary that he be in full possession of his mental faculties. However, the patient is not always in a position to form his wishes in this way, either because his competence is diminished or because he lacks it altogether. This incompetence may be the result of a variety of circumstances: a) temporary, in the case of minors; b) permanent, when the patient is affected by mental illness or disability, which may or may not be the reason for treatment; and c) sudden, when the patient is unconscious as a result of the illness or for another reason (accident, poisoning, etc.), a situation which may be transitory or irreversible. The three resultant possibilities (minority, mental illness, loss of consciousness) may occur on their own or in combination (e.g., a mentally disabled child). Here, however, we are interested in the real problems which affect the competence of minors and of the mentally ill, both of whom are usually capable of expressing their wishes and where, therefore, the issue is whether these wishes should be treated as valid in the context of the specific circumstances. By contrast, in the case of a patient who is unconscious, consent must be granted by a third party.

#### 4.1.2. When the patient is a minor<sup>46</sup>

When the patient is a minor, nobody questions that the parents should grant consent on the child's behalf. And this is indeed what happens when, as is usual,

<sup>43.</sup> Jurisprudence has also understood consent in this way. See, for example, Supreme Court Ruling (Civil) 26 September 2000. Notwithstanding, liability for failure to meet this obligation may rest with the health authorities (objective liability); Supreme Court Ruling (Administrative disputes) 28 June 1999.

<sup>44.</sup> The Spanish literature in this area often uses the terms *competente* and *incompetente* when discussing if individuals do or do not have the capacity to grant their consent. These are expressions which come from the English language, in general imported by those who are not legal specialists, based on a literal translation of the English words *competent* and *incompetent*. These anglicisms should be unequivocally rejected, given that Spanish legal language already contains its own, clearly defined terminology. The Dictionary of the Royal Academy of the Spanish language defines as *competente* that person who is qualified to perform an action, through his knowledge, skill or craft. Unfortunately, these anglicisms have already been included in some legal texts, such as the Catalan legislation cited earlier (see, for example, art. 7).

<sup>45.</sup> It is for this reason that the practice of including a requirement of the agreement of both members of a couple in informed consent documents for sterilization procedures as part of family planning (still followed by some health centres) is unacceptable. Although the partner may have an interest in the process, the doctor only requires the consent of the person who is actually to undergo the intervention, and there is no basis for requiring any other consent.

<sup>46.</sup> See, for more detail, Carlos María 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 RDPC, no. 2, 1998 pp 327 and ff.; Sergio Romeo Malanda, "El valor jurídico del consentimiento prestados por los menores de edad en el ámbito sanitario (I) y (II)", in LL, no. 5185 and 5186, 2000, pp. 1 and ff.

the parents have parental authority over a young child, of whom they are also the legal representative. The question becomes more problematic as the minor develops his decision-making capacity and acquires a degree of maturity.

The exercise of parental authority, which entails both rights and duties for the parents, is the basis of their obligation to do everything necessary to safeguard the health and the life of any children under their protection. Or, once the existence of parental authority has been confirmed, the simple existence of a relationship of material dependency of the child on the adults may be sufficient. This relationship is taken for granted in the newborn child, but it also pertains for older children where the minor is able to manage on his own in many situations, but there are others where he remains dependent upon his parents.

Indeed, this conclusion receives confirmation in the civil legislation regarding parental authority. The Spanish Civil Code establishes that, "unemancipated children are under the authority of the father and mother" (art. 154, par. 1) and that "parental authority must always be exercised to the benefit of the children, in accordance with their personality", and includes, among others, the duty and power to "look out for them, accompany them, feed them, educate them and bring them up" (art. 154, par. 2, 1). There is no question that the duty to look after the child entails a duty to protect his life and health, but we must remember that bringing up a child also implies the obligation to ensure his education and the right to give him a religious education which, logically, will correspond to the religious creed of the parents. In summary, parents who hold parental authority are the legal representatives of their children who are unemancipated minors<sup>47</sup>. However, as we will see below, both the exercise of parental authority in general and legal representation are subject to some significant limitations, imposed by the law, within the general principle that parents, in exercising this authority, must act in the best interests and to the benefit of the minor.

At the same time, it has been unanimously accepted for many years<sup>48</sup> that the minor's wishes regarding the proposed treatment must be taken into account

when the minor has natural competence or sufficient maturity to understand the nature and implications of the act and the main consequences of it; this implies assessing both the maturity of the minor and his or her ability to understand the specific situation, something which depends upon the complexity and importance of the situation itself. Logically enough, this criterion does not allow the establishment of a specific age after which natural competence exists, depending as this does on the personality and mental development of the minor in question<sup>49</sup>; in principle, it is likely that this maturity will be reached at fifteen or sixteen years, but it may also be reached earlier or, indeed, later<sup>50</sup>. In any event, the emancipation of a minor implies recognizing his competence to manage his own affairs, and to decide for himself whether or not to undergo a particular treatment and the measures associated with it<sup>51</sup>.

These considerations are not simply factual in nature, but instead have a basis in law; as a result, it is necessary in each specific situation to determine whether or not the minor possesses this natural competence. And this approach is also backed by some of the provisions of the Civil Code<sup>52</sup>. But the

<sup>47.</sup> Arts. 154, par. 2, 2 and 162, par. 1 of the Spanish constitution.

<sup>48.</sup> Romeo Casabona, El Médico y el Derecho Penal. I. La actividad curativa, op. cit., pp. 314 and ff.

<sup>49.</sup> In this regard, see De Lorenzo and Montero / Sánchez Caro, *Consentimiento informado*, op. cit., p. 75.

<sup>50.</sup> Needless to say, this criterion does not make the task of the doctor any easier, particularly where there is disagreement between the parents and their child, or when the child adopts decisions which do not appear to be reasonable, but in these cases it is possible to seek legal advice.

<sup>51.</sup> This statement does not mean that there are no exceptions for certain acts for which having attained the age of majority is a legal requirement. See, for example, art. 156 of the Penal Code, in which this is required in order to be an organ donor (it is clear that this only refers to this situation, despite the general nature of the reference to the law) or to undergo surgery for the purpose of sterilization or to change sex (except, in my opinion, if both have a strictly curative or preventive purpose). Below, I will note some of the other age-based limitations (e.g., to be a blood or gamete donor; to undergo assisted reproduction; to participate in a clinical trial etc.). See also, in more detail, Romeo Malanda, *El valor jurídico del consentimiento prestados por los menores de edad en el ámbito sanitario* (I) and (II), op. cit.

<sup>52.</sup> Art. 154, par. 3: "If children have sufficient maturity, they must always be heard before adopting decisions which affect them." Art. 162: "Parents who hold parental authority are the legal representatives of their children who are unemancipated minors. With the exception of: 1 Acts relating to the rights of personality or others which the child, in accordance with the law and his own level of maturity, can perform for himself."

Spanish law governing the legal protection of minors (LPJM) acquires particular significance in so far as it tends to promote the autonomy of the minor, the full recognition of his status as the holder of certain rights, and the gradual right to exercise these for himself. However, this act not only opens up a wider field of action for the minor himself<sup>53</sup>, but also gives general backing to the right to be heard, "both in the family setting and in any administrative or legal procedure in which he is directly involved and which leads to a decision which affects his personal, family or social sphere" (art. 9) (these procedures are not, of course, equivalent to medical treatment but this illustrates clearly the nature of the law in this regard), and declares unequivocally the right of the minor "to freedom of ideology, conscience and religion" (art. 6.1), almost without restriction<sup>54</sup>, and prohibits discrimination against the minor for reasons of religion (art. 3, par. 1).

As a result, when the patient is less than 18 years of age, the decision as to whether his consent is legally binding or not is based upon this natural competence. If the minor has not attained this competence, the decision must be taken by his parents, and consent must be obtained from them for legal purposes, without prejudice to the need to listen to and take into account the minor's opinion, in recognition of his actual ability to understand.

Even when the minor has attained this natural competence to which I have been referring, there is no reason why the minor should not be accompanied by his parents (or his guardians, if they are his legal representatives) and for these to express their opinions, unless the minor expressly opposes this, so long as his request is reasonable and the medical treatment does not endanger his life or health.

Should there be any conflict regarding the parents' decision (if the doctor considers that they are abusing their parental authority by going against the clear interests of the child) or if there is a disagreement between the child and his parents, or the decision of the minor goes against his own interests, there are various options. In an emergency, the case may be decided by a judge or, where this is not possible, the doctor should decide in the best interests of the minor (in favour of his life or health); in a non-urgent situation, the doctor should explain the situation to the children's advocate so that this person can seek to resolve the situation with the involvement of all parties.

All of the above is in accordance not only with the provisions of the Civil Code, but also with the General Health Act, despite its vagueness, and above all with the Convention on Human Rights and Biomedicine (CHRBM). In fact, the General Health Act states that when the patient is not competent to take decisions, consent should be granted by his family or those close to him (art. 10 no. 6, b). Exactly who this refers to is something I will discuss below.

For its part, the CHRBM establishes as a general rule that "an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit" (art. 6.1). It also establishes the need for the authorization of a third party in place of the minor when he or she is not competent to grant consent under the law<sup>55</sup>, although this power may be withdrawn at any time in the minor's interests (art. 6.5). The older the minor and the greater his degree of competence, the more weight his consent bears (art. 6.2, par. 2).

#### 4.1.3. A patient who is incompetent to grant consent

It should be said immediately that the incompetence may be legal or it may be the expression of a practical inability to grant consent, as a result of psychological disturbance (e.g., mental illness or disability) or any other disturbance with similar effects (being under the influence of psychotropic substances, being drunk, loss of consciousness through injury or illness, etc.).

<sup>53.</sup> According to art. 2: "In the application of this law, the higher interest of the minors will take precedent over any other legitimate interest which may compete with it. (...) Limitations on the competence to act of minors will be interpreted in a restrictive manner."

<sup>54.</sup> In the following paragraphs of article 6, it states: "2. Exercise of the rights deriving from this freedom are subject only to the limitations stated by the Law, and the respect for the fundamental rights and freedoms of others. 3. Parents or guardians have the right and the duty to cooperate to enable the minor to exercise this freedom to contribute to his general development."

<sup>55.</sup> According to art. 6.2, par. 1 of the CHRBM, these third parties are his representative, an authority, or a person or body provided for by law.

Whether the individual is able to grant consent or whether this has to be granted by a representative depends on similar criteria to those established for minors, with the guiding principle remaining the best interest of the patient (art. 6.3 and 5 of the CHRBM). If the patient has been declared legally incompetent, then consent must be granted by his legal representatives; otherwise, it should be granted by his family or those close to him (art. 10.6, b General Health Act). Nor, in this case, does the existence or intervention of legal representatives mean that the patient's opinion should not be taken into account<sup>56</sup>.

In some medical interventions or actions, the interests at stake mean that the consent of the patient's legal representatives, family or those close to him is not enough, and the authorization of a judge is required, together with other guarantees. This is the case regarding the confinement of the mentally ill for treatment (art. 763 Law of Civil Procedure) and the sterilization of the mentally disabled (art. 156 Penal Code).

## 4.1.4. Consent granted by third parties: legal representatives, family and close friends

When the patient is not in a condition to grant consent then, in the first instance, his legal representative should do so. Where the patient has no legal representative (but not if the representative is temporarily absent), then consent must be granted by the patient's family or those close to him, as provided by the General Health Act (art. 10.6). Despite the fact that the General Health Act makes no mention of the representatives, it does not seem possible to argue that this Act establishes an exception to the general theory of representation, nor that it identifies the representatives with the family members, firstly because this category includes people who do not exercise any form of legal representation, and secondly because legal representatives do not necessarily need to be related to the patient.

Identifying the legal representatives is not, in principle, a major problem: parents are, by default, the representatives of their children who are unemancipated minors and of adult children who have been declared incompetent; and guardians, appointed by a judge, represent those who have been declared legally incompetent and of minors in the absence of their parents (because they are dead, absent or have been legally deprived of their parental authority).

By contrast, it is a more complicated matter to establish to which families or close friends the General Health Act is referring for the purpose of granting consent<sup>57</sup>. Their intervention may be necessary in the case of competent adults who are not in a position to grant consent for a specific medical intervention because they are unconscious (for example, as a result of injury or illness). It is not possible to establish a list of such people or a hierarchy of who should be given preference to intervene on behalf of the patient, because there is no legal basis for either of these approaches. However, given that the intention is that the decisions of third parties should reflect as closely as possible the wishes expressed previously by the patient or his interests, it seems logical to assume that those best placed to identify these wishes or interests would be the people who live with the patient, whether family or close friends, or those who, while not sharing a house with the patient, are able to demonstrate a close relationship.

#### 4.2. Information as a requirement for consent

As I have explained throughout this presentation, information prior to consent is an essential requirement if consent is to be legally valid. Obviously, the recipients of this information are in the first place the patient and then anyone who has to grant consent on his behalf. Other recipients of the information may include the family and close friends of a competent patient, but only

<sup>56.</sup> So, the CHRBM expressly states: "The individual concerned shall as far as possible take part in the authorisation procedure." (art. 6.3, par. 2).

<sup>57.</sup> In this case, the CHRBM does not provide much basis for interpretation, referring as it does to an authority, person or body identified by the law, apart from the representative (art. 6.3), and here the legislation to refer to is unquestionably the General Health Act, the scope of which we are trying to clarify here.

so long as the patient has not indicated that he is opposed to this<sup>58</sup>. The information should be provided by the doctor who is responsible for treating the patient – or the doctor in charge of the diagnosis process – alone or in cooperation with other health professionals, and if other specific interventions or tests are required during the care process, then the doctor performing these should also provide information.

The current legislation establishes this obligation in very broad terms.

"Everyone has the right to be given or for his friends and family to receive, comprehensive, ongoing information, orally and in writing, about the health process, including diagnosis, prognosis and treatment alternatives" (art. 10.5 General Health Act). This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks." (art. 5, par. 2 CHRBM). "Everyone is entitled to know any information collected about his or her health." (art. 10.2 CHRBM).

As we will see, some of these legal requirements are subject to a degree of modification, as they cannot necessarily be applied directly in all circumstances.

#### 4.2.1. Information must be appropriate

This concerns both the quantity and the quality of the information provided to the patient. In practice, this means that only that information (but no less) which is relevant to the granting of free and conscious consent by the patient should be provided: the nature of the proposed intervention, the objectives it is designed to achieve, the immediate, predictable effects, any probable or possible side effects, its consequences for the patient's life, risks, possible alternatives to the intervention, etc. This information must be provided in

terms which are comprehensible for the patient or the person granting consent on his behalf, and this means it must be adapted to the appropriate intellectual and cultural level, avoiding as far as possible the use of technical language (this should be reserved for other health professionals).

It is therefore possible that the information transmitted may be inappropriate, either because it is insufficient or because it is excessive<sup>59</sup>. If the information is insufficient, then the obligation to provide the information which forms the basis of the patient's consent will not have been fulfilled if the information does not enable the patient to form an understanding of his situation, the need for the proposed medical intervention, the risks and consequences linked to it, etc.<sup>60</sup> Excess information, apart from being unnecessary and useless, may be harmful and cause the patient unnecessary psychological suffering, and may give rise to decisions which are against the patient's interests and his likely wishes (e.g., if the decides not to undergo treatment with a very low level of risk and favourable prospects), as a result of information overload or misinformation. Both extremes may give rise to liability on part of the person who transmitted the information<sup>61</sup>.

The term "appropriate" means that the information does not necessarily have to be exhaustive, as might be deduced from the literal wording of the General Health Act (art. 10 no. 5). And the information does not have to be complete, firstly because in the majority of cases it would be impossible to comply with such a requirement, and secondly because, as explained above, such an approach would be not only unnecessary but counterproductive. For this reason, the term "appropriate" used in the CHRBM (art. 5) seems the most accurate. This convention, forming part of the Spanish legal system and, indeed, as an international treaty which does not restrict but rather adapts and interprets rights, has priority.

<sup>58.</sup> This conclusion derives from recognition of the patient's autonomy and respect for his privacy, and this also applies to the patient's relationship with his family and close friends. On this point, the General Health Act was not sufficiently clear, and stated that the information should be transmitted both to the patient and to his family or close friends (art. 10.5).

<sup>59.</sup> Isidoro Blanco Cordero, "Relevancia penal de la omisión y del exceso de información médica o terapéutica", in *AP*, 1997, pp. 575 and ff.

<sup>60.</sup> As demonstrated by Supreme Court Ruling (Civil) 26 September 2000 and 12 January 2001.

<sup>61.</sup> In this respect, see Blanco Cordero, Relevancia penal de la omisión y del exceso de información médica o terapéutica, op. cit.

#### 4.2.2. Continuity of the process

The process of transmitting information is not necessarily a one-off event. This is because sometimes there will be a series of medical acts which are independent of one another and were not necessarily scheduled or even fore-seeable at the start of treatment, and these will require further consent from the patient. In addition, the nature of things is such that health professionals cannot be omniscient at the outset but must, rather, gather information as new tests are performed and the patient develops, and this information must then be made available to the patient. As a result, this continuity implies the obligation of continuing to provide information on a gradual basis, so that the consent remains valid if the development of the patient's condition means that the situation is substantially different than it was at the outset, and such information is particularly important with regard to any new intervention which requires new consent from the patient (art. 10.5 General Health Act).

## 4.2.3. Scope of the information depending on the foreseeable risks

The 'amount' of information to be transmitted can be measured depending on the foreseeable risks associated with the intervention. To do this, it is necessary to take into account levels both of serious but infrequent risks and of mild but frequent ones. Other factors which influence the scope of information are the urgency of the intervention, and indications and contraindications which must be weighed against each other (e.g., in the case of new or experimental treatments, or treatments which are not yet fully established).

#### 4.2.4. Limitations and exceptions

While the general legislation does not recognize any limitations on the general requirement to inform, there is no doubt that it is acceptable for the information process to be postponed or for information to be transmitted gradually. So, where the prognosis is terminal, the concept of 'therapeutic privilege' may be applicable. Whatever the situation, it is important to ensu-

re that the patient does not have a completely distorted picture of reality, except in very extreme and exceptional cases where receiving information could in itself have a very harmful effect (these are the scenarios in which therapeutic privilege may arise).

There are several exceptions to the obligation to inform the patient. The first of these is when the interested party himself renounces the right to be informed, and this is legally acceptable unless serious danger may arise either to the party himself or to third parties. Recently this situation has been characterized as the right not to know<sup>62</sup>, and this may occur with respect to serious and incurable pre-symptomatic diseases (of genetic origin) or infectious-contagious diseases (e.g., carrier of HIV antibodies, while taking into account the qualifications noted above). However, it would be advisable to record this wish in writing – if possible, signed by the patient – in order to avoid potential disputes, and also to supply the information to the patient's family and close friends, so long as this does not violate the patient's privacy; and it would also still be desirable to inform the patient of any proposed treatment.

Nor is it necessary to inform the patient when he is not competent to take decisions. In this situation, there is still an obligation to inform, but the recipients of the information are those people who have to grant consent on behalf of the patient, whether his legal representatives, family or close friends, as applicable (art. 10.6, b General Health Act; art. 6.4 CHRBM). However, information must be given to the patient in so far as his condition means that his opinions should be taken into account.

Finally, a similar situation arises with respect to emergency treatment, where the patient is unconscious or unable to understand the information or the implications of granting consent, and it is not possible to talk to family or close friends (art. 10.6, c General Health Act).

<sup>62.</sup> According to art. 10.2 of the CHRBM: "[...] However, the wishes of individuals not to be so informed shall be observed." See in this regard Ann Cavoukian, "La confidencialidad en la genética: la necesidad del derecho a la intimidad y el derecho a 'no saber'," in *Rev Der Gen H*, no. 2. 1995, pp. 53 and ff; Jochen Taupitz, "El derecho a no saber en la legislación alemana (I y II)", in *Rev Der Gen H*, no. 8 and 9, 1998, pp. 105 and ff. and 163 and ff.; Carlos María Romeo Casabona, *The right not to know vs the right to know* (in print).

#### 4.3. The object of consent

It is important for legal purposes to define exactly what the patient is really consenting to: in other words, what is the object of consent and what is its scope. Needless to say, the object may not be in contradiction to current ethical-social principles, something which in any event is unlikely to occur with genuinely therapeutic interventions<sup>63</sup>. But there are other aspects which demand closer consideration.

The patient's consent determines the field of action within which the doctor may legitimately operate. Firstly, it must be noted that the patient's consent is of an individual nature, in so far as it only applies to the doctor to whom it has been granted. However, consent granted to one doctor for one or several medical interventions (including diagnostic procedures) also covers all the other professionals who must participate in these, irrespective of whether they are doctors, or other qualified medical or nursing staff, so long as all the requirements of the consent are satisfied, in particular that concerning information<sup>64</sup>, and unless the patient has expressly indicated that only a specific doctor may perform the procedure and that the consent does not extend to any replacement<sup>65</sup>.

Any expression of consent must specify the type of medical intervention (diagnostic or therapeutic) and the limits or duration of it. In principle, consent is granted solely with respect to the intervention described in the information supplied by the doctor. Consent therefore covers the treatment or intervention planned, together with any complementary or additional measures linked to it, and any extension of the intervention which may arise, which has been foreseen by the doctor and regarding which the relevant prior infor-

63. The same cannot be said when consent relates to a health intervention which affects an intimate personal right (a legal good, which is protected by Criminal Law): experimentation, live donation of organs, tissues or gametes, etc.

mation has been provided. Otherwise, consent does not cover such extension and the doctor must refrain from carrying it out and wait to obtain renewed consent under the required conditions. If the intervention must be extended in an emergency, then the treatment is being administered in the absence of consent, and the conditions governing such cases are discussed below.

Consent covers both the possibility of success and the foreseeable risks, both of which are accepted by the patient. However, the patient's consent can only apply to treatment which is performed correctly: that is, treatment which is medically indicated and is performed competently<sup>66</sup>, irrespective of whether or not the treatment has achieved its proposed purpose. This, after all, is the basis for the acceptance of risk; no doctor can guarantee a favourable outcome. In no event will consent cover treatment which does not meet these conditions and, as a result, it does not cover any harm caused by careless conduct<sup>67</sup>, in the event of which the doctor is liable for reckless injury (or homicide). This conclusion is based on the fact that the patient is only informed about and accepts correct – although not necessarily favourable – treatment, and (as we saw earlier) it is not possible under the law for the individual to renounce protected goods (to health or life), even if he wished to consent to a treatment in which the doctor failed to comply with his duty of care<sup>68</sup>.

It is possible to submit the consent to certain conditions (e.g., making treatment conditional upon the outcome of an earlier intervention) without in principle affecting the rules governing consent in general.

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<sup>64.</sup> See Günther Stratenwerth, "Arbeitsteilung und ärztliche Sorgfaltspflicht", in *Festschrift für Eberhardt Schmidt*, Vandenhoeck und Ruprecht, Göttingen, 1961, pp. 383 and ff.

<sup>65.</sup> See Gerd Geilen, *Einwilligung und ärztliche Aufklärungspflicht*, op. cit., p. 99. With the exception of the powers granted for the purposes of public health.

<sup>66.</sup> Romeo Casabona, C. El Médico y el Derecho Penal. La actividad curativa, I, op. cit.

<sup>67.</sup> Romeo Casabona, C. El Médico y el Derecho Penal.La actividad curativa, I, op. cit., and bibliography in n.211.

<sup>68.</sup> From a legal perspective, consent cannot exempt illegal conduct such as bodily injury caused by negligence, according to Spanish law (arts. 155 and 156 of the Penal Code). However, the wording of art. 155 of the current Penal Code means that it may have an attenuating effect both with regard to intentional and reckless acts (with the previous Penal Code, this was not possible; for reckless conduct, consent could only be accepted with respect to risk associated with the conduct of a third party, not to the typical outcome of a third party's reckless behaviour). See Carlos María Romeo Casabona, "El consentimiento en las lesiones en el Proyecto de Código Penal de 1980", in *CPC*, no. 17, 1982, pp. 287 and ff. and 292 and ff.

#### 4.4. The form of consent

The form of consent refers to how consent should be recorded, in particular the information and the consent itself. There is no hard and fast rule that requires that consent must always be granted in writing, and it can in fact be given orally, depending on the situation and the medical intervention to be performed. In fact, the majority of medical interventions are based on verbal consent or, even more frequently, tacit consent (which should not be confused with assumed consent, as we will see below); and, by the same token, the majority of information is provided verbally.

In general, consent and the information relating to it are provided in writing – by the patient and the doctor, respectively – where the intervention is more serious (for example, if it involves an invasive procedure) or presents known risks, with the exception of emergencies in which delay would pose a threat to the life or health of the patient.

As a result, the information does not have to be exhaustive when it is provided in writing, either; and it is understood that this essential information will have been expanded upon verbally by the doctor. A range of protocols have been developed by scientific societies and hospital care committees for use in standard situations. Although these provide an acceptable starting point and may offer useful guidelines for health professionals in the situations they cover, this does not mean that they do not need to be adapted for the specific patient for whom they are to be used (something which may be done through appendices to the different protocols). It can never be acceptable to satisfy the obligation to provide written information as part of the consent process by resorting to general leaflets, as these cannot satisfy the basic requirement of recording that the patient has been adequately informed before granting valid consent. If a third party who reviews the document containing this information (e.g., the judge) is not able to understand and identify the key aspects of the medical treatment to which consent has supposedly been granted, then nor can it be deemed acceptable that the patient has had to take his decision on the sole basis of this document. Nor should such documents be seen merely as a tool to defend against possible legal claims, and go to the other extreme by including every possible eventuality, however remote or unimportant it may be for the patient. In this regard, it should be noted that if the information document has been compiled correctly then it will help to protect the doctor by providing evidence of proper conduct and that the patient, after having been informed and granting his consent, had accepted the risks associated with medical treatment. However, it is also futile to use these documents to introduce clauses exempting health professionals from any liability. Regardless of the patient's agreement, such clauses have no legal force, because the patient has granted his consent to correct professional practice but not to negligence, and it would therefore be reasonable to assume that this did not cover any type of exemption<sup>69</sup>.

#### 4.5. The moment of consent

Consent must be prior or simultaneous to the intervention. In principle, retrospective consent would have no legal weight, and this could be significant should any civil or criminal case arise. Indeed, retrospective consent is irrelevant in criminal law, where its only role is in the pardon of an offender by the victim.

Prior consent – prior to treatment, that is – relates to a specific, planned intervention. However, it is possible to accept for legal purposes wishes which have been stated with regard to a hypothetical situation, which is not certain to actually occur, in the event that the interested party is not in a position to state his wishes when the situation actually arises (prior wishes or advance directive)<sup>70</sup>. For this reason, there is no requirement for the situation under discussion to be imminent. This aspect, the legal legitimacy of which has been the focus of debate among legal specialists, in particular with regard

<sup>69.</sup> In fact, such exemption is not an option under Spanish criminal law, where, at least in the case of reckless homicide and most injuries, potentially criminally acts are investigated by the judge, and it is sufficient for these acts to be reported for the judge to intervene.

<sup>70.</sup> Consent or opposition to the donation of organs or tissue could also be one such case, and could be expressed through the legal provision "on advance directives" referred to in the following note. See Juana Marco Molina, "El régimen jurídico de la extracción y del trasplante de órganos", in *LL*, no. 5343, 2001, p. 4, n. 30.

to what have been referred to as 'living wills', is expressly recognised in the CHRBM<sup>71</sup>. In any event, it is necessary to ensure that the document where this directive is recorded offers adequate guarantees as to the authenticity and accuracy of its contents.

#### 4.6. The rectification or revocation of consent

The possibility of revoking or withdrawing consent after it has been granted is simply a necessary consequence of the widely recognized principle of patient autonomy, and all the more so when all that is involved is whether to rectify or modify a decision which has already been taken.

In fact, one of the most significant aspects of consent in the medical context, a consequence of the special characteristics described above – which means that it necessarily transcends any individual area of the law and is instead conceived as a right which interlinks with other fundamental rights – is the extensive opportunity for rectification without this being subject to any special procedures. Consent once granted is not irrevocably binding upon the patient, who is instead enabled to modify his decision right up to the moment when treatment begins. This means that the patient may restrict or extend the initial terms of his declaration, and the doctor must then adapt to the new situation<sup>72</sup>.

The patient's wishes may extend as far as complete revocation of any consent which has been granted. In all of these changes to the terms of the patient's authorisation, the doctor is obliged to respect them and to adapt to them. Clearly, anything which has been done before the revocation or restriction remains legitimate; and if the changes require that treatment be interrupted, then it may still be necessary to complete treatment which is already under way.

Revocation may occur at any moment, without special procedures (although it is advisable to record this in writing if consent was also recorded in this way), and without prejudice to the treatment the patient receives, apart from any expenses which may have been occurred.

This situation should not be confused with what happens when the patient refuses to undergo treatment (although this may also entail the revocation of consent) which has not yet been started or which can be interrupted but which is necessary from a medical viewpoint, because the relevant legal mechanisms are different, as we will see below.

Although the General Health Act contains no explicit reference to the possibility of revoking consent, the CHRBM mentions it expressly<sup>73</sup>.

#### 4.7. Exceptions to the right to grant consent

As we have seen throughout this paper, consent is a key element of the doctor-patient relationship. However, at times it has no place in this relationship, either because it is considered irrelevant by the law (e.g., compulsory interventions), or it is not possible for the patient or his representatives to grant it and waiting to obtain it would make a bad situation worse (e.g., emergency situations where the patient is unconscious)<sup>74</sup>. In both cases, which represent clear exceptions to the general need for the patient's consent, the professional is allowed to act so long as he does so within a specific framework, generally established by the law.

The exceptions to the right to consent are covered by the General Health Act on these terms: a) when not intervening poses a risk to public health; b) cases where the patient is not competent to take decisions; and c) in urgent situations where there is a risk of death or irreversible injury to the patient (art. 10.6).

<sup>71.</sup> In accordance with art. 9: "The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account." A similar provision appears in Catalan Act 21/2000 (art. 8) and in the Proposed Legislation approved by the Senate in 2001 (art. 8).

<sup>72.</sup> Romeo Casabona, El Médico y el Derecho Penal. La actividad curativa, I, op. cit.

<sup>73.</sup> According to art. 5, par. 3: "The person concerned may freely withdraw consent at any time."

<sup>74.</sup> See Fernández Hierro, Sistema de responsabilidad médica, op. cit., p. 141.

In reality, in the three scenarios described above, only the first (risk to public health) involves an exception to the right of autonomy as reflected in the act of granting consent. The same cannot be said of the other two. With regard to the second scenario (incompetent patient), we have already seen that what occurs is rather a displacement of this right onto those responsible for authorizing treatment, without the right to grant consent and the obligation of the doctor to obtain this actually being affected, even if this is through a third party. And nor does the third scenario (emergency treatment) represent an exclusion of the right to consent. Rather, for practical reasons of extreme urgency, it is not possible to wait to obtain this either directly from the patient (e.g., because he is unconscious) or from his legal representatives or family or close friends (if they cannot be contacted immediately). As we have already discussed the second of these scenarios in some detail above, we will now focus our attention on the other two.

#### 4.7.1. The supremacy of collective interests

Sometimes, collective interests may take priority over individual ones. This conflict arises with particular intensity in the health sector, when seeking to protect collective (or public) health against the risks which might derive from the uncontrolled spread of a disease which is easily transmitted to human beings (e.g., in the event of a pandemic being declared, of the spread of an infectious-contagious disease). In these circumstances, higher motives of the protection of public health may lead to the imposition of certain measures which restrict not only the decision-making autonomy of citizens who may transmit a disease (as carriers of pathogenic agents) but even of their freedom of movement or that of certain social groups or of society as a whole. To this end, the authorities may agree preventive measures (such as imposing compulsory vaccination campaigns or prohibiting access to certain places) or obligatory treatment, including monitoring and temporary detainment or isolation. These restrictive measures may be legitimate even though they affect a fundamental right so long as they do not deprive it of its essential content.

By the same token, both the interests of the patient and the need to safeguard collective security may lead to the compulsory internment of some mental

patients in exceptional situations. This issue is currently regulated in art. 763 of the Law of Civil Procedure.

The Spanish Constitution requires, in cases where laws affect the development of fundamental rights and public freedoms, that these must have the status of basic legislation (leves orgánicas) which means that they must be approved by an absolute majority in parliament (see arts. 53 and 81 of the Spanish Constitution). This was the case with the legislation on Special Measures in Public Health<sup>75</sup>, which deals with the legal provisions the authorities may adopt when there is a serious risk to public health. In accordance with this Act, the competent health authorities may adopt measures to identify, treat, hospitalize or control individuals when there are reasonable indicators of the existence of a threat to the health of the population due to the specific health situation of a person or group of people or due to the health conditions under which an activity is performed (art. 2). At the same time, it establishes that, in order to control transmissible diseases, the health authorities, in addition to performing general preventive actions, may adopt the necessary measures to control patients, people who are in or have been in contact with them and the immediate environment, and those measures deemed necessary in the event of a transmissible risk (art. 3).

A detailed analysis of the impact of such powers on individual rights is beyond the scope of this presentation<sup>76</sup>, and so I will restrict myself to noting that the doctor, by order of the competent authority acting under this Act<sup>77</sup>, may find himself in the position of being obliged to perform treatment or other health interventions of a coercive nature: that is, against the will of the patient or, even, of others in some way affected by the risks to public health identified by the Act.

<sup>75.</sup> LO 3/1986, 14 April. See also Chapter V of the General Health Act, "On public intervention in regard to individual and collective health".

<sup>76.</sup> See for more detail, Eduardo Cobreros Mendazona, *Los tratamientos sanitarios obligatorios y el derecho a la salud*, HAEE/IVAP, Oñati, 1988, pp. 331 and ff.

<sup>77.</sup> As Cobreros Mendazona explains, it is not easy to determine who the competent health authorities are, despite the fact that this question is one of great importance. See in this regard, Eduardo Cobreros Mendazona, *Los tratamientos sanitarios obligatorios y el derecho a la salud*, op. cit., pp. 336 and ff.

#### 4.7.2. Life-threatening emergencies

The starting point consists of the existence of a life-threatening emergency for the patient in which the patient is unable to grant consent – because he is in a coma, or suffers from a profound mental disability – and it is not possible to obtain consent from the patient's legal representatives, family or close friends. As a result, it is not possible to obtain the required consent.

Implicit or assumed consent – which should not be confused with tacit consent, in which there is genuine consent, but it has to be deduced from previous statements, behaviour or attitudes – is a legal resource used by jurists in some situations. However, it is usually rejected as a legal basis for the action of a doctor who has been unable to obtain the express consent of the patient or competent third parties<sup>78</sup>, including in life-threatening emergencies, given its conceptual ambiguity (e.g., as regards the basis on which it can be applied in each specific case, the limits on it, excessive caution, etc.) and the legal uncertainty this may generate when the doctor may be accused of having injured the patient's legally protected personal rights.

By contrast, Spanish legislation provides far clearer and therefore more reliable guidance on the issue of assumed consent with respect to the conditions under which it is valid and applicable. This is based on the actual level of emergency (e.g., exemption from criminal liability in a situation of emergency, art. 20.5 of the Penal Code, on a general basis, and General Health Act, art. 10.6, c, and the CHRBM, art. 8, specifically for the medical context)<sup>79</sup>. These considerations do not, however, mean that the patient's wishes to the contrary can be ignored if these are known by indirect means.

We do, however, find a clear reference to assumed consent in abortion carried out in emergencies where there is a risk to the pregnant woman's life

(so-called therapeutic abortion, Penal Code, art. 417. 1. circ. 1, par. 2), which provides the authority to "dispense with express consent", which might lead one to think that tacit consent exists. However, in reality this continues to take as its legal basis the state of emergency caused by the danger to the life of the pregnant woman, and does not, therefore, represent a divergence from the positions set out here. When the situation is not urgent, the doctor has no basis on which to act (neither the CHRBM or Spain's General Health Act authorize him to do so) except to prevent a worsening of the patient's state. Major interventions must be postponed until the consent of the patient or of his family or close friends has been obtained.

A more complex situation is the one which arises when, during the course of an operation (in which the patient is under general anaesthetic and therefore unconscious), the doctor considers whether to extend the operation or change the original objectives. Here again we have to consider whether or not the extension is necessary and urgent. If extension is both necessary and urgent (e.g., during surgery the doctor observes other circumstances which had not been foreseen or if complications arise, etc.) then it is covered by the conditions discussed earlier, designed to ensure the successful outcome of treatment and to protect the patient. If, on the contrary, the intervention is necessary but not urgent, or the doctor is taking the opportunity of the operation to extend it in terms which are not strictly necessary, then he must refrain from going beyond the original consent.

This has been the approach adopted in case law, although the reasoning has not always been consistent. So, in Supreme Court Ruling of 10 March 1959, on the unnecessary extension of surgery without the patient's consent (removal of the penis due to an assumed but unproven sarcoma, observed in the course of a groin hernia operation). The Supreme Court correctly rejected the defence that the surgeon was legitimately exercising his profession (art. 20.6 of the current Penal Code) and found him guilty of reckless practice, on the basis not so much of the absence of consent as on the apparent absence of any proven medical indication for the extension and on the doctor's failure to satisfy standards of professional good practice, which was the real underlying problem. In the Supreme Court Ruling of 26 October 1995, the doctor was found guilty of

<sup>78.</sup> As early as the 19th century there are references to assumed consent with respect to medical treatment, such as the case of Manzini, cited by Roland RIZ, *Il trattamento medico e le cause di giustificazione*, CEDAM, Padova, 1975, p. 80, n. 153.

<sup>79.</sup> Case law has also rejected the validity of appeals to assumed consent in the medical sphere: Supreme Court Ruling 26 October 1995 (see commentary below). However, it appears to be accepted by the Ruling of the Provincial Court of Soria of 12 December 1994.

reckless injury for having performed a hysterectomy on the patient in the course of a Caesarean delivery with complications - haemorrhage - which was resolved. Although the measure was necessary to prevent problems in the future, it was not urgent, and the doctor did not have the patient's consent and had not consulted her family, who were waiting outside the operating theatre. However, the sentence imposed by the Supreme Court was light, reflecting the fact that the doctor incorrectly believed he was acting properly. In this case, the ruling of reckless injury does not strike me as correct, given that the intervention itself was indicated, although not urgent and the doctor should not have extended the scope of the operation. Rather, I believe the doctor should have been found guilty of negligence for assessing as urgent an intervention which was not. In the absence of recklessness, the doctor should have been found not guilty, leaving open the possibility of a finding of civil liability for damages<sup>80</sup>, as the charge of duress does not appear to apply in this case: while it is true that the doctor violated the patient's freedom, the facts of the case mean that it does not fall within the definition of coercion. Finally, Barcelona Provincial Court Ruling of 25 June 1993 absolved the defendant of a charge of assault for extending an intervention in which a second molar was extracted, in addition to the one initially planned, on the basis that it was an emergency. In any event, we must accept that it is not always easy to evaluate any given situation, and there is the potential for conflict between legal principles, on the one hand, and the doctor's wish to relieve the patient of the discomfort of a subsequent operation by taking advantage of the opportunity offered by the operation under way, on the other. This may at times lead to unfortunate consequences, but respect for the patient's wishes must prevail<sup>81</sup>.

It is even more difficult to evaluate other situations such as, for example, the one already mentioned in which the doctor considers an expansion of the treatment which appears to be necessary but in no sense urgent. Here the question is what decision should be taken if it is found that the doctor did not foresee this expansion, but it was easily foreseeable? Strict application of the criteria regarding objectively necessary care and recklessness would in any event lead to the liability of the doctor: if the doctor decides to act, doing so without the patient's consent and in a situation which is not urgent will lead to a violation of the patient's autonomy, which the courts have found to constitute reckless injury; and if the doctor does not extend treatment, having failed to diagnose or predict the new situation, he may well fall short of his duty of care and be liable for carelessness for this omission prior to the operation. However, this must be clearly demonstrated.

In all these cases in which the degree of urgency is cited as justification, the doctor must have well-founded doubts as to whether the patient would have refused to authorize treatment had he had the opportunity to do so. The proponents of assumed consent tend to advocate not extending treatment<sup>82</sup>. In reality, the situation is closely related to that of the express opposition of the patient, and should be considered together with it.

## 4.8. Withholding of consent as a rejection of medical treatment

As mentioned above, a patient who is competent to grant consent has the legal capacity to reject any medical treatment, whether diagnostic, preventative or therapeutic, and whatever the prognosis which results from not undergoing treatment (even if this is life-threatening), apart from the scenarios already discussed and without prejudice to any special problems which may arise due to exceptional situations (hunger strikes by prisoners; the refusal to receive blood transfusions or other life-saving treatments for religious reasons, see below).

<sup>80.</sup> Supreme Court Ruling of 24 May 1995, in a very similar case (tying the fallopian tubes during an operation), despite the fact that in this case the surgeon had the husband's authorization, ruled that the surgeon had civil liability on the basis that this authorization was not valid because it did not relate to an emergency and consent was strictly personal.

<sup>81.</sup> Supreme Court Ruling of 12 January 2001 addresses the issue of when an intervention can be deemed to be urgent.

<sup>82.</sup> It should be noted that if one argues from the basis of (assumed) consent instead of citing necessity, the doctor may in some situations be protected by the defence that he was acting in good faith in the event of it having been impossible to identify the patient's wishes regarding emergency treatment. However, this argument is not employed by the advocates of this position.

In accordance with art. 10.9 of the General Health Act, everyone has the right:

"To refuse treatment, except in the cases identified in section 6; in which case he must request voluntary discharge, on the terms set out in section 4 of the following article."

For its part, art. 11.4 establishes:

"With respect to the institutions and bodies of the health system, citizens have the obligation to sign the voluntary discharge document should they not accept treatment. If they refuse to do so, the Management of the Health Centre, at the suggestion of the doctor responsible for the case, may discharge the patient."

In this event, the provisions of the Spanish legislation consist of obliging the patient to sign the voluntary discharge document, bringing to an end his relationship with the medical staff. This regulation strikes me as excessively schematic<sup>83</sup>, as it fails to consider the possibility of alternatives to the treatment initially proposed by the doctor or care to ameliorate the patient's symptoms (with respect to treatment, and the same is true of a specific diagnostic test or preventive treatment). It should be borne in mind that refusal may be due to a range of motives – not necessarily issues of personal belief, as we will see below – such as the level of risk associated with the medical treatment. At the same time, it is possible that this refusal may be accepted by the health professional, who will then identify and propose alternatives. Finally, this clause would make no sense in the case of outpatients, and nor do I believe that we should seek to establish an equivalent measure for such patients, beyond what is indicated below.

Voluntary discharge is relevant when there is no longer any point in the patient continuing to stay in or attend the health centre because there are no longer any options available to the health staff with which to treat the patient, other than that which has been rejected by him. As a result, only when this

rejection obstructs or prevents medical treatment can we conclude that the patient has unilaterally severed the relationship which linked him to the health professionals and the centre, as a consequence of which it is appropriate to formalize this break in the form of a discharge document, although even in this case it should be noted that it is euphemistic to classify this as voluntary when it would in fact be compulsory. In this scenario, receipt of the discharge report and signature of it by the patient formalizes the end of the relationship.

## 5. The system of consent in other healthrelated activities

#### 5.1. Organ and tissue transplant

Consent for the live donation of a body part to benefit the health or life of another depends upon the characteristics and conditions of the specific donation. This area is covered by strict legislation, and this in turn conditions the requirements for the validity of consent and the restrictions which apply to it. As a result, although a person's decision to make a live organ donation violates their bodily integrity and is thus in principle a criminal offence (arts. 147 and ff of the Penal Code, crime of bodily injury), it is expressly authorized by the Act of 1979<sup>84</sup> and by the Spanish Penal Code (art. 156). For this authorization to be effective, however, it is not sufficient that the person removing the organ is a doctor; rather, the consent of the donor is required, together with other strict requirements imposed by the Act (art. 4), CHRBM (arts. 20 and f.) and Royal Decree of 1999 (art. 9)<sup>85</sup>.

<sup>83.</sup> For strong criticism of the requirement to request voluntary discharge, GRACIA GUILLEN, *Fundamentos de Bioética*, op. cit., 181 and f.

<sup>84.</sup> Act 30/1979 on the Removal and Transplant of Organs.

<sup>85.</sup> Royal Decree 2070/1999, of 30 December, regulating the activities of obtaining and clinical use of human organs and regional coordination in the matter of the donation and transplant of organs and tissues. Art. 9.1.c specifies as a requirement that the donor has been given prior information about the consequences, and has expressly granted his free, conscious and unbiased consent.

The current legislation raises a number of questions with respect to live donation, and these provide a basis for a legal assessment of the solutions or criteria adopted. To start with, it is important to insist that Spanish law must continue to authorize live donations, including the donation of individual paired organs (particularly kidney donations) and the donation of regenerative tissue (such as bone marrow or bones which do not produce functional impairment)86 or sections or parts of single organs (such as the liver), which do not compromise the donor's life and may be decisive in treating patients whose condition is life-threatening. At the same time, this legislation has been accompanied by a strategy on the part of the authorities to promote organ donation after death, together with a range of supporting measures, and this means that the use of live donors is in practice likely to be reduced to those cases where it is the only option. This trend has been confirmed by statistics for this type of transplant in Spain, above all since the approval of the 1979 Act and the creation of the National Transplant Organization<sup>87</sup>. By contrast, in those countries where the legal situation does not favour transplants from deceased persons or where the necessary infrastructure has not been established, live donors account for a high percentage of total donations (e.g., in some Scandinavian countries); and there are even legal models authorizing the sale of organs by the living.

Finally, from an ethical perspective, nobody now doubts the legitimacy of live transplants even if, as we have noted, these should be a last resort. In any event, live donation should be designed to improve the life of a specific patient<sup>88</sup>.

In recent years, there has been a vigorous debate as to whether or not there should be a genetic relationship between live donor and recipient. The current Spanish legislation says nothing in this regard, and it therefore appears that live donation is also legally permitted when there is no such relationship. Technical considerations apart, the main aim of requiring a genetic relationship is to prevent situations where there may be motives other than altruism behind the decision (and these may be concealed and therefore unknown to doctors and the authorities involved in the donation). However, although the principle of genetic relationship is a good one, I believe that the Spanish legislation already contains sufficient provisions to prevent such undesirable situations from developing, while refraining from a blanket ban leaves open the possibility of attending to exceptional situations and allowing donations motivated by genuine feelings of solidarity and affection between donor and recipient (spouses, partners) in which the existence of sufficient biological compatibility to ensure the success of the operation in accordance with medical science has been confirmed.

In comparative law, there has been a trend towards restriction. This is the case of the new French legislation, which requires that the recipient must be the parent, offspring or sibling of the donor, except in the case of bone marrow extraction, and in emergencies, where a spouse may also donate<sup>89</sup>.

In any case, in live donations doubts as to spontaneity frequently remain in so far as family members (whether blood relatives or not) may be subject to moral or psychological pressure both to donate and to accept the donation, and this poses a problem when it comes to assessing whether the consent has been granted freely and without interference, as the law clearly requires. This assessment must be made by all of those involved in the treatment and who must authorize it: the Civil Registrar, the doctor who must accredit the physical and mental health of the donor, and the person who must give consent for the operation to go ahead. For this reason, the detailed procedures established in the Act and in RD 1999 strike me as appropriate.

<sup>86.</sup> See Royal Decree 411/1996, of 1 March, regulating activities with regard to the use of human tissues.

<sup>87.</sup> In Spain the problem also exists, although it is less acute due to the relatively high rate of organ donation after death (33.9 donations per million inhabitants and 83% of multi-organ donations in 2000, according to data supplied by Spain's National Transplant Organization), and this has remained at a very high level compared to other developed countries: the figures for 1999 are 13.8 for Eurotrasplant, 12.7 in Germany, 16.2 in France, 13.7 in Italy, 19.1 in Portugal, 13.0 in the United Kingdom, and 14.1 in Canada, compared to 33.6 in Spain for the same period.

<sup>88.</sup> In this regard, the CHRBM (art. 19.1) and Royal Decree 2070/1999 (art. 4) are clearer than Act 30/1979.

<sup>89.</sup> See Act no. 654/1994, art. L. 671–3. The German legislation, in the case of non-regenerative organs, limits recipients to parents, offspring or siblings, as well as the spouse, partner or other people with whom the donor has a recognized close, constant relationship (art. 7.1).

Designed as it is to ensure that consent is genuine, I think the Spanish Organ Transplant Act is correct to prevent minors and the incompetent (whether de facto or de jure) from being donors, with the exception in the case of minors of regenerative tissues (specifically, bone marrow), regardless of whether their legal representatives have granted consent. Although it is true that this approach means there will be cases in which the recipient is prevented from receiving vital care, the experience in some countries of, in my opinion, abuse of the minor by his parents, even if motivated by the desire to save the life of another child, means that such people should be afforded special protection. A different but related problem has arisen in some countries where a second child is conceived so that he or she can donate tissue to an elder sibling. Irrespective of how one may view this from an ethical perspective, the legal provisions for donations by minors are quite clear, without any need to have recourse to specific legal instruments prohibiting such pregnancies (something which would, anyway, represent excessive interference in the private sphere): in Spain, it would not be possible except in the case of bone marrow transplant (so long as this did not endanger the life of the minor or produce permanent functional impairment), because minors are not allowed to donate organs.

The CHRBM adopts a similar position and allows, as an exception, the donation of regenerative tissues by a person who is not competent to consent (either a minor or an incompetent adult), and adding certain additional procedural guarantees<sup>90</sup>.

The Spanish legislation also includes guarantees to protect the patient receiving the organ, as this is the person most at risk. These guarantees are: curative aim of intervention; performance of appropriate medical and preparatory tests; information and consent of recipient or family or legal representatives, in the case of a minor or a patient with mental handicap (art.

6). This is an example of how careful Spanish law has been in protecting all the legal rights involved, and in particular the specific rights of patients who undergo organ transplant, anticipating the rights of health service users established in art. 10 of the General Health Act, which also apply.

Because these decisions are of great importance for the recipient, one must insist on the need to comply very strictly with the requirement for advance information, which due to the nature of the operation will generally need to be given in two stages: when transplant is identified as necessary, so that the patient may be added to a waiting list; and immediately prior to the operation, when an organ is available for the recipient. This requirement is clearly established in the Organ Transplant Act (art. 6.1 and 2) and in RD (art. 15.1 and 2), and also, more generically, in the General Health Act and the CHRBM, as noted above.

## 5.2. Assisted reproduction techniques

Assisted reproduction techniques involve the wishes of various people, with respect to a range of legal issues: the recipient, the gamete donors (male or female) or embryo donors (married or unmarried couples), and the husband or partner of the recipient. It should be noted that in some legal systems, the consent of the husband or partner is not always required, if single women are allowed to benefit from assisted reproduction (as occurs in art 5 of the Spanish legislation). In fact, what is required is not just the consent of the recipient, but rather that she has freely and consciously requested it.

Consent or acceptance requires prior information and even advice (art. 2.1, b and 2). The donors are also part of this information process, delivered by the medical teams and management of the health facilities where the procedures are performed. This information (and advice) process should cover a range of the aspects and possible implications of ARTs, together with the expected outcomes and foreseeable risks; and it should also cover all information of a biological, legal, ethical and financial nature related to such techniques. Apart from being impossible to satisfy (how far would one have to go in explaining "all information of a biological, legal, ethical and financial

<sup>90.</sup> The conditions are: "there is no compatible donor available who has the capacity to consent; the recipient is a brother or sister of the donor; the donation must have the potential to be life-saving for the recipient; the authorisation ... has been given specifically and in writing, in accordance with the law and with the approval of the competent body; [and] the potential donor concerned does not object." (art. 20.2).

nature related to such techniques"?), information of an ethical nature does not seem to be of any relevance, relating as it does to private individual choices, while the other information is only relevant in so far as it has a bearing upon the specific case and its consequences (e.g., as relating to offspring).

Consent should be recorded in writing in a standard form (art. 2.3), and all of the information related to the use of these techniques must be included in individual medical records, ensuring confidentiality with regard to users, donors and any children born as a result (art. 2.5). As can be seen, most of these issues are already covered by the General Health Act (arts. 10 and 61), which can be applied to such cases as well. A peculiarity of these techniques is the need to obtain the husband's consent, because he will have to assume paternity of the child even if it is not biologically his (for example, if the child is produced using sperm or embryo donation). This requirement is correct, in contrast with other situations, such as sterilization as a family planning measure, where it is both unethical and in fact illegal to require the consent of the member of the couple not undergoing the procedure, despite which it frequently occurs.

The woman receiving treatment may withdraw her consent at any time, in which case the procedure must be suspended immediately (art. 2.4). Although the right of the woman to reject treatment is self-evident, determining exactly how far it extends may be problematic because once the woman has been fertilized or the pre-embryo has been transferred and becomes embedded in the endometrium, its existence is protected by criminal law and 'removing' or 'extracting' it from the uterus would constitute abortion and would be an offence unless there was a therapeutic motive or an embryopathy had been detected. In any event, the law refers to the immediate suspension of the procedure, which would appear only to include interruption of the procedure designed to make the woman pregnant, but not after this procedure has been completed, or interventions actively designed to roll back the process if it has given rise to gestation (in this regard, one should also note the offence defined in art. 20.2, B, b). And finally, it should be noted that the practice of assisted reproduction without the consent of the woman was defined as a criminal offence in the Penal Code of 1995 (art. 162).

# 5.3. Other activities which are subject to special regulations

It is not possible here to analyse in detail the different regulatory systems established to cover activities which do not bring any benefit to the participant and which may, moreover, pose a risk. Interesting as these are, I shall limit myself here to a brief overview.

- use of embryos and foetuses for various purposes<sup>91</sup>
- donation of blood and blood products<sup>92</sup>
- clinical trials with human beings<sup>93</sup>
- clinical autopsies for research or other purposes<sup>94</sup>
- voluntary termination of pregnancy<sup>95</sup>
- sterilization of competent adults and the mentally disabled%.

# 6. A particularly controversial case: refusal to consent to life-saving treatment for religious reasons

In the clinical sphere from time to time the issue arises of how to respond to a patient's refusal to consent to certain treatments. The importance of such

- 95. See art 417 bis of the Penal Code of 1973, which has remained in force.
- 96. See art. 156 of the Penal Code.

<sup>91.</sup> Act 42/1988, 28 December, on the donation and use of human embryos and foetuses or their cells, tissues or organs (art. 2). Also, Act 35/1998, 22 November, on assisted reproduction techniques (arts. 14 and ff.).

<sup>92.</sup> Blood donation, human blood and plasma, blood and tissue banks are regulated by Royal Decree 1945/1985 of 9 October, Royal Decree 478/1993, of 2 April, and Royal Decree 1845/1993, of 22 October (art. 22).

<sup>93.</sup> Act 25/1990, of 20 December, on Medicines (art. 60), and Royal Decree 563/1993, of 16 April, on Clinical Trials (art. 12).

<sup>94.</sup> Act 29/1980, of 21 June, regulating clinical autopsies (art. 3) and Royal Decree 2230/1982, of 18 June, which developed upon it.

cases lies not so much in the individual cases themselves but rather in the social implications and in the fact that they involve situations where the patient's life is at risk (or rather, where the patient puts his or her own life at risk). At the same time, they are usually the cause of confusion on the part of health professionals, who are unsure as to the legal position regarding medical treatment in such situations.

One example is the rejection of blood transfusions for religious reasons, when these may be necessary to save the patient's life. Disputes relating to rejections by Jehovah's Witnesses have occurred primarily in cases involving adult patients, who either refused to receive a blood transfusion or on whose behalf the transfusion was refused by their companions because the proposed recipient was not in a position to express his or her wishes. These cases have also been the focus both of theoretical debate and of various legal rulings with respect to the decisions of these individuals, their families and their fellow believers<sup>97</sup>. Analysis of this specific issue provides an opportunity to consider some issues which have not been addressed in cases involving minors, or which have only been addressed in passing.

The rejection of treatment by adult patients for religious reasons (in particular, blood transfusions) is generally treated as an example of conscientious objection<sup>98</sup>. In these situations, there is a conflict between the individual's duties, which are constrained by the dictates of his conscience; however, in practice this conflict does not take the characteristic form of conscientious

objection. In these cases, although there may be religious or conscientious motives, a prior question arises: that of the freedom of any patient to undergo treatment, whether life-saving or not, and whatever the reason for deciding to reject this treatment if so desired. As we have already seen, this freedom is recognized in the General Health Act<sup>99</sup> and, as I explain below, it has constitutional support not in the right but the freedom to dispose of one's life for oneself<sup>100</sup>.

It is not my intention to argue that there is no underlying issue of conscience, as this is indeed a potential cause of conflict; however, from a legal perspective it is not necessary to resolve it in terms of a conflict of duties. The issue, in sum, is the recognition of the individual's autonomy as a competent adult who understands what he is doing, even when this results in the loss of his own life. As we have already noted, this encompasses the apparent contradiction between individual duties (and, indeed, between the individual's moral duties) which operate at the level of the individual affected and which should, therefore, be addressed exclusively at this level. Only if one concludes that the individual does not have the freedom to dispose of his or her life – a position which I do not share  $^{101}$  – does a confrontation arise between life and health, on the one hand, and freedom of conscience, on the other. However, if in reality there is no constitutional duty to continue living against one's will (it should be noted that the right to life in art. 15 of the Spanish Constitution operates as a guarantee)  $^{102}$ , then it is hard to argue that any conflict of duties

<sup>97.</sup> The following is based on my earlier studies "La objeción de conciencia en la praxis médica", in Libertad ideológica y derecho a no ser discriminado, in Cuadernos de Derecho Judicial, Consejo General del Poder Judicial, Madrid, 1996, pp. 69 and ff.; 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), op. cit.

<sup>98.</sup> However, sometimes the leaders of this religious group or its official publications make claims as to the unreliability of blood transfusions because they transmit a large number of diseases; in other words, they present it as a medical issue. Regardless of whether they are right or wrong to argue this, it does not strike me as correct to seek to confuse or complicate the issue: for people who belong to the Jehovah's Witnesses the rejection of blood products is fundamentally a religious decision (see below), and other issues are secondary and distract attention from the core of the problem.

<sup>99.</sup> Specifically, art. 10 nos. 6 and 9.

<sup>100 .</sup> Similar considerations lead Carlos Perez Del Valle, *Conciencia y Derecho Penal. Límites a la eficacia del Derecho Penal in comportamientos de conciencia*, Ed. Comares, Granada, 1994, p. 166, to argue that it is irrelevant whether constitutional support is based on the principle of the dignity of the individual or on the free development of one's personality, or on the fact that the decision derives from a duty of conscience.

<sup>101.</sup> See my earlier work, "Los derechos del enfermo a la luz de la Constitución española", in TH, no. 62, 1989; Configuración sistemática de los derechos de los pacientes en el ámbito del Derecho español, op. cit., pp. 171 and ff.; El Derecho y la Bioética ante los límites de la vida humana, Ed. Centro de Estudios Ramón Areces, Madrid, 1994, pp. 95 and ff.

<sup>102.</sup> Constitutional Court Ruling, of 27 June 1990, op. cit.: "the right to life therefore contains an element of positive protection which means it cannot be configured as a freedom which

exists<sup>103</sup>. From the perspective of criminal law, these cases do not meet the definition of an offence<sup>104</sup>.

However, this conflict may affect third parties involved in the decision, in particular the health professional caring for the patient, both because of his obligation to provide a high standard of care (*lex artis*),<sup>105</sup> to operate within the law, and because the action required by the patient – in general concerning the withholding of treatment – may clash with the doctor's own moral convictions; and the judge may also be affected if he is asked to intervene to decide which course of action is lawful. At the same time, the patient's family and friends – or fellow-believers who share the patient's religious faith – may also feel called by their conscience to intervene to ensure that the patient is not submitted to a treatment which contravenes his beliefs, particularly if the patient is not in a condition to express his wishes. This is when potentially

includes the right to one's own death. This, however, does not prevent us from recognizing that, as his life is a legal right of the individual which forms part of his wider freedoms, that person may also in fact decide upon his own death, but this decision constitutes an expression of the freedom to act, in so far as the law does not prohibit the individual from accepting his own death."

- 103. Explicitly, Provincial Court Ruling of Ciudad Real of 27 January 1995 stated: "We do not believe that the conflict which arises is between personal freedom and conscience on the one hand and the right to life on the other, in the sense expressed in the Ruling, and this, because what the Constitution guarantees is precisely a right to live... However, the person to whom the right belongs is not thus subject to a duty to live, as is shown by the absence of any penalty for attempted suicide, and less still is there a duty to live at all costs... It is not, then, a conflict between the duty to live, and personal and ideological freedom and freedom of conscience which arises (f.j. 3)".
- 104. I consider this in my study La objeción de conciencia y su relevancia en el Derecho Penal (pending publication). See also Perez Del Valle, Conciencia y Derecho Penal. Límites a la eficacia del Derecho Penal en comportamientos de conciencia, op. cit., pp.136 and 166, for whom the constitutional right to freedom of conscience would be a valid criterion in determining responsibility for decisions in situations where an individual exposes himself to risk.
- 105. See Manuel Espinosa Labella, "Las transfusiones de sangre a los testigos de Jehová: un conflicto entre el médico y el enfermo", in *AP*,1996, p. 944.

problematic issues for the Criminal Law may arise – at least apparently –  $^{106}$  and this has indeed happened. Although, as has been noted, because in these cases the duty to take specific action to save another person's life disappears, there would be no crime either of omission in the strict sense or of commission by omission. For this reason, and taking as our starting point the premises outlined above, we shall review the problems which have arisen both in Spanish legal theory and, above all, in practice, from the perspective of the objector.

In fact, taking a consistent approach to this religious belief may raise serious conflicts both at the care and the legal level, when the rejection of transfusion is accompanied by a situation of serious risk to the life of a member of this religious group, such as, for example, if the patient has suffered a major haemorrhage as a result of accident or illness (e.g., a gastric ulcer) or is to undergo surgery in which the support of blood transfusion is expected to be required.

<sup>106.</sup> Some legal rulings deny the relevance of criminal law in these cases: Supreme Court Ruling of Madrid, 23 December 1992 (f.j. no. 11, see below), Provincial Court Ruling of Palma de Mallorca, 29 June 1993 ("if one starts from the position that transfusion should not be imposed, and it has been confirmed that consent is free and there are no indications of interference with the patient's wishes, then the issue has nothing to do with the criminal law" (f.j. no. 2).

<sup>107.</sup> In an earlier work, I argued that, "at present, this possibility is covered by certain hospitals, when there is sufficient time, by extracting from the patient prior to surgery enough of his own blood to meet the expected need – auto-transfusion – a measure to which, it appears, the Jehovah's Witnesses are not opposed." (El Derecho y la Bioética ante los límites de la vida humana, op. cit. p. 448). I should point out here that it appears that according to strict orthodoxy this approach is not accepted by the Jehovah's Witnesses either, even though it is sometimes used: "Departamentos Médicos y de Investigación de la Sociedad Watchtower Bible and Tract, Los testigos de Jehová... el desafío ético/quirúrgico", in JAMA, 1981, vol. 246, no. 21, pp. 2471 and f. According to this document, Jehovah's Witnesses do not accept auto-transfusion with prior donation, or intraoperative collection or haemodilution techniques which involve the use of previously stored blood; intraoperative blood salvage techniques appear to be acceptable so long as extracorporeal circulation is not interrupted (as do the use of cardio-pulmonary dialyzers or pumps, so long as they are not supplied with blood).

As has been argued in the case of blood transfusions for Jehovah's Witnesses, doctors must take into account the need to respect the patient's religious freedom, when treatment goes against the patient's religious beliefs or conscience, and based on respect for the patient's autonomy, if they are to avoid the charge of coercion (article 172 of the Penal Code) if they resort to physical force; infringing the patient's freedom of conscience (arts. 522 and following), although it seems unlikely that providing a blood transfusion in itself would constitute an infringement of religious freedom given the literal wording of the law (arguably insufficient), because the doctor would not be forcing the patient to perform actions which would reveal his or her religious beliefs or the absence thereof, nor force the patient to conceal these beliefs, but rather the action would infringe some of the patient's religious precepts<sup>108</sup>. Respecting the patient's wishes ought not to pose a problem, particularly if the doctor has anticipated this possibility and is able to offer the patient other treatments or products in accordance with objective scientific criteria (best practice)<sup>109</sup>, even if these are more difficult and risky to apply - burdens which must be accepted by the patient after receiving detailed and ongoing information from the professionals caring for him<sup>110</sup>.

If there are no available therapeutic options as an alternative to blood transfusion, something which also has to be confirmed, then the possibility of conflict arises. The immediate question is whether a refusal to receive transfusion can be considered to be a suicidal attitude. Jehovah's Witnesses themselves insist that they are not suicidal and nor are they exercising the 'right to die' when they reject transfusion: "The fact is that Jehovah's Witnesses want to carry on living. This is why they seek medical help. However, they cannot and will not violate their religious beliefs, which are firmly based on the Bible."<sup>111</sup>

These beliefs are easy enough to comprehend: Jehovah's Witnesses want to live, but without violating their religious beliefs, something which seems worthy of respect, regardless of whether one shares such minority beliefs. However, when there are no alternative treatments (a hypothesis which must be accepted as the starting point for extreme cases, although these are probably isolated in practice) and blood transfusion appears to be the only means possible, viewed objectively, of removing an imminent threat to the life of a patient who belongs to this religious group and who remains faithful to his religion by persisting in rejecting transfusion, then we have to accept that through this attitude the patient is accepting the possibility of death, and there is a willingness to die, at least indirectly, if the patient is aware that there is no other way of saving his life. From a legal perspective, this acceptance of the likely or certain occurrence of death is close to a suicidal attitude in so far as it is the necessary consequence of rejection a life-saving transfusion<sup>112</sup> which, at the same time, is respectable from an ethical perspective if it

<sup>108.</sup> According to art. 522 of the Penal Code (the only one which, in my opinion, is potentially applicable): "A sentence of between four and ten months will apply to: 1. Those who, by means of violence, intimidation, force or any other illegal pressure prevent a member or members of a religious group from following the practices associated with their beliefs or attending such practices. 2. Those who by the same measures force another person or persons to practise or attend religious acts or rites or to perform acts which reveal his or her religious beliefs or the absence thereof, nor force the patient to conceal these beliefs." See, however, José Cerezo Mir, *Curso de Derecho Penal Español, Parte General*, II, Tecnos, Madrid, 1996,p. 50.

<sup>109.</sup> See Tratamiento a pacientes testigos cristianos de Jehová. Cuestiones Éticas, Comité de Enlace con los hospitales, s/f., which indicates bloodless medical treatment strategies: surgical techniques and devices to locate and stop internal haemorrhage; techniques and devices to stop external haemorrhage and recover from a state of shock; surgical and anaesthetic techniques to reduce haemorrhage during surgery; devices to monitor blood oxygen levels and techniques to reduce blood sampling; volume expanders; haemostatic agents for clotting problems or haemorrhage; therapeutic agents and techniques for the treatment of anaemia.

<sup>110.</sup> See General Health Act, art. 10. 5. Also Provincial Court Ruling Ciudad Real, 27 January 1995, op. cit. (f.j. 3 and 8).

<sup>111.</sup> Los testigos de Jehová y la cuestión de la sangre, op. cit., p. 21.

<sup>112.</sup> Although this issue is hotly debated at the theoretical level, from a legal perspective how it is classified is irrelevant (even for those of us who hold this position), as can be deduced from the text and we will confirm below. On the meaning of the text, see Diez Ripolles, "La huelga de hambre en el ámbito penitenciario", in *CPC*, no. 39, 1986, p. 609; Romeo Casabona, *El Médico y el Derecho Penal, I. La actividad curativa*, op. cit., p. 375. Alfonso Ruiz Miguel, "Autonomía individual y derecho a la propia vida (un análisis filosófico-jurídico)", in *REC*, no.. 14, 1993, p. 155, n. 16, with regard to hunger strikers. Luzon Peña, "Estado de necesidad e intervención médica (o funcionarial o de terceros) en casos de huelgas de hambre, de suicidio y de autolesión: algunas tesis", in *Estudios de Derecho Penal* (ed. S. Mir

is the result of personal decisions which have been freely reached and are rooted in the conscience of the individual. It should also be noted that for some social groups there are values which demand respect which are higher even than life itself in certain circumstances<sup>113</sup>, and that this combines with principles of tolerance in relations with minorities and respect for ideological pluralism.

Under the previous Penal Code (Revised Text) 1973, there was initially a conflict of duties (to protect the life of the patient in accordance with art. 409, on the one hand, and to respect the patient's personal freedom, art. 496, and even his ideological freedom or freedom of conscience, but in accordance with art. 16 of the Spanish Constitution). However, in these cases too one could apply the criteria set out above<sup>114</sup> that a mentally well person who is free of external psychological pressure may reject treatment, even if by so doing he endangers his own life, without thereby committing the crime of abetting suicide by omission, because in these circumstances there is no third party failing to act as guarantor, performing for this purpose a constitutional revision of the previous Penal Code (which on its own, that is to say, without the constitutional filter, offered a vision of absolute preference for the protection of life against other rights or interests with which it might be in

Puig), PPU, Barcelona, 1991, pp.181 and ff. (p.183), argues that Jehovah's Witness are not suicidal, even though there is a wish to die. In contrast, Bajo Fernandez, "La intervención médica contra la voluntad del paciente", in *ADPCP*, 1980, pp. 494 and ff.; and, "Testigo de Jehová y transfusión de sangre", in *Jano*, vol. XLVIII, no. 1114, p. 638; Francisco Bueno arus, "Límites del consentimiento en la disposición del propio cuerpo desde la perspectiva del Derecho Penal", in *PJ*, 1985, p. 15; Cobreros Mendazona, "La negativa a los tratamientos sanitarios", op. cit. p. 34; Espinosa Labella, "Las transfusiones de sangre a los testigos de Jehová: un conflicto entre el médico y el enfermo", op. cit., p. 944. See for more extensive discussion of this debate, with bibliographical references to both sides, Diez Ripollés, *Comentarios al Código Penal. Parte Especial*, I, op. cit., pp.189 and ff. (at p. 190 and f. develops his position with arguments which I basically share).

conflict)<sup>115</sup>, in accordance with which the protection of human life against the wishes of the holder of that life are not covered by the framework of guarantees of the Spanish Constitution.

The Penal Code of 1995 is also compatible with this restrictive interpretation regarding the omission with respect to the equivalent law (art. 143), but now even more clearly<sup>116</sup>. This, despite the poor wording where, in the final paragraph (art. 143.4), it states "anyone who causes or actively cooperates with acts necessary and directly related to the death of another...", while earlier articles only refer to "anyone who cooperates with acts necessary..." (art. 143.2) and "if cooperation should extend to the point of causing death" (art. 143.3). That is, the first reference uses the word "actively", suggesting the interpretation that this does not include omission or failure to act. All three paragraphs include the word "acts" as an integral part of the action, and this therefore excludes omission, without any requirement to resort to the first argument which would, in any event, merely confirm this conclusion. Bear in mind that, in order to bring out certain key differences with other similar situations where life-saving action by others is rejected, we started from the assumption that the doctor has expressly offered the treatment and has informed the patient of its importance for his life. As a result, the doctor has fulfilled his initial obligation of acting to safeguard the patient's life and, if the patient persists in rejecting treatment, then the doctor no longer has a duty to safeguard the patient's life and there is no longer a clash of duties117 with res-

<sup>113.</sup> Carlos M. Romeo Casabona, *El Médico ante el Derecho*, Serv. Publicaciones del Ministerio de Sanidad y Consumo, Madrid, 1985, p. 49.

<sup>114.</sup> See in general my analysis of the legal aspects which may be relevant to the end of human life, Romeo Casabona, *El Derecho y la Bioética ante los límites de la vida humana*, op. cit., p. 415 and ff.

<sup>115.</sup> See, however, prior to the adoption of the Spanish Constitution of 1978, the ruling of the Provincial Court of Alicante of 29 March 1977: "acts freely performed by the individual upon his own life are not prohibited by current legislation, as criminal law does not punish suicide where it is unsuccessful (considerando cdo. no. 4).

<sup>116.</sup> See, in this regard, Diez Ripollés, *Comentarios al Código Penal. Parte Especial*, I, op. cit., pp. 214 and ff., 221 and f. and 260.

<sup>117.</sup> This is treated as a clash of duties by Cerezo Mir, *Curso de Derecho Penal Español, Parte General, II*, op. cit., p. 50, and resolved on the basis that it would be illegal for a judge to authorize transfusion because this would constitute a serious assault on the dignity of the individual. With respect to the problems associated with a state of necessity to remove criminal liability in the event of coercive transfusion, see Romeo Casabona, *El Médico y el Derecho Penal, I. La actividad curativa*, op. cit., pp. 372 and ff. Here I argued that transfu-

pect to this source of danger although, logically, this does not apply to other treatments which have not been rejected by the patient, and which the doctor remains under a professional obligation to prevent<sup>118</sup>. Compliance with these guidelines also excludes the existence of a crime of omission through failure of the duty to provide assistance (art. 195 of the Penal Code), as the patient is not helpless in the sense described in the definition of this offence<sup>119</sup>.

If the patient has been unable to state and declare his rejection of a possible blood transfusion as being against his religious beliefs, another problem arises, which is not uncommon in hospitals: relatives of the patient, or even members of his religious group who are unrelated to him, oppose the transfusion<sup>120</sup>. Because these wishes, expressed on behalf of the patient, would represent a serious risk to his life, it is essential to identify with absolute clarity what would have been the wishes of the unconscious adult patient had he been able to express them; that is, it is necessary to demonstrate both the patient's membership of the group and his wish to reject transfusion or to remain faithful to his beliefs, preferably in writing, because we should not in principle assume anyone's capacity for heroism, sacrifice or martyrdom, just as we would not assume such a capacity in the members of other, more widespread religious groups.

Given the seriousness of the case and the legal repercussions which it may have for others (the doctors who have taken responsibility for treating the

patient, or the judge who has been asked for authorization), it might not be excessive to require a written declaration similar to so-called 'living wills' or 'advance directives', and that members of this religious group should adopt this precaution. Only in this way may one assume that these third parties are acting in accordance with the wishes of the patient, which is the basis of representation, otherwise it would be no more acceptable than assumed consent<sup>121</sup>. This problem could be resolved by the provisions of Act 21/2000 in Catalonia, which recognizes the possibility of drawing up an advance directive (art. 8), and in the draft legislation, approved by the Senate, which is currently going through the Spanish Parliament. Both texts establish as an exception those decisions which are contrary "to existing legislation or to good clinical practice" (art. 8.3), a stipulation which raises the question of exactly what the scope of these exceptions, particular the first one, would be. However, in the light of the arguments set out above, it is clear that an advance decision such as the one being analysed here would not be contrary to the law. There may, however, be other problems, which I will consider below.

It is important to recognize that doubts as to the validity of such a document are more intense than those regarding an advance directive (designed to put an end to a treatment which in itself appears ineffective in the light of the patient's situation, in contrast with the case which concerns us here) given that the fact that the religious motives behind it and the closed nature of such religious groups leaves open the very real possibility that the document may only have been signed under pressure and at the urging of others. But in the absence of such doubts, the document should be recognized<sup>122</sup>.

This policy of respecting the decision of a Jehovah's Witness has not, however, been recognized in practice in Spain, despite the fact that other channels favourable to the same conclusion have begun to open up. The most common response to situations where life is put at danger by refusal of the trans-

sion is not an appropriate means to a just end (that of saving the patient's life), and the inappropriateness would derive precisely from the indignity of the means highlighted by Cerezo.

<sup>118.</sup> Bajo Fernandez, *Agresión médica y consentimiento del paciente*, op. cit., p. 137, deems it preferable, for reasons of hospital discipline, to perform the blood transfusion against the patient's wishes than to discharge him, also against his wishes.

<sup>119.</sup> See, of the same opinion, Diez Ripollés, *Comentarios al Código Penal. Parte Especial, I*,op. cit., p. 260.

<sup>120.</sup> Supreme Court Ruling of 27 March 1990 addressed interventions by others in such situations, finding a member of this religious group guilty of the charge of voluntary manslaughter for disconnecting the catheter being used to perform transfusion on a fellow-believer.

<sup>121.</sup> In this regard, see Cerezo Mir, *Curso de Derecho Penal Español, Parte General, II*, op. cit., pp. 100 and ff: "In the event of assumed consent, there is no renunciation, and nor has the individual recorded his wishes in advance" (101).

<sup>122.</sup> For the argument against its acceptance, see Cobreros Mendazona, *La negativa a los tratamientos sanitarios*, op. cit., p. 36, n.14.

fusion of plasma products, and where there are no obvious effective alternative treatments, is for doctors to apply to the courts for a ruling on the appropriate course of action, and for the court to order medically necessary transfusions to be performed, with the support of the police if required. In some cases (probably only a small proportion of those involving forced administration of a life-saving transfusion) the patient or his family have lodged a complaint against the judge who authorized or ordered the transfusion, but the Spanish courts have always ruled against them.

In this respect, we must refer back to an old Supreme Court ruling<sup>123</sup>, which confirmed the judge's ruling issued to a doctor who had applied for an order to administer a blood transfusion to save the life of a Jehovah's Witness who had rejected it. This ruling endorsed the judge's decision, on the basis of both the obligation and the right to intervene in the manner described in order to avoid being guilty of passive cooperative with suicide (art. 409 of the Penal Code Revised Text 1973), or of failing to come to someone's aid (art. 489 bis), and that it was also justified due to the situation of need (no. 7 of art. 8 of the Penal Code)<sup>124</sup>.

Subsequently, the Supreme Court has ruled that it was legal to administer a transfusion to a member of the Jehovah's Witnesses, despite which the patient died<sup>125</sup>. On this occasion, the decision's interest lay in the fact that it deployed different, but complementary, arguments to those used in the 1979 case: claims of coercion and the violation of religious freedom were rejected, and with respect to the issue of religious freedom it was noted that the Basic Legislation on religious freedom of 5 July 1980 was limited, among other things, by the need to "protect safety, health and public morality" (article 3, paragraph 1). This case even reached the Constitutional Court, where an appeal hearing found that no offence had been committed and confirmed –

indirectly, as it did not address the underlying issue – the legal reasoning of the Supreme Court<sup>126</sup>. This judgement of the Constitutional Court does not appear to be consistent with the later ruling of 27 June 1990 in an appeal with respect to the issue of hunger strikes.

In this regard, it has been debated whether the Religious Freedom Act refers to individual or public health and, in the latter case, whether this also includes individual health. However, as noted<sup>127</sup>, what is truly important is that in these extreme situations what is at stake is not health (whether individual or collective) but rather the life of an individual, and I have already stated my position with respect to a person's right to dispose of his own life and its consistency with the Spanish Constitution.

For its part, the Supreme Court has considered life to be a right which cannot be disposed of, as a result of which the consent of the patient is irrelevant where a blood transfusion is administered in order to save life<sup>128</sup>. Finally, the Supreme Court has opened up a new channel<sup>129</sup>, although this was not the direct purpose of the case: "A competent adult may raise a conscientious objection to medical treatment and his decision must be respected, except where this endangers the rights or interests of others, poses a threat to public health, or threatens other rights which require special protection."

Despite the exception noted above<sup>130</sup>, this line of argument taken by Spain highest courts has not found much resonance in other courts where a range

<sup>123.</sup> Supreme Court (2), Ruling of 14 March 1979.

<sup>124.</sup> This is what the Ruling states, not what I argue, as was incorrectly attributed to me in his otherwise excellent study by Enrique Diaz Aranda, *Dogmática del suicidio y homicidio consentido*, Centro de Estudios Judiciales y Serv. de Publ. de la Facultad de Derecho de la Universidad Complutense de Madrid, Madrid, 1995, p. 254.

<sup>125.</sup> Rulings of 22 December 1983 and 25 January 1984.

<sup>126.</sup> Constitutional Court Ruling of 20 June 1984.

<sup>127.</sup> Martín-Retortillo Baquer, "Derechos fundamentales en tensión (¿Puede el Juez ordenar una transfusión de sangre en peligro de muerte, aún en contra de la voluntad del paciente?)", op. cit., p. 38.

<sup>128.</sup> Supreme Court Ruling 27 March 1990, op. cit.

<sup>129.</sup> Supreme Court Ruling of 27 June 1997, which condemned the parents, who were Jehovah's Witnesses, for causing the death of their child (a thirteen year-old) by rejecting a blood transfusion and seeking alternative treatments, although without success.

<sup>130.</sup> Although there were already other precedents more in keeping with the approach described later, such as the ruling of the Provincial Court of Alicante of 29 March 1977, op. cit., which absolved the doctor and the wife of a Jehovah's Witness of the charge of failing to provide assistance.

of issues related to refusals to receive blood transfusions have been considered; indeed, to the contrary, some of these have courts have followed lines of reasoning which not only differ from the ones outlined earlier, but which are in some cases in conflict with them<sup>131</sup>. Thus, in a case similar to those discussed above, the High Court of Justice of Madrid<sup>132</sup> rejected an appeal for the acceptance of a claim against the magistrate who had ordered the administration of a blood transfusion to a Jehovah's Witness. However, in its arguments, the Court, while it did not find any evidence of a criminal offence in the judge's decision (of preventing a person from exercising his civil rights as recognized by the law, and of perverting the course of justice, among others), did not endorse the decision, and nor did it share the criteria applied by the Supreme Court in the first ruling cited above:

"Nor does the Court share the thesis, rejected by the Office of the Director of Public Prosecutions, that the judge must authorize transfusion in order to avoid being guilty of failing to provide aid, as described and penalized in art. 489.3 of the Penal Code. If the patient is an adult who has taken his decision freely (and not a minor or an incapacitated adult) the judge is not under any strict obligation to grant authorization for transfusion, a procedure which involves a clear risk and to which there are alternative methods and solutions. There is certainly not a state of necessity, and nor can it constitute abetting suicide by omission, as the Jehovah's Witnesses want not to live but to die, although not at any cost or at any price, or by infringing their beliefs, and their attitude cannot thus be classified as suicidal either from a psychological or a legal pers-

pective" (f. j. no. 8). And elsewhere it adds, "... nor is this an issue which must be resolved by Criminal Law, in terms of the selection of risks, and it is therefore wrong to argue that in all cases the right to life should prevail, without any type of limitation. Instead we must take into account the freedom of the individual and his ethical limits, respecting the individual's religious beliefs and dignity, and taking into account that any transfusion represents a risk and admits of alternative solutions" (f. j. no. 11).

While avoiding becoming enmeshed in issues such as the medical nature of blood transfusion, whether or not there is a state of necessity to justify a particular course of action, or if the patient has suicidal intentions, all issues which have been debated by legal theorists and addressed in case law, as we have seen, what is beyond dispute is that this ruling – together with the other two which preceded it in the same year - opens up a line of reasoning which is more consistent with the interests of the freedom of decision by adults with respect to life-saving treatment, and which should continue to be followed in the future. However, it highlights the confusion which exists in this area, and which must be clarified by the Constitutional Court when it hears one of these cases and finally has the opportunity to enter into the issue in detail. As a result, if the Constitutional Court or the ordinary courts are to adopt appropriate criteria it is essential that complicating factors which may distract from the core issue are not introduced; and for this reason, in my opinion, it should only address the protection of fundamental rights which are claimed to have been violated (through appeal procedures to the ordinary courts, or by the means of claims to the Constitutional Court, as applicable) and not complaints against a judge or a doctor for the coercive imposition of life-saving treatment (blood transfusion)<sup>133</sup>.

At the same time, I am unclear as to what constitutes the correct approach when the patient has lost consciousness, having previously stated his refusal to receive a transfusion. In this respect, some legal rulings which lean towards respecting the decision of the patient who rejects transfusion, indi-

<sup>131.</sup> See, for example, the Supreme Court Rulings of Castilla-La Mancha and Extremadura, of 15 April 1991 and 4 March 1992, respectively: "... practice [the rejection of blood transfusion for religious motives] which cannot be classified as contrary to public safety or public order, or to public health or morals, or to the protection of the rights and freedoms of others" (f.j. 2 of the second ruling, supporting the first). Both refer to international conventions, the Spanish Constitution and Basic Law of 5 July 1980 in support of their arguments. See also Rulings of the Provisional Courts of Palma de Mallorca of 29 July 1993 and of Ciudad Real of 27 January 1995, op. cit., and the Rulings of the Courts of Orihuela 25 November 1994, Villajoyosa 1 December 1994 and Lorca 20 October 1995.

<sup>132.</sup> Ruling of 23 December 1992.

<sup>133.</sup> Along similar lines, see Cobreros Mendazona, *La negativa a los tratamientos sanitarios*, op. cit., p. 36.

cate that "in the event of [the patient] losing consciousness, whatever treatment is necessary should be administered, just as before we have sought to reason with the patient's opposition"<sup>134</sup>. In my opinion, consistency with the initial position should lead to respect for the patient's wishes with all of the consequences thereof, even after the patient loses consciousness, so long as the patient has been kept informed about his situation and its immediate development (including loss of consciousness and death). In contrast with other cases<sup>135</sup>, the patient who is motivated by reasons of conscience although here what we are concerned with is to respect a freely taken decision, as noted above - has taken a decision which corresponds to his own concept of life, in accordance with which there are values which transcend life, and it is not possible to assume that this would have changed were the patient to regain consciousness. At the same time, this would not represent a great deal of progress, because the loss of consciousness before death is a common occurrence, and if the doctor deemed a blood transfusion, together with other cumulative treatments, to be necessary, then the patient's wishes would not be satisfied. As a result, in the event of loss of consciousness, all available measures except transfusion should be applied.

In any event, it must be agreed that health professionals should not have to take such complex decisions with major legal consequences and regarding which there is no definitive agreement<sup>136</sup> on the part of judges<sup>137</sup> and specialists; as a result, so long as this legal ambiguity and uncertainty persists, we

should also accept that judges should continue to tell doctors how to act in these cases, irrespective of the legal framework<sup>138</sup> which confers such competencies upon the judges.

And this is another area for debate: whether judges have the competency to take this class of decision and, if they do, to which court it corresponds. Regarding this issue, the Provincial Court of Palma de Mallorca has stated<sup>139</sup>:

"It is important to note that some of those who have analysed this issue are inclined to consider it as a procedure of voluntary jurisdiction of article 1811 of the Law of Civil Procedure, which can be invoked on any day and at any time (art. 1812) and it would correspond to the Magistrates Court to rule upon it if it were invoked outside of the normal hours of the Civil Courts, given the urgency with which a decision would be required. Some authors consider the competency of the Magistrate within his powers to prevent the possible effects of a crime, with the resultant obstacle that no crime has been committed and that the problem is, rather, to avoid potential medical liability, or to confirm that the decision taken is fully conscious or free, and not subject to coercion. (...) However, if we start from the position that transfusion should not be imposed by force, and the judge has confirmed that consent has been freely given and there is no evidence of possible coercion, then the issue lies beyond the scope of criminal law" (f.j. 2).

The issue is a long way from being resolved, because what is at stake is how to avoid potential liability of the doctor or to impose transfusion by force and this, as the ruling notes, is a matter for criminal law<sup>140</sup>. If, by contrast, what is

<sup>134.</sup> Ruling of the Provincial Court of Ciudad Real, 27 January 1995, f.j. 8. Also, Rulings of the Provincial Court of Palma de Mallorca of 29 July 1993, and – apparently – of the Court of Lorca of 20 October 1995.

<sup>135.</sup> E.g., prison hunger strike with demands, in which the motives, while they may be firmly held, respond to exceptional circumstances. See other reflections in this regard, Romeo Casabona, El Derecho y la Bioética ante los límites de la vida humana, op. cit., pp. 457 and f.

<sup>136.</sup> The Ruling of the Court of Barcelona of 2 May 1994 refers to this.

<sup>137.</sup> There are also recent rulings which follow the same approach as the Supreme Court: Rulings of the Provincial Court of San Sebastián of 29 July 1995 (which records, as its only source, the Ruling of the Supreme Court of 22 December 1983, although in this case no complaint was lodged against the judge), of the Court of Barcelona of 2 May 1994 and of the Court of Instruction no. 4 of Bilbao of 25 November 1995.

<sup>138.</sup> See in this respect art. 9.2 of LOPJ.

<sup>139.</sup> Ruling of 29 July 1993, op. cit. See also the very extensive and well-documented argument – on this point – of the Ruling of the Court of Barcelona of 2 May 1994, op. cit., which rejects the lack of competency, confirmed by Ruling of the Provincial Court of Barcelona of 28 June 1994.

<sup>140.</sup> The offence of coercion would come into play here. In this respect, see Adela Asua Batarrita / Norberto J. De La Mata, "El delito de coacciones y el tratamiento médico realizado sin consentimiento o con consentimiento viciado" in *La Ley*, no. 2539, 1990, pp. 2 and ff.; Asua

sought is solely to protect a person exercising his freedom to reject treatment for whatever reason, the criterion is different. Therefore, when a legal consensus is achieved and the issue is addressed from this perspective, or to assist the doctor when doubts arise as to the validity of consent in a specific case, it would be possible and desirable to keep this separate from any considerations of criminal law, despite the paradox that this depends, in the final analysis, on a problem of the interpretation of the legal system<sup>141</sup>. Indeed, I am convinced that precisely as a result of the complexity and confusion which accompanies this issue, a doctor who, without consulting a judge, decided as a matter of conscience either to respect the wishes expressed by an adult patient or to perform a life-saving transfusion to which there were no alternatives, would not be convicted by any Court; however, he might not be able to avoid the inconvenience of a trial (think, for example, of a possible complaint lodged by a pro-life association) although this outcome seems less likely. This is a disappointing conclusion to have to reach. Not only does it reflect a confused situation, but in doing so it reveals legal insecurity and the distrust this may generate among lay people with respect to the efficacy of legal instruments.

A different issue is when the patient rejecting life-saving treatment – in the form of blood transfusion – is a minor. Here, opinion is unanimous (and I discussed this in detail earlier) that parental authority must be exercised in the best interests of the minor. This does not empower the parents to take irreversible decisions which may endanger the life of their children by giving priority to other concerns<sup>142</sup>, even if these are relevant and supposedly in the

minor's interests, such as, for example, both the parents and the child remaining faithful to the religious beliefs of the parents and in which their child has presumably also been brought up. With respect to the minor, the parents must bear ultimate criminal responsibility for obstructing or hindering lifesaving treatment for their child in any way<sup>143</sup>.

Batarrita, *Tratamiento curativo sin consentimiento del paciente y responsabilidad penal*, op. cit., p. 620. See also, along the lines of the text, the Ruling of 2 May 1994, op. cit.

<sup>141.</sup> Other issues of legal interest, which I am not going to consider here, are voluntary discharge when there are alternative treatments, and the reimbursement of expenses, if the patient, as a consequence of discharge, has been treated in the private medical sector. See in this regard the Rulings, op. cit., of 29 July 1993, 2 May 1994, 25 November 1994 and 1 December 1994, and Supreme Court Ruling (Social Chamber) of 14 April 1993 (refusing the reimbursement of expenses).

<sup>142.</sup> With respect to Jehovah's Witnesses and the rejection of blood transfusions, Edorta Cobreros Mendazona, "La negativa a los tratamientos sanitarios", in *Los derechos de los usuarios* 

de los servicios sanitarios (Cuarto Congreso "Derecho y Salud"), Vitoria, 1996, p. 36, n. 13; Diez Ripollés, in Comentarios al Código Penal. Parte Especial, I, op. cit., p. 265; María Luisa Maqueda Abreu, "Sectas y Derecho Penal: Una aproximación a su análisis desde la jurisprudencia de los tribunales", in Libertad ideológica y derecho a no ser discriminado, Cuadernos de Derecho Judicial, Consejo General del Poder Judicial, Madrid, 1996, p. 196, n. 34; José M. Tamarit Sumalla, La Libertad Ideológica en el Derecho Penal, Publicaciones del Instituto de Criminología de Barcelona-PPU, Barcelona, 1989, p. 427.

<sup>143.</sup> See Supreme Court Ruling 27 June 1997, op. cit., and extensive discussion of it in my work, cited earlier, ¿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).

CASE STUDIES
Informed consent:
the gaps which appear
when one takes a closer
look at the reality
(which sometimes
outdoes fiction)
Pablo Simón Lorda

## 1. Antonia Montoya and cultural relativism

Antonia Montoya is a 61 year old gypsy woman, who is obese and has high blood pressure.

She met her family doctor, who only recently started working at the health centre, when she went to pick up a prescription for the drugs she has been taking for four years, since she was found to have high blood pressure. However, her previous doctor, who has just retired and who she had been seeing for almost 15 years, had never taken down a medical history. So she was pleased when this young doctor asked her to come in to see him in four days' time so that he could "set up her medical records".

When her husband, Pedro, found out he offered to accompany her to the doctor's. That way, he would also meet the new doctor. Pedro Montoya, who is 68, is also a gypsy and, like his wife, suffers from obesity, but has hardly ever been to the doctor. He marred his cousin, the woman who is now his wife, 42 years ago, and they have 6 children. They work as market traders.

The new doctor was happy to see that Antonia's husband had decided to come too. However, he did not find it easy to take down Antonia's medical history, because Pedro answered all of the questions for her. At the same time, this did not seem to bother Antonia, despite the doctor continuing to address her and ignore her husband.

The most difficult moment came when the doctor asked Antonia her opinion about what she would want him to do if he found that she had a serious illness: would she want him to tell her the truth or not? At that point, before Antonia could answer, Pedro intervened, saying that obviously he was the one who would have to be told and be consulted, "and that if it was a question of operating, then him and his brothers-in-law would decide what was to be done."

Antonia lowered her head and nodded in resignation.

## 2. A nurse in difficulty

A nurse doing home visits goes to see a patient on the instructions of the patient's doctor, replacing the patient's usual nurse, who is on holiday.

The patient is 86 and suffers from advanced Alzheimer's disease, and is lying in bed in the foetal position. She has removed her nasogastric tube through which she receives nutrition and hydration. The doctor has told the nurse to replace the nasogastric tube, as the other nurse did two months ago, on his instructions.

The nurse is unsure as to whether this is the correct decision. She asks the family for their opinion. The patient's son, who is 56, says the tube should be put back in, because otherwise it would be like leaving her to die, but his wife – who is the one who looks after her on a daily basis – thinks this is pointless, that this is just making her suffer, and that she will take it out again sooner or later.

## 3. Mr Rodríguez wants information

Mr Rodríguez, a 51 year old high school teacher, has come to see Dr B, his family doctor. He is very scared because the pills she gave him to treat his first episode of acute gout have given him a bad attack of diarrhoea.

When Dr B explains that this is a "common side effect" of these pills and, what's more, that it is explained in the patient information leaflet, Mr Rodríguez becomes angry because he had not been warned of this, and asks if there is no alternative treatment.

Dr B says that there is, although in her experience it is less effective and has other side effects, such as heartburn and the remote possibility of internal bleeding.

Mr Rodríguez asks why this wasn't explained to him, because perhaps he would have preferred this treatment.

The doctor replies that her obligation is to treat patients as effectively as possible in the small amount of time available for each, and if he isn't happy he should look for another doctor.

# 4. The concerns of Mrs Fernanda, and the opinion of her doctor

Today Mrs Fernanda has come back to see me. I sent her to the Hospital Cardiology Service because her ECG showed some changes that I wasn't happy about. She has had high blood pressure for the last 15 years, with electrocardiographic signs of ventricular hypertrophy.

From the manner in which she enters, it is clear there has been a problem. She seems sad or worried, as if she wanted to say something but doesn't dare to.

But she tells me they treated her very well at the hospital. She was seen by two doctors at the same time, one of whom was explaining things to the others. ("A registrar and a house officer," I realize.) She tells me they asked her a lot of questions and then examined her, took her blood pressure and moved her to another room where there was a device with a TV and a microphone like the ones they use on pregnant women. ("Wow!" I thought, "they did a scan on the spot. That's impressive!")

Then she tells me that they told her that everything was fine, but there was a minor, unimportant problem in her heart which had to be treated, but that the hospital had just received a new treatment and, if she wanted, they could use it on her. ("Now I understand what's going on," I thought.)

Mrs Fernanda said they should, of course, do what they thought was best. Then they told her she had to sign some papers to certify that she was taking her medication, and that she then had to come to the hospital every four weeks for 6 months, for a blood test, an ECG and so they could have a look at her with the TV device. After signing, they gave her a white bottle with a barcode label and Mrs Fernanda left the hospital in a bit of a daze.

The reason for her concern was that she had to come to tell me that she didn't really fancy going to the hospital every four weeks to have all these things done, but that she was worried that the hospital doctors and I would be angry, because we were all very good and treated her very well. Poor Mrs Fernanda! Without realizing it, she had signed a consent form and been included in a clinical trial.

# 5. Bad luck, it didn't turn out the way he hoped, or the way the rest of us hoped

The plastic surgeon who operated on my 78-year-old grandma for a tumour of the face is sorry. The operation didn't turn out the way he had hoped, and grandma has a massive scar. He told us he was going to use a new technique he was perfecting with some Americans, and that it was much better than the usual approach. It didn't turn out well but, hey ... what a great surgeon!

## 6. The competence of Mrs Genoveva

Mrs Genoveva is 87 years old. Her daughter-in-law, Carmen, who is 56, has forced her to come and see Dr J because the old lady sleeps very little, gets up, talks to herself, wanders around the house and ends up waking up the whole family.

Carmen is desperate for Dr J to give Mrs Genoveva some sleeping pills. But Mrs Genoveva doesn't want the pills. She says she sleeps enough, that it's okay, she just wants to be left in peace. And she says she doesn't talk to herself; she talks to her husband, who died 26 years ago, and who she wants to join because she's tired of living.

## 7. Juan got angry

Juan is 56 and is under observation for an enlarged spleen and liver. Yesterday he was admitted to the Internal Medicine Service of his local hospital. He

really doesn't feel like being in hospital, what with everything he has to do; he's in a bad mood.

This morning he was visited by a doctor accompanied by five young people in lab coats. They looked as if they were students. The doctor greeted him by name, but didn't introduce himself or his companions. Then he asked Juan to undo his pyjamas because he needed to examine him. Juan did so a little reluctantly, because in the morning the doctor who seems to be the one who will be looking after him already spent a while feeling his stomach, and it was pretty uncomfortable.

After examining him, this new doctor (who he had never seen before) turned to the students and told them to come closer because now they were going to examine him. When the third student was getting ready to touch him, Juan became angry, did up his pyjamas, and said that nobody else was going to lay a finger on him.

The doctor also got angry and told him he was in a hospital where they taught medical students and that he had to put up with it; that it was essential for the students to learn and that if he didn't like it he should go to another hospital. Juan told him he came here because it was his local hospital, and that nobody had told him about any of this before. Then he turned away, and the doctor went off with the students looking annoyed.

## 8. A complaint and the response

Complaint against a Health Centre: The reasons for my complaint are as follows. This is the second time I've come to have a blood test, and both times it's been done by a girl who didn't have a clue. After trying three or four times, a nurse called Ascensión had to come and show her. I don't expect Florence Nightingale to take my blood, but I do expect it to be someone more professional, because the thought of coming back terrifies me.

**Response of the Medical Manager of the Centre**: Dear Madam, With regard to the complaint you submitted on 15 March 2000, I would like to inform you that this centre provides practice placements for students in the 3rd year

of the University Diploma in Nursing. These are official practice placements which are supervised by the Centre's nursing staff. I am sorry to hear about your experiences, but learning, under the supervision of the nursing professionals who work at the Centre, is necessary if students are to acquire the skills which are a vital part of their training. Please accept my apologies and I would advise you, before your next blood sample is taken, to report your previous experience. Yours sincerely,

# 9. Informed consent as a 'new model of the doctor-patient relationship'

Mrs Fernández has been referred to the gynaecologist at the Specialist Care Centre by her family doctor, Dr J, so that they can reassess her clinical situation. The gynaecologist tells her that they may have to operate. Mrs Fernández is 52 years old, and was diagnosed with uterine fibroids four years ago, which have been monitored by this gynaecologist. The fibroids are causing pain in the hypogastric region, regular uterine bleeding and, in the latests tests performed by Dr J, significant anaemia.

Mrs Fernández went to see the gynaecologist. On seeing the test results, he told her that she needed to undergo surgery for a "hysterectomy with double laparotomy", asked her for a pre-operative study, started the hospital admission procedure and gave her a form "to sign and bring back on the day you come in for the operation". Then, without giving Mrs Fernández the chance to discuss or ask about anything, he brought the consultation to an end.

Mrs Fernández, after leaving the hospital admission form with the Admissions department, left the Specialist Care Centre reading the other documents. The one which the gynaecologist told her she had to sign is headed "Informed consent for hysterectomy with double laparotomy". She started to read it, but it is very fuzzy because it's a photocopy. She barely understands it, and what she does understand is not exactly reassuring. Among the other papers and requests there is one headed "HIV test" and she doesn't know what it is.

Mrs Fernández decides to go and see Ana, Dr J's nurse, who she really trusts, for an explanation of what this is all about and so that she can advise her what to do.

# 10. The secretary of the urology service

In the waiting room of the Diagnostic Unit of the Urology Service of a large hospital. The waiting room is quite small. There is a wide window behind which a secretary, around 35 years old, seated at a large desk, gives appointments to patients who have been referred to the Unit by their urologist for tests. Behind the chair where the secretary is sitting there is an open door, through which one can hear voices from the adjoining rooms, where the tests are performed.

The secretary is dressed informally, with an unbuttoned white lab coat on top. It is almost impossible to speak to the secretary without everyone else hearing. She also answers the phone in a loud voice.

The unit performs ultrasound, video urodynamic tests and prostate biopsies. Each test is recorded in a book. On the table there is a pile of appointment books, a phone, papers, pens, etc.

One patient, Mr K, aged between 45 and 50, enters the waiting room slowly, looking a little uncertain. He has glasses and is smartly dressed, with a jacket and tie. He is holding a leaflet in his hand. He is on his own. There are three other patients in the room, each accompanied by relatives. Mr K goes up to the window, which is free.

Mr K. Good morning (sounding nervous and speaking quietly).

**Secretary** (in a loud, relaxed voice): Good morning. How can I help?

Mr K: Is this where you give appointments for urology tests?

Secretary: Yes, go ahead.

**Mr K**: My urologist has asked me to do this (*showing her the leaflet*), I think it's for a 'prostate biopsy'.

**Secretary**: Let's see (taking the leaflet out of his hands). Yes, it's a prostate biopsy ... (moves several appointment books until she finds the one that says 'prostate biopsy', opens it and starts to look for the first blank space, turning the pages backwards and forwards).

**Mr K**: (while the secretary looks for the book and then goes through the appointment pages) Excuse me, you know about these things ... (sounding uncertain), the thing is, my urologist told me I had to have this done, but I don't really know what it involves .... Does it hurt?

**Secretary**: (distracted, while she looks through the pages). (in a low voice) Let's see ..., let's see .... Not that day ..., that one, they've got a Conference ... (Louder) No, of course it doesn't hurt! Don't worry. Ah ..., there we go, Wednesday September the 11th at 10 o'clock. Is that okay for you?

**Mr K**: Yes, yes I think so ..., but ... (sounding uncertain) What exactly does the test involve? The urologist only told me it was a little jab.

**Secretary**: Yes, it's very simple. They put a tube up your behind, like when you get a suppository or an enema, and they give you a jab where your prostate is, and that's it.

Mr K: (grimacing) But that's going to hurt.

**Secretary**: Not at all! Look, they do it through their (*pointing at a door*) in that room at the side, and I've never seen anyone come out crying or shouting. It's nothing.

**Mr K**: I don't know ... (*looking worried*), to be honest I'm not too keen on it ... And what about the complications? (*The phone rings. The secretary picks it up and starts having a conversation with a friend. After a while she hangs up.*)

**Secretary**: Don't worry, it's no big deal. They give you a jab, so sometimes there's a bit of blood when you go to the toilet, but that's all. It's very easy.

**Mr K**: Well, I don't know ... I guess I have to have it done because the doctor says so.

**Secretary**: That's right! They do them all the time, and they know what they're doing. If the doctor has requested it then you have to get it done. It's what's best for you. The doctors know what they're doing.

**Mr K**: Yes, I guess you're right. Well (bringing the conversation to a close) What day did you say? Wait (he takes a pen out of his pocket to make a note on a piece of paper).

Secretary: No, no, don't worry. I'll write it here. (The secretary writes the day, time and floor on the appointment leaflet) (While writing, she reads aloud): 11th of September, at 10 o'clock, here, on the sixth floor. (When she finishes writing and while handing him a document with instructions) The day before you come in you have to take this enema to clean you up, and do what it says on the paper. And also (giving him another piece of paper, which is an informed consent form), you have to sign this and bring it along, okay? (Finally she hands over the appointment form.)

**Mr K**: (picking up all the papers without stopping to look at them) Well, thanks a lot. Goodbye.

**Secretary**: You're welcome ... Bye ... (she gets up quickly and leaves through the door behind her).

Mr K leaves the waiting room. (End of scene.)

**Epilogue**: The efficient urologists of the efficient service where the efficient secretary works met the targets of their clinical management contract, including one which required that informed consent be obtained in writing for at least 95% of a pre-established set of diagnostic and therapeutic procedures and that the copy of the signed form must be included in the patient's medical records. Obviously, they were paid the agreed incentives.

# 11. And I ran away!

I had had toothache for two days, and it looked like I was going to have to have the tooth out, so I went straight to my dentist to have it removed. When I arrived at the practice and said I had come to have a tooth removed, a friendly nurse turned around, went into the surgery, and came back with this document in her hand. She said, "read it and sign it before you go through." So I sat down in the waiting room and read it.

#### INFORMED CONSENT FORM FOR SIMPLE EXTRACTION

Mr/Mrs/Miss/Ms:

(Patient's name and surname)

Name and social security no.

Address:

I DECLARE

That the doctor:

(Name and surname of doctor providing the information)

has explained to me that, in my position, it is necessary to undergo

#### EXTRACTION OF A TOOTH

As a result, I understand that I will no longer have this tooth and that, it can only be replaced by a false tooth.

- 1. The purpose of the intervention is the extraction of the tooth, due to the fact that while techniques such as gum or root canal treatment could be used in an attempt to conserve the tooth, I have ruled this out due to the state of the tooth, making it impossible to conserve it.
- 2. The treatment may require local anaesthesia, and I have also been informed of the risks associated with this.
- 3. The treatment consists of applying forceps to the crown of the tooth, loosening it with sideways movements, in order to enable the tooth to be easily removed from the socket in which it is embedded.
- 4. Although the necessary diagnostic measures have been performed (X-ray), I understand that it is possible that inflammation of the tooth to be extracted may cause an infectious process, which may require treatment with antibiotics and/or anti-inflammatories, and also that during the procedure bleeding may occur which would require, in order to stem bleeding, the insertion of a pad of dry cotton into the socket.

I am also aware that during the course of the procedure, although not common, there is a possibility of the crown breaking, of damage to the lining of the cheek or to the tongue, insertion of the root into the maxillary sinus, fracture of the interradicular septum or the maxillary tuberosity, which do not depend on the form or manner in which the treatment is performed nor upon its being performed correctly but are, rather, unpredictable, in which case the dentist will take the necessary measures and will continue with the extraction.

5. The dentist/dental surgeon has explained that every surgical intervention carries the risk of a series of common and potentially serious complications which might require additional medical and surgical treatment, and that my current health status (diabetes, heart disease, high blood pressure, anaemia, old age, obesity) may increase risks and complications such as:

I have understood the explanations which have been provided in clear, simple language, and the dentist treating me gave me an opportunity to ask questions and to clarify any doubts I raised.

I also understand that, at any time and without the need to provide any explanation, I may revoke the consent which I am granting here.

I therefore state that I am satisfied with the information received and that I understand the scope of the treatment and the risks associated with it.

And in these circumstances: I GRANT MY CONSENT to the EXTRACTION OF THE TOOTH.

At (PLACE): Date:
Signed: The dentist.
Signed: The Patient.

And I ran away before the nurse reappeared to call me in!

Introduction to discussion Marc Antoni Broggi This morning we heard the magnificent presentations by Pablo and Carlos, who I thank without reservation. In addition to these presentations, the speakers also provided more extensive, written versions of their papers, and I would like to thank them again for their diligence in doing so. And now, on the basis of their input and our own experiences and thoughts, it is time to move on to the general discussion. Today's participants come from a wide range of backgrounds: clinical practice, doctors with experience of treating critical, acute or chronic patients, professionals working in the area of clinical trials, nursing professionals, specialists in criminal and civil law, including practising lawyers and those working in the academic sector, representatives of the health authorities, philosophers etc. Any intervention which is based on such experience is sure to enrich the rest of us. Everyone, whatever their background, has a clear interest in the issue of informed consent, and is also familiar with bioethical analysis.

We have produced a list of questions, ranging from the general to the specific, which is not intended to be followed rigidly but which we hope will serve to keep the discussion focused.

## **Guideline questions**

## 1. Ethical and legal basis of informed consent

Is autonomy a general condition of morality, or is it one principle among many?

Is the right to consent a fundamental citizen's right, one which is "highly personal" and which cannot be delegated nor subject to cultural exceptions (North Africans, gypsies etc.) in care practice?

By contrast, should the right to know be more influenced by cultural context and personal needs, and could it therefore give rise to consent which is to some degree based on ignorance? How should we view excessive information? Is it maleficent or non-beneficent?

Is the defensive practice of informed consent the greatest threat at the moment? How can we prevent doctors from simply shifting from a paternalistic model to a contractual one, encouraging them instead to opt for a more personalized, interpretative and deliberative approach? What responsibilities

do professional training programmes, health institutions, the law and legal theory bear in this regard?

## 2. How to request informed consent

Who should inform the patient and request consent? Who decides what treatment is necessary, and who carries it out? What is the role of the nursing profession in informed consent and detecting gaps?

Who should determine a patient's competence? What is the role of nursing in this?

What is the role of the family? Should patients be informed of the fact that they may be treated by doctors who are undergoing training? Is it sufficient to provide information as to the fact that the care centre is a teaching hospital, or should this be specified in each written informed consent document?

With regard to clinical trials, how do we mitigate the effect of the doctor as double agent, seeking to serve both the interests of the patient and the need for recruitment?

#### 3. Forms

What should be the characteristics of a written informed consent form? How should we adapt the need to personalize written forms? Is it possible to combine an open consent form to be completed in the patient's presence, with more exhaustive printed information booklets?

How should we evaluate informed consent forms?

# 4. Special situations

Should we accept the common practice in emergency departments of requesting only oral consent?

Should the patient sign the rejection of treatment?

Should the patient be informed of an innovative technique, even if it is not yet common practice?

Discussion

Ramon Bayés. Within the first block, I would begin by linking the fourth question to the last part of Carlos Romeo's presentation, where he talked about a climate of trust and depersonalization. I believe that informed consent must, in any case, be situated within a framework of sensitivity to the patient's needs. Without this basis, there is the risk that informed consent becomes a mere bureaucratic procedure at the service of defensive medicine. There is information to suggest that, while many doctors are indeed attuned to the suffering of their patients, there is another sector whose sensitivity leaves much to be desired and which remains very far removed from the basis of excellence identified by Diego Gracia. Sometimes, in their daily clinical practice health professionals stop doing things which do not entail any additional financial cost and which do, however, bring significant emotional benefits to the patient or his family. For this reason, before we consider informed consent in particular, we need to become aware of the general health needs of each individual patient. Without such awareness, informed consent is quickly transformed from the universal right of all patients to information into an administrative manoeuvre of self-defence on the part of the health professional.

Victoria Camps. The philosophers here today have been talking over lunch, and we have identified some areas of agreement but also some differences. With respect to Diego Gracia's proposal regarding the two levels of the principles of bioethics, as we are considering the practical problems of informed consent, it may be useful not to establish too many hierarchies and, above all, not to set up the principle of autonomy as a prior requirement of any other principle. For example, in the case of the conflict between nonmaleficence and autonomy, it is not always the case that not respecting the patient's autonomy constitutes an instance of maleficence. Clitoral ablation is a very clear example of this; the case of the Jehovah's Witnesses might be another. By contrast, I would argue that the example of the gypsy couple presented by Pablo Simón contradicts his own theory. In the end, he said that maybe it was best not to ask her for her consent. In which case, here it is not the principle of autonomy which prevails but rather a custom which it is best not to correct in too dramatic a fashion. I personally believe that the principle of justice comes before the principle of autonomy, in the sense that one cannot be truly autonomous without a minimum of justice, and I would therefore disagree with the vision of autonomy as a more fundamental principle.

**Margarita Boladeras.** This is where the argument between philosophers starts, because I believe that beneficence, non-maleficence, justice and autonomy should be located at the same level and considered together as *prima facie* principles, even if in each specific case it may be helpful to identify one or other as being of more importance. However, as principles, and if we stick to what is meant by *prima facie* principles, they are on the same level. And autonomy forces us to reconsider, to formulate in a specific way, what we may understand by beneficence, non-maleficence etc. Therefore, in this respect, autonomy has an important role – not necessarily greater or lesser but one which is definitely significant – in determining what we understand by beneficence, maleficence, even justice in some cases, although I agree with Victoria Camps that the principle of justice has very specific requirements.

**Àngel Puyol.** Staying with the comments of the group of philosophers, one of the things you said, Pablo, very unequivocally, is that today paternalism is not an option. I would like you to explain what you mean by this, because I think that few people would dispute that there are some occasions in social life on which it is good to be paternalistic, for example when we oblige mature, responsible adults to wear seatbelts or motorbike helmets; when we provide free health care and do not expect every individual to pay for all of the care they need; when we offer programmes to support families or minority arts, because we believe that it is good for everyone, even if only a minority enjoy them directly. In addition, I believe that at times paternalism is a condition of autonomy, for example, when we prohibit the trade in organs or human blood. Autonomy in its strictest sense would mean that everyone could do whatever they wanted with their bodies. However, this is not something we permit because there are situations of scarcity of resources or staff, situations of poverty, situations of male dominance, in which people are not fully autonomous; it seems we should distinguish between formal autonomy and full autonomy. I don't know if you would agree with that.

**Encarna Roca**. Firstly, I would like to apologize because I was unable to attend Carlos Romeo's presentation, and it may be that what I am about to say

either repeats what Carlos has said or only relates to the discussion indirectly, which is more philosophical than legal. I believe that there is one issue underlying all these questions; what Carlos Romeo is clearly arguing is that, from his perspective, informed consent can have all the philosophical underpinnings you like but when you set it out in legislation it must have a legal basis, and this is that the individual holds certain fundamental rights, and this includes children, because they are people too. I know that this issue has been raised, and I would like to comment on it if it comes up again. Consent has its basis, I believe, in the individual's right to decide about his or her own body and prevent unwanted interventions, as a result of which the conscious patient is the holder of fundamental rights. The individual is always the holder of fundamental rights. Therefore, taking a decision means exercising these fundamental rights and nothing more. And I think this is a solution which perhaps the philosophers will think is very simple but to my mind is very practical. I think it's practical because I have the right to decide, because I am a person, I am competent and in full command of my fundamental rights. As soon as I cease to have this competency, I will not be in full command of my fundamental rights, even if this incompetency is de facto. And another person will therefore have to decide for me. But so long as I am competent, I decide and that's that. And I believe this is a problem which is the result of a whole theory. This is not the start, but rather the point of arrival; not, I repeat, a path, but rather the destination of a whole theory. I'm sorry, but however much I listen to ethicists I cannot see any beyond this issue.

**Mercè Rius.** I would like to pick up on Victoria Camps' comments. Although I am a philosopher, I didn't take part in the conversation she mentioned. I believe we have to distinguish between the principles on which informed consent is based and the ways in which it is applied. In this respect, we need to discuss both *prima facie* principles and potential ethical dilemmas, as Margarita Boladeras has pointed out. However, it seems beyond dispute that informed consent has its basis in the 'principle of autonomy', as Encarna Roca has explained. A separate issue is whether this basis should be strictly legal, and on this I disagree with her. Nor, of course, do I believe that the philosopher's word is final; indeed, I do not find the principle of autonomy to be as clear-cut as the speakers have presented it. Historically, it has

been recognized as deriving from the individual's condition as a rational subject; however, this leaves us with the problem of establishing what is and is not rational given that we live in a pluralistic society. Furthermore, Kant (to whom the principle can be dated, in the 18th century) argued that moral reason and, therefore, individual autonomy, transcend empirical, observable conditions and do not depend upon them. And this also applies in medical practice.

It is true that, despite the challenges of pluralism, we maintain 'the formula of universality'; those standards of behaviour which can be generalized are reasonable. But at this point I cannot avoid making another observation. If the principle of autonomy is the basis of the right (and the duty) of informed consent and does not, as I believe, come into direct conflict with the law, this is because this autonomy consists in the right to freely dispose of one's own body, as Encarna Roca has defined it in legal terms. This is then something which precedes the social coexistence of which justice is a part, although logically it would have no reason to exist on the margin of such coexistence. All in all, if we are dealing with an 'individual right', even in a more basic sense than any of the other fundamental rights or, to put it more accurately, precisely for that reason, I am unsure whether a justification along current neoliberal lines is sufficient.

**Encarna Roca.** Excuse me, but I would like to make a brief clarification. I would agree with you, because fundamental rights are nothing other than the legal expression of previously stated philosophical problems.

**Pablo Simón.** Well, let's see if we can make some sense of all this. First of all, I absolutely agree with what you have said, Ramón. In fact, I believe that the whole point of this event and of our presence here is to address this issue, that of sensitivity and, underlying it, a change in the attitude of health professionals. This is what will decide whether we succeed or fail, and if we do not strive to achieve this then I agree that we won't get very far.

So what about the so-called principle of autonomy? I said earlier that I started from a criticism based within the framework of Diego Gracia; in other words, I begin by locating myself within his framework, and therefore I do

not exclude the existence of something called the principle of autonomy in the sense, so clearly set out by my colleague, of a practical principle, a maxim, a subjective principle of action or whatever one wishes to call it, which we call the principle of autonomy. We can question whether this exists or not. All I would say is that, within the context of the principlist framework and the theory of Diego Gracia - and here I should say that agree with the classification into levels in the sense of links to duties which constitute absolute and relative obligations - the statement of a principle of autonomy generates instability within that framework. And in this sense I would say that it does not exist. Where is the notion of autonomy? Well, this is where we disagree. I believe that the notion of autonomy belongs to a basic principle and is linked to our justification of our moral framework. And here I appeal to a basis of a Kantian type. Well, one might say mediated by Zubirián, but underpinned by a Kantian basis, which places the formal, canonical founding principle - not material but formal, canonical - on the idea of dignity. And the idea of dignity is affected by the idea of autonomy and, therefore, is underpinned by an anthropological principle which transmits a specific way of understanding human beings. I believe that what defines us as human beings is the fact that we are rational and possess the capacity to govern ourselves, this is where autonomy is located, but this is a founding principle, a material decision-making principle within the framework of Diego Gracia. I really want to stress this, because I am not saying that if we manage to create another framework of normative principles then the principle of autonomy would fit in perfectly, but rather that within Diego Gracia's framework it generates instability because of the way it has been formulated. Therefore, when I say that the principle of autonomy does not exist, I am speaking within Diego Gracia's framework of a material principle which is properly coordinated with the other principles.

And then, in the case of Antonia Montoya, at the end I left the door open. I believe that Antonia Montoya must be asked for her informed consent. The issue is that we must be careful in doing so, and at this point we must consider the implications of what we do on the basis of very general principles. Sometimes the repercussions of our actions may create problems for people, and all I have done is to argue that, while we must ask Antonia Montoya for

her informed consent, we must also bear in mind the consequences this may have in a particular cultural framework. Because at the end it may create a difficult situation for Antonia Montoya, and that's all I've said.

I would also like to make a brief comment on the question of paternalism. When I talk of paternalism I am speaking primarily of the paternalistic model of the doctor–patient relationship; I am talking about a relationship in which a competent individual tells another competent individual what to do, because he thinks this is better; in other words, he is defining what is good. I believe, within this framework, the paternalism of the doctor–patient relationship is exclusive. In other settings this might be open to discussion, such as in the examples you raise. I'm not absolutely sure, so I put it forward as a general suggestion, but one that is open for discussion.

Finally, I would also say that the sort of argument put forward by Encarna Roca embodies a legal positivism with which I find it hard to agree. That is, things don't exist simply because they have a legal basis. There are other, underlying issues, because legal positivism ultimately results in fundamental logical contradictions which do not lead anywhere.

Javier Hernández. I do not intend to become too embroiled in defending Encarna Roca, who is more than capable of sticking up for herself, but I would like to say that her contribution was clearly anti-positivist. I do not believe that a normative approach should be reduced to standards, laws, regulations or decrees, but rather that the new normative framework is made up of principles: principles which, evidently, constitute a new normative reality which brings together both ethics and the law. The fact that the regulatory principles of the Constitution have a normative character does not entail a positivist perspective but rather just the opposite; debate around the theory of rights, led by Hart and Dworkin, is located precisely at the borders between norms and the operationality of principles. This is an open-ended debate which is based on a fundamentally anti-positivist discourse which encourages us to reflect in terms of legal principles.

**Carlos Romeo**. I would like to echo what Javier Hernández has just said. Normally, as legal specialists we refer to a framework of fundamental rights

and public freedoms or human rights, depending on whether these have been 'positivized' (given expression in legislation) or not. But we are aware that underlying these is a whole body of philosophical, political and legal thought. In reality, it does not seem relevant to go back to arcane issues such as the origins of this body of thought in the Enlightenment during the 18th century, but rather to hold firm to something which, I believe we all agree, is a basic reference point which is not subject to dispute or rejection: the theory of human rights which, when transferred to the constitutional sphere, configure our fundamental rights, while of course remaining aware that these have a theoretical basis. I do not, therefore, believe that such an approach is simplistic, but rather that for our purposes it is sufficient to refer back to this basis; it is logical that from a philosophical perspective one would need to consider more deeply the basis of the concepts and ideas which have underpinned it both in the past and in the present.

This having been said, I would also like to say that I fully agree with what Encarna Roca has said about fundamental rights. I would like to add that these basic bioethical principles, identified as such by North American moral philosophers and now taken as axiomatic – which, incidentally, are scarcely an innovation for the Law – are not the subject of debate and I therefore do not intend to question them. However, I have to say that I struggle to understand why it is felt necessary to order them hierarchically. It strikes me as more practical - without thereby having recourse to utilitarian criteria - to put these ethical principles on the same level, without prejudice to the fact that there may at times be conflicts between them. These conflicts between the different principles may lead to two different situations. Firstly, that the principles involved lead to the same solution, without any contradiction between them, as a result of which the resultant solution will actually be reinforced by the fact that it is based on more than one principle. And secondly, that a real conflict actually arises between the principles involved in the specific situation. It is in this case that the problem of how to resolve the conflict arises, of which of the principles should take priority, and this is when we feel the need for a higher criterion which enables us to identify the correct solution. This is in a sense what Pablo Simón was referring to, but he probably restricts it too much in terms of the concept of the human being and dignity, an idea which I share but which has perhaps been overused in bioethics. However, if we manage to correctly identify its scope, it could serve as a reference for resolving precisely such conflicts, in particular where there is a clash between the principles. In law, the clash between duties or legally protected interests is resolved through the use of weighting, which is used to take into account all the interests at stake on all sides of the conflict and, by weighting them, reaches a decision in favour of those which are of greatest value for the Law. As a result, the methodological starting point is much more flexible and tailored to the specific situation than an approach based on a rigid *a priori* hierarchy of ethical principles.

I would stress, then, that any conflict may arise in many ways, and that there are no absolute criteria for resolving such conflicts. For example, in accordance with this weighting approach, the principle of non-maleficence does not necessarily always have to take precedence over that of autonomy, or vice versa. Sometimes it might, and sometimes it might not. The problem lies, then, in how decisions are reached, and in the law there are many examples according to which the solution may give priority to one or other principle, without this being an arbitrary process.

It has also been noted that the principle of beneficence would be a maximal standard which would not be legally enforceable. However, in Law, or at least since the development of modern Law, some of the manifestations of the principle of beneficence have indeed been given legislative expression. I refer, for example, to the principle of solidarity, which is found in several legal standards, evidence of its (albeit limited) legal status. For this reason, it is questionable whether it is correct that this principle represents a maximal ethics.

Finally, with regard to the sensitivity to the ethical dimensions which should be part of the doctor-patient relationship, as I argued in my presentation, I believe that this is important but also that it is very difficult to achieve, particularly if we are to avoid expectations of such attitudes and behaviours of health professionals becoming simply one more task which is added onto their care duties. Health professional must be convinced of the necessity of becoming engaged in the ethical aspects of their work, and know exactly

what their purpose is and what function they perform within the doctorpatient relationship, beyond any legal basis or legal requirements which the doctor must satisfy.

**Victoria Camps.** The comments by Encarna Roca and other interventions which followed have got me thinking. I believe we all agree that informed consent has its basis in fundamental rights. The problem is when fundamental rights come into conflict with each other. I believe that the conflict between autonomy and non-maleficence is one of these, as is the conflict between autonomy and beneficence. If we have to respect people, but we see that somebody is harming himself and is going against another fundamental right, then pointing to these fundamental rights as the basis for informed consent does not resolve the issue. This is why the principles of bioethics are helpful in establishing a dialectic and striving to identify in each case which principle should prevail.

At the same time, I would like to raise something else with respect to what Carlos Romeo said about the term *competencia* which, in his opinion, is a term which lacks any legal basis. I wonder whether it would be helpful, when dealing with practical problems of informed consent, to consider whether there are cases in which we cannot talk either of *capacidad* or *incapacidad* but rather of *incompetencia*, in the sense in which this is defined by the Real Academia; in other words, that *competencia* is not the same as *capacidad*. It is not the same, but there are cases in which one can say that a person is not competent to decide. He may lack culture, education, be in a depression; he is not competent at that moment, but this does not mean that he is incompetent.

**María Casado.** Of the many interesting issues which have arisen so far, I would like to focus on two aspects which I consider to be fundamental to this discussion: firstly whether it is possible and desirable to establish a hierarchy of bioethical principles and secondly with regard to the concept of competence.

The principles of bioethics have found an echo in so far as they have proved useful in taking decisions; they help health decision-makers primarily becau-

se they simplify matters. In my opinion, this is their greatest significance. At the same time, we should not forget that these principles already existed in law and in moral thought, and also in the ethical codes which established the obligations of medical professionals.

Therefore, if the principles help in decision making then it is good to apply them; but if we have to distort reality in order for it to fit in with the theoretical framework we have established to explain it, then we are making the mistake of applying a model which complicates matters rather than simplifying them. It is not reality which should be adapted to fit models of interpretation but rather the model which must change if it does not reflect reality.

And so it may be that the notion of establishing a hierarchy of principles, however attractive it seems, does not help us. It strikes me as clear from Pablo Simón's contribution that if we have to force the framework to adapt it to the proposed hierarchy to the point where it is proposed to remove the principle of autonomy from the hierarchy, then the hierarchy itself is of little use. Initially, for the simple reason that this complicates more than it clarifies. And, of course, because it is precisely the principle of autonomy which gives rise to bioethics and informed consent (the need to respect the wishes and life projects of every individual).

For this reason, as a legal philosopher, although I was not sitting at the philosophers' table, I agree with them that establishing a hierarchy is not advisable; it is preferable to do what any high court would do and weight them and, seeking to respect all of the principles as far as possible, to decide on the basis of what is best for the individual case.

And all of this connects with the issue of competence. I am against using the word *competencia*; in this context, it is what translators call a 'false friend'. And adding *competencia* as a new category, as Victoria has suggested and as is occurring in many spheres, introduces a serious danger with regard to which I would like to ask all of you, and especially the doctors, who decides whether or not somebody is competent? That person's doctor? Because once again we are back to the perennial problem of placing the decision in the hands of health professionals.

Ramon Bayés. I would like to recall the fact that in the State of Oregon, where assisted suicide and euthanasia are legal, between 1997 and 2000 the number of people requesting it has risen because they felt they were a burden to their loved ones, something which may limit their freedom of choice. In this case, who has the capacity to decide to what degree a person has complete autonomy to request euthanasia?

The influence of depressive states on this sort of request has also been mentioned. And who is able, in this case, to evaluate the depression of a person who asks for euthanasia? In research conducted in the United States and the United Kingdom, many psychiatrists felt that they were not capable, in many cases, of diagnosing whether a person was truly depressed or not, in a situation in which the patient requested assisted suicide or euthanasia.

**Màrius Morlans.** Vall d'Hebron University Hospital, Barcelona. As the spokesperson for the group of people with care duties, not necessarily clinical, multidisciplinary, who spent lunch coming up with a whole raft of ideas, I will be explaining what those suggestions were. But I also want to comment on what has been said so far.

I would like to start by highlighting two things which have already been noted, and which I think are important. One of these underpins all the major discussions in this area, and this is the question as to what the limits to individual liberty are, and whether the group has the right to impose its standards. This is a major dilemma today, for example in the debate about euthanasia. As Camus said, suicide is the big philosophical question, because a person who commits suicide dispenses with collective moral standards and takes a decision. By contrast, a person who requests euthanasia, by so doing, recognizes the moral attributes and right to judge of others. This dilemma is present in every debate, and we encounter it in daily life in the form of the obligation to wear seatbelts and crash helmets. Society imposes its standards. Therefore, while there may be a philosophical debate, in practice it is society which imposes the standard. We may be more or less happy about this, but just now that's the way things are. It is clear that in reality individual autonomy has limits in every sphere.

The other issue which I think is useful to clarify is the concept of competence. The experts among you can decide upon the name. I would also like to note that in the Catalan legislation, the word *competencia* is used; I don't know if in Catalan it has the same connotations as in English, but that is the term they use. Whatever we call it, in practice it is useful to distinguish between the legal concept of *capacidad* and the faculty which we perceive in the patient which enables him to decide or not. This is a very real problem, one of the essential practical problems. It worries us so much that we generally involve other people – a psychiatrist, for example. So, before we even talk in legal terms, assessing whether the patient is competent to decide can already be very difficult.

This is a fundamental issue. John Benjamin Dossetor (from Edmonton, Canada), who inspired my interest in bioethics, used to say that when a patient with uraemia was admitted to hospital because he needed dialysis, and signed a consent form, this had no legal or ethical value, because he would sign anything at this point, given that he needs dialysis to prevent him from dying. I became involved in the debate around bioethics because this statement aroused my interest in meeting somebody who, in the 1980s and in the part of the world where the concept of concept was being developed, was raising doubts about it. As a result, my first steps in bioethics were guided by this marvellous professional who founded the Health Ethics Centre at the University of Alberta. He would say to his house officers that if a patient comes in and is dying, he will sign whatever you want because his need limits his capacity to decide. This may be arguable, but it seems like a good way to address issues such as how to apply consent.

And now I will discharge the duties with which I have been entrusted. I would like to stress that in practice it is helpful to be able to distinguish between legal competence and natural or *de facto* competence. I believe that ethics and philosophy contribute concepts, arguments and methods and that, in these cases, clear language is very helpful. It is already difficult enough in practice if, on top of everything else, we are unable to distinguish between concepts which are appropriate to each situation. And I will return to the guideline questions, which asked us to consider whether informed consent is currently practised as a form of defensive medicine.

We believe that, at the moment, informed consent in practice means the completion of informed consent documents; in other words, our health professionals primarily see consent as a process which involves complex, wordy documents which use medical language which is incomprehensible for health service users and citizens, and have generally been produced by lawyers at the request of professional associations, with purely defensive aims. And this should be criticized, because it is the main obstacle which we face as care professionals when we defend informed consent; we have to start by making it clear that informed consent is not this.

Here I should recall the relief with which a colleague in the Nephrology Service greeted my words a couple of weeks ago when she came to me with the informed consent suggested for use in kidney transplants by the Spanish Urology Society. The document consisted of three sheets which summarized the chapter from Harrison. She had a conflict, because she refused to give these pages to patients, as instructed by the Urology Service. I have kept it as an example of what should not be done. Three pages! I can give a copy to anyone who asks for them. The complications described include de novo glomerulonephritis, which occurs in one in every 600 transplants and is explained in a medical language which I doubt whether the ordinary person can understand. So it is important that we consider the fact that this is what is generally going on in hospitals, at the urging of many (but not all) professional associations. This defensive attitude is easy to counter, with two arguments. Firstly, when the lawyer asks the patient if he understands the document, and the patient says "no", and secondly, when he asks if the document was given to him by the surgeon whose conduct is under question, and the answer is that it was given to him by a member of the administrative staff, as Pablo Simón explained this morning. These two arguments undermine the defensive approach, and I use them to help my colleagues to consider what they are doing. But this defensive attitude is nonetheless very real and does not help. That is our assessment of the situation.

And the second point which I believe also comes into play here is the role of institutions, which I think is crucial. If the managers of health institutions take the approach of assessing formal outcomes by counting the number of

signed consent forms, then they are reinforcing the defensive approach. The result of this alliance between defence-minded professional associations and management by results is what we see today. Institutions (both hospitals and primary care centres) and their management teams should promote declarations of intent, a set of values or an ethical code in which consent appears as a guarantee of the citizen's right to decide upon the care he receives. And this requires a cultural change, a different attitude. If this attitude is not supported by management teams then the pressures to engage in defensive medicine, combined with managers prepared to reward formal results with incentives, leads to the situation illustrated by Pablo Simón this morning. And these are the points discussed by the members of our group: Juan Pablo Beca, Pablo Simón, Xavier Carné, Virtudes Pacheco, Pablo Hernando, Manuel de los Reyes and Juan Viñas.

Manuel Valdés. I'd like to start by talking a little about identity. It can be difficult for a psychiatrist to know how reliable any given identity is. Often patients tell us, "Doctor, I feel great today." In other words, we don't know if it is him or if it's somebody else, or when they say, "Doctor, now I'm really back to my old self," we don't know if he was somebody else before. As a result, we seek to control the unreliability of conditions, opinions, and decisions. The same person, without suffering from any psychopathological state, may make very different decisions about whether to grant or withhold consent over a period of time. For this reason, I am very sceptical, at least in the context of my professional practice, when dealing with somebody who, while not necessarily incompetent, is inconsistent. When this happens, I find it hard to see beyond what I would call the paternalistic, informative, persuasive, deliberative model, and this is why, as part of teaching programmes, we try to teach house officers to explain themselves well. It is difficult to explain a disease to a customer or health service user (the term 'patient' appears to have gone out of fashion) but there are doctors who explain things so well that they sign immediately, while other doctors explain things so poorly, even with documentation, that any colleague listening would advise the patient not to sign.

With this, I want to say that there are two aspects which I think are inseparable. Firstly, there is the question as to whether the dialogue is capable of pro-

ducing a reliable decision, and I am talking not only of psychiatric patients but of patients in general. The majority of patients, as Ramon Bayés has said, are under psychological stress of one sort or another. In a hospital context, where one has to take a decision about a risky procedure, the patient has often been in a bad state for some time and is not in a position to take a position calmly, but instead agrees to whatever is offered. So I would sum up by saying that, firstly, it is questionable whether there is a stable identity which enables a reliable decision and, secondly, that there is no way of arriving at informed consent other than through the persuasive approach, which always has both an informative and a paternalistic element. It seems hard to find a way beyond this, despite the many theoretical principles which come into play.

Carlos Romeo. The last few interventions would seem to suggest that consent is somewhat lacking. What is clear is that consent involves a set of requirements, among which are that it must be freely granted. With regard to the comments of Ramón Bayés about the State of Oregon, one must distinguish between the cause and the motive for any particular decision. If the cause were indeed this (feeling that one was a burden to others and deciding to take one's own life), then perhaps this consent would not be free. If, on the other hand, it was the motive, then perhaps consent is less free, but we would still have to ask to what degree the person's capacity for autonomy has been eliminated. In my opinion, it does not eliminate it, but we must also add other issues which have been mentioned earlier. And, what is more, consent must be granted consciously, something which brings us to the concerns raised by Victoria Camps about competence and the example given by Pablo Simón this morning of the gypsy couple; in other words, it links in with the question we are discussing just now.

In both cases, we need to make certain qualifications. The Law only evaluates the competence of an individual to take a valid decision for a specific act, and it is true that this validity may be conditioned by a profound depressive state, which could affect his wishes; or by profound intellectual or cultural shortcomings, which could affect his intellectual grasp of the situation regarding which consent is to be granted. As a result, a person in such circumstances may be legally incompetent to grant consent without the requirement to

assess his material competence, something which is far more complex. At the same time, cultural diversity also exists in other countries, often to a far greater degree than in Spain; for example, in Latin America there are indigenous populations whose cultures and values are very different. Along the same lines, I would like to mention another issue which the courts have had to deal with in the context of the criminal law: whether indigenous people are responsible before the law when they commit a crime as a result of following their own cultural traditions. (Of course, we cannot automatically transfer this example to our own area of interest.) This example highlights the imposition of the dominant culture, while recognizing the importance of the minority one, taking as its starting point the formula that the act is against the law, while at the same time accepting that this prohibition may be the result of culturally conditioned error, with the result that the 'offender' should not be held responsible.

With this example, I simply want to point out that cultural diversity can also be relevant to the Law, and may even lead to exempting a person of responsibility for a crime. In the specific case under discussion here (that is, that consent is a basic and highly personal right of every citizen, but one in which he or she can be substituted if necessary) it is possible to accept that consent is shared by the two members of the gypsy couple, but what is important when accepting its validity is to confirm that this decision has also been accepted by the other party, even if there has been a degree of interference in the patient's private sphere by her partner. The challenge is to identify whether the woman really has consented, regardless of her passive attitude. If we can show that she has consented, albeit on those terms, then I believe we should accept it as part of the cultural diversity of our society (a society which, until recently, we believed to be far more homogeneous). If, by contrast, there is evidence of genuine rejection, as may occur in more extreme situations such as clitoral ablation in girls, then in this case consent would not be acceptable. And there would be an added problem, because the mother would be the one to take the decision on behalf of her child, and she would in turn be under pressure from a cultural tradition from which she herself had suffered in her own childhood, one which is sexist and discriminates against women.

**Pablo Simón.** I continue to be concerned by the question of the hierarchical ordering of principles. Perhaps I have not succeeded in explaining myself properly. Establishing an *a priori* hierarchy of principles is one thing, while taking decisions in light of the consequences of actions is another. To explain what I mean, one may consider that certain principles have greater moral relevance, but this does not mean they are set in stone. Material principles are never absolute. In certain situations, we can say that one principle should have prevalence over another, even if this principle is lower in the hierarchy, but this is something we decide in light of the consequences of things. So, with regard to the concept of *a priori* hierarchies, I would like to ask a question. Imagine that there is a blind man waiting at a traffic light. If there is no *a priori* hierarchy for our moral duties, would you say that my duty not to push him when a car passes is exactly the same as my duty to help him cross the road?

I also wonder whether absolute obligations are not perhaps superior to relative ones. I believe in principle that my duty not to push is far more important and binding than my duty to help cross the road. The first is a duty of an ethics of minimums, and the second is a duty of an ethics of maximums. If I walk past and leave the blind man standing there while the light goes green the worst that can be said of me is that I am rude, ill-mannered, a hypocrite or a person of low moral standing. By contrast, if I decide to push him as a car goes by, it is unlikely that the reaction will be limited to moral censure. So I believe that there is a significant moral difference between our *a priori* duties. Another issue concerns how, in real situations, we apply these principles.

And I have another concern with regard to what our colleague the psychiatrist had to say about the psychopathological context, and that is that I am concerned when we start to view things through this lens. It may be true that hospitals do not exactly favour mental lucidity at times, but I wonder whether, when one ask the bank for a loan and you know what it involves, from a psychopathological perspective it would be possible to question your mental lucidity at the moment of signing the loan. In other words, while I share your concerns, I think we must be wary of going too far, because otherwise we will end up questioning whether there is a clear identity at all; everything

can be viewed from a psychopathological perspective and that is an approach we should be very careful of. I know that is not the intention of your contribution, but I feel it was necessary to clarify this point.

Mercè Rius. Starting from my ignorance, as a philosopher, of practical questions, I would like to ask the experts here a question. However, before I formulate my question I would like to clarify a few points relating to my earlier contribution. I said earlier that health care develops on the basis of empirical experience, and therefore does not respond exactly to the concept of autonomy defined by Kant as supra-empirical. Of course, health staff must be capable of acting morally in the most challenging circumstances. However, as far as informed consent is concerned, these circumstances arise when the doctor is unable to count on the active cooperation of the patient, that is, when the patient's autonomy is damaged by a mental disorder (the physical disorders we take for granted; after all, without them there would be no need for treatment at all). Only in the event of mental disorder, then, can other considerations take precedent over the patient's autonomy: that is, to stand in for it but not to supplant. And my question is the following: who decides when this is the case? It is not enough to note that the simple act of being ill brings with it, to a lesser or greater degree, a loss of autonomy. This is both obvious and completely 'normal'; a pathological response, by contrast, would be not to be afraid or to alter one's conduct in the face of imminent danger. A very different situation is raised by mental illness as such, which may indeed significantly affect our autonomy by distorting our capacity to reason in a permanent rather than a temporary manner. If this occurs, because the mental functions have an empirical basis (although Kant may seek to transcend this), the decision is in the hands of the psychiatrist, whose potential errors we will be unable to remedy, together with the restraints imposed by the level of our scientific knowledge.

So, who decides about patient's autonomy when the patient is a member of a particular sociocultural group: for example, the Jehovah's Witnesses discussed by Carlos Romeo in some detail? Who decides that an individual who belongs to this group has sufficient autonomy to reject a transfusion while the member of another sect, one which is considered to be pernicious and to

practise 'brainwashing', is deemed to lack it? Perhaps a parallel could be drawn with the issue of clitoral ablation, as Victoria Camps suggested earlier.

**Octavi Quintana.** I would like to focus on the issue of 'practical problems' identified in the title of this seminar, with an emphasis on the word 'practical'. In this respect, I would like to offer two considerations: a reaction and a proposal. Firstly, I would like to respond to the comments of the group represented by Màrius Morlans on the arrangement between management and professional associations to evaluate informed consent through the measurement of outcomes. Well, I think you can either wait for cultural change to occur or you can try to make it happen. And there is no question, and I believe that experience demonstrates this, that promoting it through incentives and evaluating managers and encouraging them down this road has meant that this cultural change is happening, for better or worse, at a much faster rate than would have been the case had we simply waited for it to occur. The cultural change will happen anyway, but there is a difference between promoting and pushing it and just waiting for it to happen, and I firmly believe that it is much better to push it and promote it, even if this does lead to aberrations, as we have seen in certain cases.

We at the Spanish Health Service, when I was with them, saw around 16,000 informed consent documents, and it is true that quite a few of them were pretty confusing, but very many of them were good. Not all of them were like the ones reported here, a disaster, but rather there are some people who have understood what informed consent is all about and others who haven't understood anything. Informed consent promoted by top-down decisions and regulations has not always led to failure. In some cases it has, and in others it hasn't. I don't know how things would have been otherwise, but I do know how it has been in reality.

My proposal, which is the second part of my contribution, is that given the complexity of effectively evaluating the patient's competence, given that the patient, as Manuel Valdés has said, is probably subject to a series of conditions which mean that his competence to take decisions, even at his most lucid, may vary depending on changes in the situation. An alternative proposal would be, instead of consent for each situation, for each patient to do

what Beach of Georgetown proposes, and to choose a health professional with whom the patient believes he shares fundamental values, and for this professional to take the decisions as the patient's delegate, discussing them continuously, but with the decisions being taken, in principle, by the health professional. So the health professional would be the one to take the decisions. It goes without saying that this proposal is not without flaws and drawbacks, but it also has its advantages, and I believe that it is at the very least worth discussing. Specifically, there is an advantage in very complex illnesses in which the patient's situation may be very difficult and very complicated. Above all, when suffering from chronic illness it would be very helpful for patients to have somebody they could rely upon to support and lead them in making decisions, which is clearly what many patients hope for from their health professionals.

Josep Lluís Lafarga. I don't intend to resolve this dispute because I am sure it will continue elsewhere, but I would like to lend some support to Pablo Simón from the perspective of legal theory with regard to the problem as to whether there should be a hierarchy of principles. I will address this from a legal and specifically from a constitutional perspective. I believe that autonomy is indissolubly linked to the dignity of the person and to the right to freedom, both of which are absolutely fundamental to the constitutional state. As a result, they are the basis on which all the other rights depend and for this reason, in my opinion, must in practice prevail over the other values which we discussed: the principles of beneficence, non-maleficence and justice. In other words, this is a theoretical problem but which has practical implications, and I would like to stress this here.

At the same time, as I see it, the principle of autonomy is an immutable principle in relation to the other principles of beneficence, non-maleficence and even more so of justice, which are conditioned by situational and cultural factors. They change over time, while the principle of autonomy is permanent. The right to self-determination is indissolubly linked to the dignity of the individual, and as a result decisions may vary according to the time, place or cultural setting, despite which this capacity for self-determination remains unchanged from what we might call an intellectual perspective. For this rea-

son, I think that there is a hierarchy, and this is why both at the theoretical level and in the law there are concepts which clearly give primacy to the right to autonomy over the other values we have discussed here.

Clara Llubià. In my daily work, I constantly have to make decisions in difficult situations. Listening to Encarna Roca saying that the right to decide is a fundamental right of the individual has made me wonder how our patients can exercise this right (or their relatives when the patients are unable to do so). Although there is sufficient ethical and legal basis for it, the reality is that on most occasions they do not know what to decide, and often the information provided is of little help. Imagine that you required mechanical ventilation, and were asked if you preferred to be ventilated by pressure or by volume. You would not know how to answer. They need something on which to base their decision, and this is why both what the doctor says and how he says it is so important. In anxious situations (which are what is usual when important decisions have to be taken) the patient is in more need than ever of empathy and humanity on the part of the doctor. Neutral information, which is the norm given the lack of time and space in our hospitals, does not solve the problem. Instead, it reduces the issues to a mere formula. Communication skills and an empathetic approach are essential if information is truly to be received by the patient, enabling him to take a decision. The managers of health institutions should view the time dedicated to these tasks as an essential part of the daily work of their staff and of the doctor-patient relationship. The 'excellence' of institutions depends upon it.

**Xavier Carné.** Following on from the argument which Clara Llubià has just put forward, I would like to say that one of the key elements we are discussing is the question of information. Informed consent means granting one's consent to something about which one has previously been informed. And the problem, in my opinion, is that the scientific methodology employed by medicine is largely based on a method which, following Popper, we might describe as refutationist. In other words, we reject things but are never certain which of the many options available is the most favourable. Medicine advances in many directions at once, but only on the basis of great uncertainty, and when a patient is in a critical situation the last thing he wants is to

hear of uncertainty. He prefers to seize hold of anything which gives him hope. So the main principle of the scientific method (which is the one used by medicine) and its application in each specific case, are in contradiction. This is because the information which people receive is derived from scientific knowledge which is in its very essence uncertain and relative, and yet the people to whom this information is given couldn't care a fig about probabilities. In medicine, we talk of probabilities and population studies. In a population with these characteristics there is a particular distribution, a particular probability of responses, but there is no certainty that a specific individual with specific characteristics will respond in the same way. In other words, clinical trials or meta-analysis give us populational data, not individual data; they do not allow us to make individual predictions. As Victoria Camps says, the results always have to be interpreted. And this runs contrary to the immediate, automatic application of the results of clinical trials or meta-analysis to a specific case, hence the problem of how to translate this message in comprehensible terms in a situation in which none of those involved, including the experts, can be sure of which elements will come into play. This is my first consideration.

But, as if this were not complicated enough, the history of medicine shows that the efficacy of therapeutic interventions depends in part on the conviction of the person performing treatment. In other words, a treatment provided by a doctor who is convinced that it will work is indeed more likely to be successful than the same treatment being applied by a doctor who is convinced that it is pointless. This probably explains part of the efficacy of some alternative medicines. In this context, in which belief in the efficacy of an intervention by the doctor is part of what makes the treatment effective, it is logical that a degree of persuasion should be involved. If I believe in it, then it will work better than if I do not. This is a lesson which we cannot deny. As a result, things are not so simple; translating information based on populational studies into individual terms is very complex. How much information should we give? I think this is very difficult. Which of the potential undesired effects of a medicine should be explained to the patient? What probability? If something occurs in one in every million treatments, should we mention it or not? And what about 1 in 100,000? Or 1 in 10,000? So there are no clear

limits. The limits have to be chosen by the expert. This means we are in a situation in which part of the information has to be interpreted, and the person who interprets it is also the person who provides it.

Josep Enric Rebés. I was very relieved to hear Octavi Quintana talking about the practical aspects, even though we are still at the beginning. I prefer to speak from my experience of having dealt with lots of medical records. And when it comes to consent, I would say that the issue is dealt with in a more reasonable manner. If anyone was watching this meeting through the eyes of a patient, I think they would throw themselves out of the window! They would understand nothing at all. In other words, this whole event is for the benefit of the patient and anyone who doesn't understand that stick to research, because I think the final beneficiary here is the patient (and I mean the patient, not the lawyers!). As a result, doctors pay little attention to the issue of informed consent, just as they dedicate little time to the non-clinical human aspect of the patient. And I think it would be good if the Foundation addressed this issue in some way.

Any information which is supplied has to be appropriate, proportionate and reasonable. And by that, I don't mean copying out a section of Harrison – anyone can do that. What we need to do is explain things in a way which allows them to be understood. If the psychiatrist tells a person that he has a neurovegetative disorder, it's likely that the patient won't understand what on earth the psychiatrist is talking about; but if you tell him he's hysterical, then he will not only understand but be upset. There are many ways of explaining things, and lots of different types of patient. Of course, the majority of patients find themselves in a position of reduced autonomy. From the moment when they undress you and put you in pyjamas and everyone examines you, you lose your true individuality. And when you get dressed again, you become a real person again and it's all over. That's what happens in hospital, and that's why I feel you have to explain things and to do so without taking them out of their context so that the recipient of the information can understand it. There's no need for overwhelming people with percentages and the like.

I was pleasantly surprised by what Octavi Quintana had to say about the rediscovery by the University of Georgetown regarding the notion of the

doctor as guardian and protector. Well done! We've remembered the family doctor, the GP. What did families do before? What did the family say? Nothing. The one who decided was the family doctor. If the doctor said you had to have an operation for whatever, well great, you had the operation. If the family doctor wasn't so sure, he talked to the family and said, "Look, I'm not absolutely clear about this. We should consult a specialist. We'll ask Dr Broggi, or Dr. Whoever what to do, and that's that." And here the top doctors fulfilled that function, because the family was doing what it seems the Americans have now reinvented, they've discovered that there is somebody to take care of the issue. Well that's great. As a legal expert, I completely disagree with this situation, because it means treating patients as children, although I understand that some patients need guidance; in other words, you can do this, you can do that, if you aren't very sure then the doctor must be confident enough to say, "We've got to consult somebody else."

And one final word regarding the examples of Genoveva and Mr Rodríguez and the rest. Congratulations to them, and I'm very happy for them, because they were healthy and stood up for themselves, and that means they were fully able to act. One final question concerns the fact that informed consent is becoming, from a legal perspective, an issue which arises on an opportunistic basis. And one further conclusion regarding medical records: I believe that doctors should write more, they should write more so that medical records can not only be understood by somebody who is competent in the area, but by anybody, so that lawyers and judges can read and understand them.

**Javier Sánchez Caro.** I will try to keep things brief, because I know we are pushed for time. To start with, I completely agree with what has just been said, because this whole theory is based on the fact that a person, just because he is ill, should not be treated as an invalid. And that is what is at the bottom of the problem, despite the fact that in the past it was not properly understood. A person, simply as a result of being ill, was deemed incapable of taking a decision for himself, and this is what has changed. Of course, this doesn't mean that there are no exceptions. Those of us who deal with the law know that there are exceptions, some of which have been discussed here in

detail. And then, of course, there are emergency situations. If someone arrives at a hospital and is at death's door and you stop to ask them whether or not they want you to perform this or that procedure, you may find that you are not only in dereliction of the duty to help but that you are in violation of the Penal Code, by failing to provide assistance. So everything has to be placed in context. I won't go over the basics again. All I want to say is that there is no turning back. Whatever the basis, there is no turning back, as is demonstrated by the fact that Spain has signed the Oviedo Convention, the European Convention on Human Rights, which came into force on 1 January 2000, and which binds us irrevocably. And without question, as José Luis Lafarga has said, autonomy, freedom, the constitution, respect for the individual, liberalism, the Enlightenment are all good; there's no need to continue the list.

The problem of informed consent arose first in the legal sphere, and we then sought an ethical basis. But we need to bear in mind how it first came about. The judges were in fact the first ones to seek this ethical basis. Supreme Court Justice Cardozo did so in 1914, but this does not alter the fact that the conflict first arose in the courts and only then was a bioethical basis sought. For this reason, in the United States, textbooks such as Appelbaum start with the legal issue and then go onto the ethical one, unlike in Spain, where we start by studying the ethical principles and then consider the legal situation. Reversing history which, as Carlos Romeo noted earlier, saw the development of court cases in the 1980s and 1990s, followed by an attempt to provide an ethical basis for decisions.

I am no expert in bioethics, and certainly Pablo Simón knows far more than I do in this field, as do many others here. However, I believe it is very difficult to reduce life to a set of principles. This is not possible. Indeed, this position has been described as weak, in the sense that it does not take full account of human beings and the world in which they live, trying instead to reduce all decisions to the manipulation, in the best sense of the word, of four principles. If no law is absolute, as our Constitutional Court says, then the competing principles must be weighted in each individual case, taking into account the cultural values and the specific situation and circumstances, something

which can only be done in practice, not in theory. It is, in my opinion, impossible to establish a theoretical list of situations which would enable us to solve all the problems, regardless of how they are raised. The cases which have been discussed here demonstrate this, although this does not mean they lack interest.

Words are important, regardless of the question of principles; the word *competencia* is foreign, extraneous, does not appear in the Dictionary of Spain's Royal Academy, and completely contradicts our shared experience. The word *competencia*, what is more, presupposes the existence of *capacidad*; all it adds is ability, and that is not the question here, but rather whether a person is able to take a decision by virtue of his natural decision-making capacity, not his specific skills, which are a separate issue, regardless of the fact that any capacity only applies to a specific act. We should therefore expunge the term *competencia*, and we also need to ensure that any alternative we choose is logical and easily understood if we are to avoid massive confusion. The problem arises from a literal translation of the American terms *capacity* and *competency* which fails to take account of the differences between North American and Spanish culture.

As legal specialists, what concerns us is the need to recognize how we have described the issue in the past, and how we have solved specific problems. The justification comes, as always, from the hard edge of criminal law. When the doctor was seen as being at the centre of the relationship, the patient's well-being was the basis of this. But the patient's well-being was defined by the doctor. By contrast, when we are governed by respect for the patient's wishes, which is the new theory, then this puts the patient at the centre of things and makes him the protagonist wherever possible, and then the patient's wishes become part of the justification. Albin Esser expressed it using elegant Latin phrases: either we accept salus aegrot i suprema lex (the patient's well-being as the supreme law) decided of course by the doctor, or we accept voluntas aegroti suprema lex (the patient's wishes as the supreme law). And of course there are exceptions, because nobody could believe that a single principle can solve every problem which arises in life. That would make no sense. In that case, we need to identify a balance between these two

values – the patient's wishes and the patient's well-being – in each case, and that is exactly what happens.

The problem of written or spoken information is a major issue. When we talk about informed consent and how it has developed in Spain, we have tended to confuse informed consent with the written document, and this is a grave misunderstanding which continues to hamper our efforts. Because when we say that patients must be informed, we forget something very basic: that there can be no limit on oral information. The only limits are the level of interest shown by the patient and the ability of the doctor to answer, but this does not apply in the case of written consent. So you would end up just attaching Harrison's *Principles of Internal Medicine*, which so I am told contains everything you need to know about medicine.

**Joan Viñas**. Following on from what has been said, I'd like to talk about my experience as a surgical care doctor. First of all, I'd like to say that I'm very pleased and grateful for the opportunity to be here, because I've learned a lot.

When you are more or less healthy, as we are today, everyone is on an even playing field: legal experts, doctors, nurses, philosophers etc., and it's good for us to try to find solutions to problems to defend the patient's dignity and equality, not to violate their basic human rights and so on. But when you fall ill, then you are no longer on the same level. And it is when people are ill that we ask them for informed consent, give them information and so on. I don't agree with the way informed consent has been implemented in Spain, because it has led to a lot of fear; caused by lots of different people, I don't want to point fingers, but this includes things like the court cases which appear in the press. There has been a cultural change in which the doctor has lost power, which is good because we should at least give the patient the capacity to control his illness and decide about it, as he's the one who is suffering. But doctors have also been offered a response to this loss of power, which consists of an informed consent form, a signature, and defensive medicine. The informed consent guidelines of many professional associations have been drafted and overseen by lawyers, and as a result are designed to defend the doctor (in the event of legal conflict) and are hostile to the patient (see, for example, what Xavier Carné has said about how frightening percentages can be).

This defensive medicine is, in my opinion, maleficent, as likewise it would be maleficent of the doctor to abdicate his beneficent function and leave the patient in a situation of absolute autonomy, and in this sense I think the term 'paternalism' has been used incorrectly. The doctor must be involved with the patient and the family; we can't wash our hands of them by offering a menu and asking them to take their pick. Giving information like that isn't good; if you don't get involved, then it isn't good medicine.

With regard to the debate about the hierarchy of principles, I believe that on a practical level this helps clinical ethics committee. I know that there are many competing principles, and that these include such principles as solidarity and other individual principles, but in practice where there is a conflict between principles, the methodology of applying a hierarchy is no bad thing, and I think that subdividing autonomy into two, following Diego Gracia and Zubirián, is a good idea; it's given me something to think about.

Finally, I would like to say that good medical practice means providing a high quality of care, and that involves a range of factors: remaining abreast of scientific knowledge; acquiring practical and technical skills, especially as a surgeon; acting ethically; showing one's humanity, and taking a human approach to health care and the way in which one treats patients; and patients perceiving the care they receive as good – user satisfaction. These are all things we have to strive to achieve. We need training in communication skills, this is something medical schools should do, and some of them do so already, together with training in bioethics, which only happens in a few.

Manuel de los Reyes. As a cardiologist dealing with clinical care on a daily basis, I would like to raise a few issues. The first of these relates to the context within which the clinical relationship occurs, the type of society, and the culture and customs associated with it, which it is not always easy or even desirable to change. In Latin cultures, the doctor–patient relationship is generally based on trust. And when we seek to build this, we realize that there is no trust without confidentiality, and no confidentiality without secrets. It is true that in some emergency situations relationships occur between 'moral strangers', and here we cannot talk of trust in the strictest sense. However,

even these cases should be governed by mutual respect, despite the potentially unequal or asymmetrical nature of the relationship.

Problems arise at the interface between the 'biological facts' which the doctor handles and the 'biographical values' of patients, which are by their nature subjective and may not coincide with the values of the doctor. There are lots of examples where this occurs, and we see it even where the patient is also a doctor or health professional.

With regard to cultural differences, I believe that both the scientific and the legal aspects of the English-speaking world exercise a great degree of influence on our behaviour and our expectations; indeed, at times we have been almost subservient in our adoption of fashions and ways of doing things. The only thing which is clear is that the existence of a 'moral Esperanto' – to paraphrase Daniel Callahan – is not acceptable, because the heritage and traditions, beliefs and attitudes of different countries are distinct and at times incompatible, a reflection both of the moral pluralism of our societies and the diversity of our health sectors.

The second question which concerns me relates to the information which the doctor transmits. If the doctor's attitude is absolutely vital, no less so is the way in which he uses language. Words can help to communicate ideas, emotions and feelings, to identify values, to explain options and to set out the health professional's preferences. And the doctor must do all of this with a degree of conviction but without manipulating or coercing the patient's wishes. But the doctor must also give information which is appropriate, adapted to the specific reality of the particular individual, in a way which is intelligible, honest and comprehensible. The key question is, "Do we do it like that?". And if the answer is "no", then "Why not?" In the Oviedo Convention on Bioethics, which came into force in Spain in January 2000, mention is made of the existence both of the right "to know" and the right "not to know". In my opinion, the latter should be the right "not to know any more", but starting from a certain minimum level of information. Were this not the case, the right would either be empty or with little ethical content.

There is a third issue I would like to raise. In Article 10 of the General Health Act of 1986, it states that informed consent is applicable in both the public

and the private sphere. To be honest, based on what I know of our country, I believe that the standards used to measure and assess the quality of this process both at the theoretical and practical level vary widely depending on the sphere in which it is applied and the interests at play. This is merely the reality.

I will end with the fourth issue, which has to do with the risks of diagnostic or therapeutic procedures. Talking about risk, just like that, is vague and insufficient. Risk is the probability and magnitude of physical or psychological damage, so it must be quantified and qualified. What is the estimated percentage of something occurring, and is this adverse event death, a serious or mild complication, the appearance of after-effects, discomfort or another event? When one is discussing risk, one has to be sincere and honest. What does the risk refer to? It can be based on the experience of the doctor performing the technique, the average risk among service staff, the national average recorded by the relevant scientific society, or on the technique having been identified as advisable in prestigious international medical publications. As we can see, it depends, and here we have to set the information within the context in which one operates, with common sense and caution. If we do it like this, then at least we will tell the truth. Defensive written consent forms, with a raft of statistical data, aimed at patients who lack specialist knowledge and have the additional anxiety of their illness, only add to confusion and ensure that the patient's consent is fearful rather than informed.

Ramon Bayés. I would like to refer to a recent example. Until 1996, AIDS patients had little hope of survival and many of them lived in expectation of death. After this date, in the west, the introduction of the antiretroviral cocktail changed the panorama. But recently experts have begun to realize that these new treatments, while they have brought and continue to bring significant benefits for the patient, also have highly undesirable side effects. In February 2001, it seems that Ho, the creator of the antiretroviral cocktail, at a meeting held in Chicago, after identifying the advantages and risks of a less aggressive treatment than the one being administered to date, said, "It is the patient who must choose between the effects of the illness and the side effects of treatment." If for a moment we put ourselves in the position of the patient

facing this problem – in which one can attempt to quantify the risk – we can see that the emotional impact on the patient of having to adopt a decision of this sort is considerable. How do we communicate this risk, while remaining both honest and compassionate?

**Màrius Morlans.** Once again I take up my duties as spokesperson of the self-appointed care group. I would like to correct an omission; Inés Barrio, who I forgot to mention, also made an active contribution. I would also like to say that Xavier Carné made a brilliant job of discussing the third point. He pointed out the challenge of translating medical information, which tends to be statistical, into accessible language which can be understood by the individual patient in specific circumstances. And the fourth point was also developed brilliantly by Manuel de los Reyes, who insisted on the importance of winning the patient's trust and that the health professional should be concerned to confirm that the information has been understood, not to seek a signature.

And so, I insist, the way in which health institutions tackle the problem is misconceived. I am not criticizing people's good intentions, but if we judge by results I am more pessimistic. It would have been enough to demand or recommend dialogue, and I'm glad it was a legal expert who said this. This is the only way of overcoming the challenge of translating statistical information into individual language. I can see no alternative to respectful dialogue with the patient, with enough time. But we have put the stress on documents and signatures. Instead, it should be a prior demand that there has been dialogue with the patient. And I also agree with those who have said that doctors should record the content of the dialogue in the medical records. This would help, but it has not happened. We should view the document as a minimum requirement. We have talked about levels, about minimum proof that consent has been obtained, but a document cannot replace the proper procedure, consisting of respectful dialogue with the patient, and I would have liked to hear those responsible say so.

The way in which the proposed treatment is introduced influences the outcome, as does the way in which we evaluate its success. This is the only way I know, and it reassures me to hear legal experts agree. It was also heartening to hear them say that we have to make more use of medical records; I share

this view. How we evaluate informed consent also influences how we carry it out; how we define it, how we present it, and how we evaluate it. Informed consent has been poorly implemented and poorly evaluated, because what has been evaluated is the document. It would have been better to evaluate patients' level of comprehension, how much information they had, their satisfaction, the relationship with the health professionals. This would have influenced, by stressing attitudes and dialogue, but we have gone down a different route, and that's the reality, at least in hospitals in Catalonia. I don't know what the situation is in the rest of Spain, but in Catalan hospitals the ideas being expressed here reflect the reality. It is for good reason that this seminar was titled "Practical aspects of informed consent". The ethical-legal discourse has been clear since the outset. It is very satisfying to see here two people whose work I have read avidly, Carlos Romeo and Pablo, and I would like to thank them for their efforts to enrich the concept of consent both by filling out the details and by exploring case studies. Case studies are always instructive, but I had also had the privilege of hearing Carlos Romeo set out the basic concepts at the symposium in Barcelona in 1991, and also Pablo Simón, whom I met later and whose work I have continued to read.

In the conceptual and legal sphere, things are clear. By contrast, where there are difficulties and the reason why we are meeting here today is because we are convinced that in practice we are not doing things properly, or we are not doing them as we should, and that's the root of the problem. Somebody said that six years have been wasted; I have to say, that that strikes me as optimistic. I think we have lost even more. In that sense, I'm more pessimistic. We all have to help each other, and give moral support to those who have to put informed consent into practice by backing them up with arguments. In this, we all have a duty to facilitate things, and that's why I think it's so important to emphasize the need for dialogue rather than documents. Of course, signing a document is a requirement, I don't deny that. But it is a requirement which should follow a process of dialogue. It would help to put the stress on dialogue as a prior requirement to signing the document. And we also need to focus on how we evaluate the implementation of informed consent. This is difficult and requires time, but when we are looking at the outcome of implementation, we need to develop evaluation methodologies which go

beyond simply counting the number of forms with signatures; we need to find ways of evaluating the quality and quantity of information that citizens have.

Joan Padrós. I have worked as a clinician in a general hospital for twenty-five years. Those of us who have been in the health service for so long look back over the changes which have taken place in the clinical relationship, at times with a degree of embarrassment. The paternalistic attitude towards patients was something we did not question; therapeutic privilege was the rule rather than the exception. Things have changed a lot since then. In my opinion, the great virtue of informed consent (or care consent, as some call it) has been to force a cultural change which would have taken far longer had it not been for the legislative change brought in by the General Health Act of 1986. However, together with this unquestionable progress towards the increased participation of patients in decisions about their health, there has also been a negative effect on the clinical relationship.

As care professionals this leaves us with a difficult role. On the one hand, we must represent the health needs of patients within the social context of changing values. At the same time, we must combine this job with our task as agents of a health system with growing budget problems. All of this leads to some confusion when taking decision in the workplace.

The training we received at medical school is still influenced, as I see it, by the dominant social values and these, in turn, are embedded in the subconscious of health professionals. The challenge of curing illness remains the prime concern of the medical profession; this explains, for example, why palliative medicine and bioethics are deemed to be less important. The holistic focus of the health profession is relegated to the care function of nursing professionals, while the bio-psychosocial aspects are the job of family doctors. Our fascination with hospital technology clearly influences the reductionist vision that health professionals in this area often have of the real rights and needs of patients.

We are witnessing a sea change in health decision-making. Traditional medical power is in gradual retreat: the spectacular increase in scientific knowled-

ge is not always available to us, despite the internet; the fragmentation of knowledge into specialist areas weakens our overview of many other aspects of health; technological advances are not always available in the here and now; the massification of care brings daily moral dilemmas to health professionals who worry about the fairness of our system as we struggle to micromanage it. And all of this is occurring in the context of the growing role of patients in making decisions about their health. In my opinion, only if we start by recognizing this weakness can we seek to find a new focus on the needs of the patients whom health professionals and the health system are meant to serve.

I would also like to comment on written informed consent. I believe it has been a mistake to make this compulsory. The cultural change to which I referred earlier might perhaps have occurred more slowly, but there would not have been the bureaucratization of the exchange of information between doctors and health service users which we now see. Often, those who have the highest levels of compliance with written consent forms also have the lowest respect for the ethical duty to inform.

Finally, with respect to the different models of the clinical relationship, referred to by Pablo Simón, as far as I recall from the original article by Emanuel and Emanuel, these authors argue strongly for the deliberative model, but there are also situations where other models are appropriate. In an emergency situation, the paternalistic model may often be necessary, while the so-called informative model may be more suitable for minor treatments where the associated risks are lower.

**Javier Barja**, surgeon and care doctor. One comment: in our hospital only 4.5 years ago we carried out a survey among medical staff with regard to their opinion of informed consent. I don't know if it was a surprise or not, but at the time some 83% said it was a patient's right, a little more than 70% said it improved information, and less than 30% said it was defensive medicine. In the almost five years which have passed since, whether due to social demands, legal rulings or because those of us whose task it was to advocate it have not done a good job, the fact is that I doubt that these percentages would still hold, but rather the opposite. Instead, staff see collecting a signature on a

form as an element of defensive medicine. It is hardly surprising then that professional associations have had these documents drawn up by legal experts. But let us not forget the key issue, the ethical concept of informed consent. This means the information should be given by the doctors, and that means the documents should also be written by them. I believe this is obvious, and this is something we should be working on. And what about the information itself? Either we recognize that oral information was universally inadequate, or all we have to do is transfer into writing what we were previously doing orally. It is nothing more complicated than that, as I see it. The other question is how we evaluate it. When we are working with documents, in addition to subjecting them to the Fletcher comprehension test as Pablo Simón advocates, we evaluate them and test them with a group of patients, because these are the final recipients of such information sheets. And if they don't understand it, then it is clear that the form does not fulfil its function and must be changed. So that's what we're doing. Although it is still early days, I would say that we are having some success. However, we still need to work as advocates for informed consent.

And finally, I would like to echo what other doctors, such as Clara Llubià and Manuel de los Reyes, have said. The current situation, in which a profession which is intimately concerned with human relations does not receive even the most basic training in interpersonal skills and attitudes, is deplorable. It is an insult to the intelligence.

**Pablo Simón.** Xavier Carné has touched on an issue which concerns me, but I don't know if I have understood him properly. And Màrius Morlans has also discussed it. It is true that the information we have is based on research on population series, and that it is very difficult to deduce from this what will actually happen to individual patients. I believe this is the argument you have finally put on the table. As a result, it is very difficult to present this information to patients, and therefore in the end the person who has the power to interpret things more precisely is the medical expert. I would qualify this. Almost all the information we have about most things is based on population series, for almost everything. So, we know the probability of our being involved in a traffic accident, but I don't know the probability – and nor does

anyone – of suffering a traffic accident on the way here, in Barcelona, here at the airport. This means, then, that before taking the decision about whether I should go to the airport, I should listen to the traffic report, shouldn't I? Well, I'm not so sure that's how things stand. Almost all the information we obtain is based on population series, and this happens in almost every sphere of life. So let's see, I'm not sure if I'm misinterpreting you; perhaps, but that's how I understood it and that's how I want to consider it. Regardless of where the information comes from, it is our job to engage in dialogue with patients to identify how much information they actually want. I believe that is the question.

Second issue: the introduction of targets for written informed consent forms. Perhaps this was not a good idea, but that is easy to say with the benefit of hindsight; management teams should not have done it, and that's what doctors say. However, if we had waited for scientific societies, doctors' associations and professionals to implement informed consent, to tell you the truth, I think we'd still be waiting, so maybe, even if we think it wasn't done in the best way, we must still recognize that the authorities got things moving.

Third issue: Javier said that it is not possible to reduce moral life to a set of principles. Moral life is obviously tremendously complex, and as a result we use explanatory models. It is not clear to me that explanatory models based on rules, or legislation, or specific rules of conduct bring us closer to the actual reality of our situation. I will explain what I mean. You said that the issue of informed consent arises in the legal sphere and that we then seek the ethical foundation. I think that is partly true. It is true in the sphere of research, but not in that of investigation. In fact, consent has its historical roots in the sphere of ethical discussion, where a system of rules, such as the Nuremberg Code, is shown to be ineffective and we therefore need to find a more general level, a set of general principles to guide our action to see if this enables us to understand and analyse things more accurately. I simply wanted to draw out that distinction. And I should add that I do not believe that the paternalistic approach is applied even in emergency departments.

**Juan Pablo Beca**. I would like to start by thanking the Víctor Grífols i Lucas Foundation for organizing this interesting seminar, and its president,

Victoria Camps, for representing our ideas so accurately in her position as spokesperson for the care group. I believe that what we are now facing is a dramatic cultural change, from the paternalism which has prevailed for centuries towards a new model of the clinical relationship. Coming from another culture, I can see that we are now at a different stage, and it may be interesting to consider this. The traditional vertical relationship between a person who is assumed to know everything and another who needs everything is gradually being replaced by a relationship which, in theory, is a relationship of equals, but who are never quite equal because one partner in the relationship still holds the power of knowledge while the other is suffering from illness, even if he too is a doctor or a philosopher. This means that while the relationship is in theory symmetrical, in practice it is not, and so we need to find a model for this human relationship. Clearly, what is required is a participatory model in which information and deliberation are essential. This involves the art of informing and the need to be understood, and here the emphasis must be on understanding rather than on information on its own. Nobody can reach a decision if he has not first clearly understood what is happening and what alternatives are open to him. And, at risk of being labelled paternalistic, I believe that the doctor's role of moral guide cannot be replaced by written information. A doctor who knows his patient, whether the family doctor or one who understands the patient's suffering and anxiety, is the one who should give the information; and in this situation it is difficult to avoid the information pointing in a particular direction, and perhaps such neutrality would, anyway, be undesirable.

I am a paediatrician, and I believe that the model of the clinical relationship in paediatrics is a good one for demonstrating that the patient has limits on his decision-making competence. If the child is very small, a newborn infant or a pre-school child, then clearly she cannot choose. However, by 8 or 10 years the child deserves information, even if she cannot decide. In this case, we say that the parents grant 'consent', and that the child gives her 'assent' or agreement, and this act of assent is also part of a learning process. This child will gradually develop her civil capacity as a citizen with the right to decide on health matters and on other issues. I think that the paediatric model of the clinical relationship is interesting because it is a complex model in which

autonomy is delegated to or represented by the parents, but in which this representation often entails an implicit or, more seriously, an explicit conflict of interests where what is best for the child may not be best for the parents. We are all familiar with the classic cases of this, which are widely covered in the literature. But what I would like to stress here is that the clinical relationship in paediatrics involves many agents, and is not just a theoretical model of doctor and patient. It always involves a family, a specialist, various doctors and sometimes nursing staff too. I think that the discussion has tended to neglect this aspect, where the relationship involves a health care team on the one hand and what one might call a family team on the other. We are viewing autonomy as an individual right, as if we had imported it from the more individualistic culture of the English-speaking world, when the truth is that there is also family autonomy. In the case of the gypsy couple presented by Pablo, the man was representing what the woman wanted and we cannot simply say that this is sexism or that the woman was being humiliated; this is part of their culture and the patient is accompanied in her time of need. She always belongs to a family group or a support group; this is at the core of her life and is heavily involved in the clinical relationship – we cannot ignore this and transform it all into a contractual document between two individuals. I will conclude by saying that we should see informed consent as a major cultural change which is very positive. We should see it as a complex process, with an ethical basis, a clinical basis, a legal basis, and also with a very significant cultural basis, and in which, evidently, as our spokesperson said, the informed consent paper or document is a minimum requirement but should not be seen as anything more than a certificate that the human relationship has actually occurred. Because what we are looking for is nothing other than to improve quality, improve the clinical relationship and this of course includes raising awareness among patients and citizens on the one hand, and sensitizing our health staff on the other.

**Javier Hernández.** I would like to return to the issue of terminology. I am referring here to the issue raised by Sánchez Caro and which I think is of great importance: what does competence refer to? I believe that how we define the level of competence required will condition the entire system of informed consent. The terminological problem can be identified in Act 21/2000

of the Parliament of Catalonia, which defines competence in more than one way. When it refers to adults, competence is equivalent to the general capacity to act, while when it refers to the competence required of a minor, the law considers the nature of consent, a qualified competence which means we must also evaluate the individual's emotional and intellectual capacity. Although the starting point is the deficit of competence on the part of minors, in the end what this leads to is the differing scope of the concept of competence. What does this make me think? That ultimately rigid theoretical categories continue to exert pressure on legislators. I believe that legislators in Catalonia, when referring to *competencia* did not wish to depart from the concept of the general capacity to act, something which would have been a major step. I would like to take advantage of the fact that we have here a legislative advisor (Marc Antoni Broggi) to ask him to clarify the scope of the terminology.

I would also like to insist on an issue which both Manuel de los Reyes and Josep Enric Rebés have raised: the need for a functional view of the care act, of the doctor-patient relationship. I remember a wonderful book by Alvar Aalto in which he recounts how, for a hospital project, he put himself on the horizontal plane occupied by the patient, and from this angle designed the entrance of light into the rooms, the orientation of the doors, the noise of water running from a tap, the positioning of the bed, etc. I believe that when it comes to consent we are distorting the role it should play, and I believe this is happening because we are too firmly wedded to traditional legal categories. I believe that legislators, legal experts or economists, who are the ones who make our laws, have not freed themselves from the notion of consent embodied in the idea of a contract. Consent does not only serve as authorization for the provision of a particular service, but should also serve as the basis for establishing a 'contractual relationship'. Understood in this way, consent appears to belong to the category of contract in its dimension as action, rule and relationship. Often, the aim of formal consent documents is to exclude liability, or at least to modulate it by defining its scope. I believe that such instruments are of no use when it comes to informing people. They operate as regulatory mechanisms in a strange contract through which the professional seeks to exonerate himself of any liability deriving from the medical act,

and I believe that, in this respect, Xavier Carné has made a magnificent contribution. If consent were measured in exclusively functional terms, and if information also were measured in such terms, then we should only demand that which is necessary to enable the patient to dispose of his right to physical integrity in a reasonable way. Information for consent does not, in my opinion, require either the identification of all the probability percentages of deviations from typical case histories, nor that the doctor adopt a cold, neutral stance with respect to the diagnostic method. What the information process requires of the doctor is 'activism'; a passion to inform which gives the information its value for consent.

I would like to end by view this issue from the perspective of a judge or lawyer in court, a perspective which should help to reveal clearly the naivety of some of the ideas as to the nature of relevant clinical information. The belief that a formal document of consent can constitute a mechanism which either offers exemption from or modifies the doctor's liability is remarkably naive. Formal consent has the benefit of making it easier to demonstrate that consent has been granted, but would lose any such value were it subsequently to be shown that the signatory of a document which contains four pages of Harrison cannot understand the language in which these are written or does not understand the expressions used in the document itself. I believe, then, that information must be functional; that it must be put at the service of the basic right to freedom rather than at the service of a contract which is, ultimately, defining all our care relationships, perhaps due to the decisions of health managers.

**Virtudes Pacheco.** From the perspective of user services in a hospital organization, the issue of informed consent tends to arise either in the context of a conflict of interests, or in response to questions by health professionals or patients. The conflict arises when things have not been done properly, or when the expectations of health service users have not been met. An alternative way of thinking about the scope of consent is in terms of preventing such conflicts from arising. We usually identify problems with medical practice from reports by patients or their families, or both at the same time. From this position, it is relatively straightforward to contribute to the needs analy-

sis which should underpin the organization's informed consent process. I believe we need to observe the reality, taking into account that today neither the doctor nor the nurse nor any other care professional takes decisions in isolation, at least in the context of a hospital organization. And nor, usually, does the patient, who is usually helped in reaching decisions by his family and close friends. This is set out in the table below.

Needs detected by user services in a hospital organization to standardize informed consent

From the perspective of the organization CENTRE/INSTITUTION	From the perspective of professional groups PROFESSIONALS
Comply with the law	Respect the law
Draw up agreed standards for implementation	Inform users
To facilitate action:  Writing specific information sheets Time management Providing information to service users prior to medical treatment	Facilitate autonomy in the clinical relationship  Agree on procedures which require specific information sheets
Meet social, ethical and service contract objectives	Record information process in medical records, to facilitate continuity with other health professionals and care team
Promote and support the establishment of an institution-wide CEC	Creating opportunities to discuss problems and concerns
Respect the autonomy and independence of the CEC	Consult, share doubts
Facilitate the creation of an informed consent culture, and evaluate implementation	Satisfy the ethical requirements on which achievements are based: demonstrate prior respect

I believe that this sets informed consent within the context of organizational ethics. I also believe that the process must be coherent, and that we must also think about the individual doctor, the individual nurse, etc.; the supposed distribution of roles *vis-à-vis* the patient is often more ideal than real, and in fact in organized medicine roles almost always overlap significantly. Team work has led to the depersonalization of the relationship between medical staff and patients, and informed consent is forcing us to reclaims spaces for communication and relationships between professionals and patients which had been neglected.

Pablo Simón's proposal of a distinction between level one and level two informed consent strikes me as very useful. And, if we start by analysing the different areas of responsibility, I would say that, in the first place, we must comply with the law.

Once legislation has been passed, then it must be respected, and we must explain how this is to be done. We need to take this into account, because otherwise citizens will demand it before we are in a position to deliver it, and this can only create a sensation of insecurity in the relationships between health staff and patients.

The institution, the organization where patient care is delivered, is one of the most important locations for reaching consensus regarding the procedure for informed consent.

Earlier, Màrius Morlans gave an example which helps to clarify the feeling of isolation which health professionals may experience with regard to informed consent, and this was a document he was shown by a registrar which, on the advice of a professional association and at the suggestion of the head of service, contained so much information that communication and thus truly informed consent was impossible. Just imagine the insecurity of the health professional in this situation, to say nothing of the patient. And this insecurity occurs at the heart of a very hierarchical organization, where the doctorpatient relationship – which in principle should be characterized not by hierarchy but by knowledge and understanding – has to develop while we are still to arrive at a consensus as to how to inform the patient, what this infor-

mation should consist of, and how, with whom and in what form the patient should grant his consent.

The institution and its management must support this process so that informed consent occurs under the best possible conditions. By this I mean that they should facilitate participation and agreement on the content of specific information sheets. And service users should also be informed of their rights, prior to medical treatment, through care guides which inform them of the law (their rights and obligations, etc.) as soon as they enter the hospital.

In addition to this cultural change in the relationship with service users, there is another challenge, and this is the fact that institutions have to manage both the time and the space required so that doctors and other care professionals can talk to patients, discuss concerns, and do so in privacy, as part of a wider care relationship. Recently we have heard complaints from primary care doctors that they can only spend ten minutes with each patient. This certainly gives us food for thought.

The cultural change which is gradually taking place represents a real challenge for the managers of health organizations, because the issue of informed consent and respect for the autonomy of the individual requires major changes in how we do things and how we relate to each other.

**Inés Barrio**, primary care nurse at a Madrid health centre. I would like to say a couple of things from the point of view of nurses, about their role in informed consent, and I will use the structure suggested earlier by Octavi Quintana, of a concern and a proposal. Any nurse could tell you about the experience of seeing a doctor leave a patient's room, presumably after talking to him, after informing him about something. And when the nurse goes in she is bombarded with a whole series of questions, like: Has he decided on a treatment? What does the treatment consist of? Is it intravenous or oral? Lots of things make us realize that patients see us to some extent as intermediaries or allies who can help them find their way through the maze of health information. But against this, we find that our role within the informed consent process or as part of the health information process is not regulated. The General Health Act doesn't even mention us, and the Catalan Law on Clini-

cal Information, in referring to the degree of responsibility of professionals involved in administering treatment or performing a procedure, is somewhat inadequate and of little use in telling us what we need to do. The professional code of ethics for nurses in Spain (there is a separate one in Catalonia) states that we should give patients accurate information within the limits of our responsibilities. And when these responsibilities are part of nursing duties then things are clear: we know that we need to inform and to request consent. But when they are duties which are delegated to us, things that we do on the instructions of another health professional, usually a doctor, our role is a little bit confused.

So I will propose two things. Firstly, I will try to identify some criteria which I believe would help to guide the role of nurses in the area of information and consent. Working within the framework of a team, of a group of people who accept the responsibility of keeping patients informed. I believe that sometimes the person who performs the technique should be the one who informs the patients, and as nurses we perform many techniques about which we could provide a lot of information, even if the decision as to which technique to apply is not ours: for example, how a catheter is inserted, the discomfort associated with it, why it is used, etc. For some of the procedures we perform it would be better if information was given by the person who has prescribed it, because although we may know how the procedure is administered, we are not aware of the potential consequences: e.g., lots of pharmacological preparations, vaccines, allergenic extracts.

Sometimes the person who provides information is chosen because of their accessibility to the service user, and often the most accessible person is the nurse. This is the case of a family doctor who requests an endoscopy for a patient, where there are lots of people who could explain what an endoscopy is; it has to be performed by a radiologist, but the radiologist won't see the patient until the day of the test and only has a few minutes to talk to him. So the nurse needs to explain to the patient what the test consists of. I believe, taking into account these criteria and putting them together, that we can provide tools and time and staff to ensure that patients are properly informed before taking a decision.

The second thing I would like to say with regard to nursing is what Pablo Simón has said about level 1 and level 2. I believe that, in the first place, nurses always have to respect people's autonomous decisions, among other reasons because this is a legal requirement. But perhaps our true role lies in the field of what he terms level 2 informed consent or promoting people's autonomy. I believe that nurses' proximity to patients and our desire to go beyond minimum legal requirements provide a basis for helping patients in a number of areas. Firstly, we can help maximize patient's decision-making capacity, by clarifying terminology, and informing the patient that information is not optional and something the doctor is doing as a favour, but rather that it is a right. Secondly, I believe that nurses are well placed to detect shortcomings in the informed consent process, to identify the obstacles which prevent a patient from understanding the information properly, whether because he is hard of hearing, because he doesn't understand the documents or doesn't understand the language.

We can also perform a mediating role, helping bring the patient's need for information to the attention of the doctor. Nurses are very accustomed to calling the doctor if the patient is running a high temperature or if a surgical wound has opened. And there is no different in principle in our calling a doctor when the patient has an information deficit which the doctor needs to address. In other words, we can identify insufficient information as one of the patient's potential health needs.

I also believe that the nurse's proximity to the patient and his family means that the nurse is well placed to help identify who the patient's substitute should be if the patient is incompetent or incapacitated, and is unable to take a decision.

In summary, I believe that, through the constant presence of the nurse at the patient's side, what we are striving to create is a climate of information around the patient. The creation of a climate of information around the patient is necessary because when the patient is in a health centre, a care home or a hospital, he often feels threatened and insecure. So it is important for nurses to ensure that the patient feels at ease, to provide information

about timetables, about when the doctor will come to inform him, about what the buttons are for and so on.

**Pablo Hernando**. Diego Gracia says that bioethics is concerned with quality, and that the big problem is that consent is still not seen as a part of this. In our institutions, quality applies to many things. For example, in the exam for newly qualified doctors, two or three years ago, the only question about consent related to a consent sheet in a clinical trial, if I remember correctly. This was the only indicator of the competence of health professionals with regard to information.

This is something which everyone has to demand, patients and health professionals alike, that a good doctor is not just one who performs well, but also one who informs well. I think this is a notion we have to transmit to society. This is a learning process, and it can't be restricted to informed consent forms; there are lots of people here, but nobody from the Education Department of Catalonia. Unfortunately, nobody teaches 14-year-old kids that they need to take decisions about their own bodies and do so in a responsible manner. And I mean at 14, 15 and 16 years of age, because I have daughters of that age, and I can see that they get a lot of information about their bodies but very little information about their responsibility for taking decisions. In other words, it's a problem for society as a whole, not just for health professionals. And we need to address it in terms of quality, not in terms of legal requirements, which have little direct impact on how health professionals do their job. It's a question of doing things properly: I need to avoid infections, I need to prevent complications, and I also need to inform well.

Josep Lluís Lafarga. My 'clinical experience', if one may use such a term to describe the work of a jurist, leads me to believe that the signing of an informed consent form by the patient in a situation where written informed consent is a legal requirement constitutes an element of uncertainty and unease which aggravates an already burdensome situation, a situation in which, moreover, one must question the patient's decision-making capacity simply because of his position as a patient. Given that some rulings have already clearly indicated that its appearance in the medical records is suffi-

cient proof that adequate information has occurred in accordance with the law, and that consent has been granted, I wonder whether it might be possible to replace these written consent forms with a deliberative process, a process of dialogue such as the one discussed today, while taking due care to record it in the medical records. I wonder if legal experts and, in particular judges could answer when this would be possible.

**Màrius Morlans.** That is the six million dollar question: I hope we can extend the discussion to answer it.

**Joan Viñas.** When I request consent, when I ask for a signature, I do it at the end of an explanatory process and after gaining the patient's trust within the context of the clinical relationship. So I try very hard to ensure that the signature does not break this trust. "What? And now I have to sign this?" I try to set things right so that the patient still trusts me, and normally I manage it and the patient ends up saying, "Don't worry, I'll sign it and exonerate you." That's what I've been told, and not just once but several times: "I'll sign it, I'll do you the favour of signing." That's the first thing. And the second thing is that there is no social demand for signing such documents. I've never had a patient come in and say, "Hey, where do I sign?" What they do ask for is information. And the change which has happened during the last three years has been a shift from informing the family to informing the patient, treating the patient as an adult, who says "I want information too," and this change has improved the information process. I think it has got better, and I'm going to sing the praises of the medical profession, which is reflected in the improvement in the professional codes of ethics of Spanish doctors between the late 1970s and the 1999 version. The new version seeks to combine a bit of paternalism, maybe too much for some, with the patient's right to be informed; it combines both. And the Catalan code, which is slightly earlier, drawn up in 1997, also seeks to combine these two qualities – autonomy and paternalism - and says that information should be comprehensible and cautious; it gives a set of standards, but what is clear is that the patient is now at the centre of the process; the doctor should not impose anything on the patient.

And what about institutional codes of ethics? I would like to consider an issue which is on the list but which nobody has addressed, and that is the

teaching role of institutions. In my opinion, any health institution is a teaching institution almost by definition. Some of them include the word 'University' in their names, and patients are aware of this. I think here we have to apply some common sense, a faculty which paradoxically is often quite rare. The patient has a certain social obligation upon entering such institutions, but the doctor also has an obligation: to ensure that the patient does not have five students at a time rushing into the room to examine him; to respect the patient's need for privacy; and to ensure, for example, if a student needs to learn how to perform a rectal examination that the patient is not a shy young woman, that we respect the patient's wishes not to be examined. All of this is a question of common sense.

I strongly agree with what Inés Barrio, the nurse, has said, because I have always been concerned by the position of nursing staff who may find themselves caught in the middle, obliged to do things which they do not want to do, or which they do not fully understand. I believe that medicine should involve team work, involving multidisciplinary and transdisciplinary teams, and this means that information has to be agreed upon in clinical sessions, with nurses contributing to the decisions of doctors. So the doctor carries out the information process, but the nurse has already taken part in the decision and shares in it: whether or not to operate, whether to perform a colostomy, etc. So doctors should give a greater role to nurses, enabling them to participate in decision-making and in the dissemination of information. However, as Javier Sánchez Caro has pointed out, final responsibility for clinical information lies with the doctor, and in this respect the patient must be able to go to the doctor for information; we can't allow doctors to wash their hands of it, and get nurses to provide all the information.

**Màrius Morlans.** I hope that a legal expert will find time to respond to Josep Lluís Lafarga's question. For me, this is the six million dollar question.

**Javier Sánchez Caro.** With regard to the question, it strikes me that there are two separate issues. Firstly, the need for consent, and secondly the way in which we demonstrate that it has been granted. To start with, there may be express consent or it may be tacit or implicit. In general in the world of medi-

cine, express consent does not exist. Express oral or written consent is actually the exception. For example, express oral consent would be if a patient comes to see the doctor, and when the doctor asks, "What seems to be the problem?" the patient responds, "Hang on a moment, doctor. Firstly, I authorize you to carry out on my body any tests or examination required to reach a diagnosis leading to appropriate treatment with the aim of curing or at least alleviating my condition." That would be express oral consent, but of course it doesn't happen, so we need to forget about it in principle. We also need to recognize that express written consent is exceptional and has, in fact, proved problematic; indeed, I would agree with those who have argued that another solution would have been better, although I am afraid that it may be a bit late for that now.

It is exceptional, then for consent to be granted in writing, because this is only necessary where there is a significant, known risk, so it doesn't apply to giving a blood sample. For simple procedures like that, we don't need a form, and the Catalan legislation, I would say correctly, expressly recognizes this possibility. So the general rule is not express oral or written consent, but tacit or implicit consent. And here there is an unequivocal expression of the patient's wishes.

The problem is that everything which happens thereafter, if there is a dispute, must be backed by evidence, and this is where the second part comes in. This puts us in the realm of the law. Incidentally, I would say that I agree in part with Manuel de los Reyes, but I also disagree, because if it was really so easy there would not be so many legal rulings on disputes. So, this brings us to the question of evidence, and how we prove what has happened. You say, correctly, that we can prove it by recording it in the medical records, but the evidence must be such as to convince the judge that what is written there is correct, that it was recorded at the time, and has not been altered. So it is not just a question of saying that simply because something has been written down it has actually happened, because written evidence can also be altered, and this may lead the judge to believe that it has not actually happened. Sometimes judges have decided it has, and sometimes they have decided that it hasn't. I have focused more on cases where judges have decided not, than

on those where they have decided it has. So, in principle this depends on each case and each situation. What, then, is the best way to prove it? Well, if in addition to carrying out the process of dialogue a signature is obtained, then it can't be denied, while by contrast if there is no signature then we have to provide supporting evidence and seek to convince the judge. And this is where problems arise: the problem is not the absence of consent but rather whether it can be clearly demonstrated. By contrast, a signed consent form provides such evidence unless the patient refutes its validity.

Regardless of whether the consent process has been performed well, it is a problem of evidence, and we therefore have to say what is the best evidence. Furthermore, there are necessarily cases where it must be done in writing, for example when the treatment is not clearly therapeutic: for example, an organ donation or assisted reproduction. So there is a large number of situations where everyone agrees that the scale of the interests at stake requires that consent be granted in writing. I also believe that we have now reached a point where this is irreversible, because the medical world has produced so many statistics in court, including ones which really make no sense. And if we carry on down this path then we will end up in a situation which is simply inappropriate to a public health system, which is that I will end up asking what is the risk when I undergo operation with this anaesthesia, performed by this surgeon, at this centre, at 1 o'clock in the afternoon, with the presence of a house officer. And that leaves us with the situation they have in the United States. But this is a public health system, where the standards should be set by the state, not established by a set of contractual relationships, because here doctors can't get rich simply by practising in the public health system, while in the United States they can. We have distorted their system and brought it over here. But I think it's too late to change, that's my opinion.

**Javier Hernández.** That is a massive issue which could be the subject of another seminar. The problem is what is being consented to, and how this consent is given. With regard to what is being consented to, what is clear is that by granting consent, in whatever form, the patient is not consenting indiscriminately to any medical act or treatment or any type of experiment.

The purpose of granting consent is to recognize that the medical act is not arbitrary. To achieve this purpose, how much information does the consent process need to entail? I believe that this is where things become complicated. It is clear that, in order to obtain the competent consent required to prevent the arbitrariness of the medical act, the information provided must clearly identify those conditions which might influence acceptance or rejection of treatment, such as major risks or common post-operative risks, etc. This issue can be illustrated by the theory of the general conditions of contracts. The massification of contractual activity gave rise to a phenomenon which, although you may be unaware of it, means that the contracts you sign are mass contracts or adhesion contracts. An individual contract is not generated for every legal act. When you take out a mortgage, you sign an adhesion contract, and when you buy something in a department store, you may sign a mass contract. These contracts include clauses which generally protect the offerer, the large companies selling goods or services. Offerers sought to use contracts to create immunity, areas of contractual inequality, and this imbalance sparked a defensive reaction from consumers which led to the following situation: Any contractual clauses included in the general conditions which modify the essential conditions of the contract have no validity; they are treated as if they did not exist. So all that is required is to recognize the consent specifically granted to those principal conditions of the contract which are sufficiently highlighted and of which the contracting party is aware. I believe this is the key to informed consent. What we cannot claim is that, by means of informed consent documents, the patient consents to undergo an operation, accepting the calculation of remote risks, and agreeing to the possible participation of other medical staff if required, the application of new techniques where this is considered advisable, etc. It is clear that this type of information contained in contractual documents is of no value when it comes to consent. The fact of its inclusion does not mean that the patient is granting consent; the alternative would be to make a fiction of information documents. The patient can only consent to those principal conditions which he understands. The rest – the description of the context of disclosure or the description of the reasons for the therapeutic method - do not constitute content to which the patient consents, and nor by their mere inclusion in the

consent document is the doctor in any way exempt from liability. This is the main idea, and with regard to the notion of evidence I would again insist that while a signature on a document would tend to favour its acceptance as evidence, in the Spanish system there is no such thing as full evidence or privileged evidence or authentic evidence. Rather, everything is subjected to a reasonable process of accreditation in which various sources of evidence may be called upon.

**Marc Antoni Broggi.** Time is pressing and we must wind things up. I am aware that we have left many questions not just unanswered but indeed unasked. While it is true that the discussion was not entirely systematic, it was very lively and provided the opportunity for the expression of a wide range of opinions. I will not attempt here to summarize everything – something which would, in any event, be impossible – but I will try to highlight a few of the key ideas which bioethicists in general, and the Víctor Grífols i Lucas Foundation in particular, would like to focus on from the day's discussion.

Firstly, that the practice of informed consent should be designed to ensure that the patient has the opportunity to understand the options available to him, and to make a decision on the basis of an understanding of the causes and the potential consequences. As a result, it should be based on a spoken dialogue which permits mutual comprehension; and a written document is only one of the steps in this process, unavoidable in some situations, but one which can never substitute either the process of dialogue or oral information. Any such substitution seriously undermines the patient's need for help.

The second important point, which derives from the first one, is that applying a general informed consent document, however well written it may be, does not satisfy the main purpose of consent. Deciding in each case how information is to be given, the pace at which it is given, the quantity of information, and the limits on it, must be the result of an analysis of the needs of the individual patient. The law must therefore leave a margin for the personalization which, from an ethical perspective, we demand. It is important to criticize the defensive practice of informed consent as unfair to patients and a real threat to the clinical relationship. The final contribution by the magistrate Javier Hernández was enlightening in this regard.

We will have to continue this discussion on another occasion if we wish to remain alert to changes in the clinical relationship and how decisions are made within it.

I would like to thank both Carlos Romeo and Pablo Simón for their excellent presentations and their diligence in preparing these in advance; and to everyone here for attending and for contributing to such a lively debate. I would also link to thank the staff of the Víctor Grífols i Lucas Foundation, Rosa Avellà and Gemma Acedo, for their efficiency, and the president of the Foundation, Victoria Camps, for making today's event possible.

Thank you to everyone, and I look forward to our next meeting.

# **Speakers**

- Pablo Simón Lorda. Ph.D. in Medicine, and Master's Degree in Bioethics from the Complutense University of Madrid
- Carlos Romeo Casabona. Professor of Criminal Law at the University of Deusto and Director of the Chair of Law and the Human Genome

# Chairperson

 Marc Antoni Broggi. Member of the Board of Trustees of the Víctor Grífols i Lucas Foundation and President of the Catalan Society of Bioethics

# **Seminar participants**

- Javier Barja. Surgery Service at the Hospital of Mataró, Barcelona
- Inés Barrio Cantalejo. Nurse and Master's Degree in Bioethics, Madrid
- Ramon Bayés. Professor of Basic Psychology at the Autonomous University of Barcelona and Member of the Board of Trustees of the Foundation
- Juan Pablo Beca. Paediatrician and Lecturer in Bioethics at the University of Santiago de Chile
- Margarita Boladeras. Professor of Moral Philosophy at the University of Barcelona
- Edorta Cobreros Mendazona. Professor of Administrative Law at the University of the Basque Country
- Victoria Camps. President of the Víctor Grífols i Lucas Foundation and Professor of Moral Philosophy at the Autonomous University of Barcelona

- Xavier Carné. Clinical Research Ethics Committee at the Hospital Clínic, Barcelona
- María Casado. Director of the Bioethics and Law Observatory at the University of Barcelona
- Manuel de los Reyes. Cardiologist and Director of the Fundamental and Clinical Bioethics Association of Madrid
- Javier Hernández. Magistrate and Lecturer at the School of Administrative Law, Barcelona
- Pablo Hernando. Head of User Services Department, Parc Taulí Corporation, Sabadell, Barcelona
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