ADDRESSING THE PROBLEM OF PATIENT COMPETENCY

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INTRODUCTION

The Víctor Grífols i Lucas Foundation aims to promote the analysis and discussion of issues relating to the ethics of healthcare: in this case, the fundamental question of patient competency.

We have chosen to discuss the issue of patients' decision-making competency because we believe it is one which is bound to acquire greater prominence in the near future. In turn it requires of us a more critical attitude to the question of competency in general, so that we can acquire new skills and develop new tools to deal with it. Only in this way can we properly address a problem which we believe goes largely unnoticed in our everyday practice. How often, for example, when faced with the refusal of an elderly patient to undergo surgery, have we questioned the patient's understanding of the situation or his decision-making process? How are we to distinguish between an unusual decision by an uncommunicative patient and an incompetent decision?

We must bear in mind our clinical responsibilities if we deem a patient who is defending a choice which is unreasonable and inconsistent with his own world to be competent. On the other hand, we must also be aware of the disregard for the individual's autonomy which results from labelling a patient as incompetent simply because we have failed to understand his decision.

To what degree and in what circumstances does questioning a patient's competency, investigating it and obliging him to complete a test represent an imposition which is of questionable value? How can we learn to distinguish those situations in which it would be unreasonable to perform such a test from those in which it would be essential? What is the right way to act? What criteria, what knowledge, what tools should we use?

The Grífols Foundation organized this discussion day to consider the question of the *de facto* competency or capacity to take decisions, and we were fortunate to have two excellent speakers. James Drane has been one of the pioneers of bioethics in the United States, and therefore in the world, since the 1970s. Trained as a psychiatrist at the Menninger School, a student of philosophy with Aranguren and of bioethics at the Kennedy institute, he has been Professor of Clinical Bioethics at the University of Pennsylvania for many years and has explored almost every area of the bioethical landscape. He has published books on a wide range of subjects, including *Becoming a Good Doctor*, guidance for dealing with common clinical situations in *Medical Ethics*, how to deal with terminal illness and death in *Caring to the End*, and the award-winning *More Human Medicine*. One of his most widely read contributions is the article "*The Many Faces of Competency*", in which he puts forward the notion of a sliding competency scale explained in his lecture.

We also benefited from the contribution of Pablo Simón, one of the pioneers of clinical bioethics in Spain. He has worked in general medical practice, and has completed a Master's degree in Bioethics under Diego Gracia. In addition to his clinical experience, he has occupied management positions and teaches bioethics at the Andalucian School of Public Health. He contributes to Master's degrees and other courses throughout Spain and Latin America, and is well known for his methodical and thorough approach to informed consent in articles and in his book, published by Triacastela. His recent publications include "¿Quién decidirá por mí?" [Who will decide for me?] on the subject of living wills or "advance instructions", and he has written several articles on the issue of competency.

Marc Antoni Broggi
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MEDICAL ETHICS, PROFESSIONALISM AND PATIENT COMPETENCY

James Drane

Introduction

The sophisticated instruments of contemporary medicine make possible accurate diagnoses and effective therapies. Sick people from cultures all over the world seek access to contemporary scientific medicine –your medicine. They want your diagnostic accuracy and your therapeutic effectiveness. Associated with the sharp accurate practices of contemporary medicine are ethical questions which do not lend themselves to sharp accurate answers.

Medical ethicists talk about principles of beneficence, autonomy, and justice. They talk about rights, responsibilities, duties and interests. But ethics talk rarely answers concrete questions in a definitive way, or provides concrete solutions to particular problems. Discussion about medical ethics goes on and on. It seems never ending. The fact that the ethical questions do not lend themselves to final answers leaves room for generation after generation of academic medical ethicists, and an continuing stream of conferences like the one in which we find ourselves.

This is not a criticism or a complaint. We cannot expect more accuracy or precision than a subject matter permits, and ethics in medicine just does not permit the same precision as medical science. Personally my interests have always been in trying to find at least somewhat more concrete practical answers to the ethical questions generated by contemporary medicine. My little presentation about competency evaluation is one example of an attempt to find a more concrete practical answer to the question of how to treat certain type patients.

I have another concern. I have never admitted this concern publicly but it has driven much of the work I have done. My concern is that the medical profession and medical professionals are loosing the prestige and respect which historically they enjoyed. Today's that prestige and respect is under attack from malpractice lawyers, government officials, legislatures, insurance companies, third party payers, business men, and journalists. Consequently even the relationship between doctor and patient which once reflected respect for the physician has become infected with suspicion and distrust. When the physician's authority is under attack, his or her respect is diminished. The authority of the physician means the physician's right to do what is medically best for the patient.

Although not explicitly admitted, my competency model is meant to defend the physician's authority, when he or she is forced to grapple with ambiguities inherent in treating particularly difficult patients. My competency model is an example of reaching for some little bit more accuracy and precision in handling difficult patients in order to keep such situations from being transferred outside the doctor-patient relationship to other non medical persons who claim to be better prepared to handle certain patients.

The Terri Schiavo Case

Terri Schiavo a woman in Florida was at the center of an extensive debate (both within the U.S. and outside) about several issues: 1.) who has the right to decide life and death when the patient is incompetent; 2.) is it right to withdraw artificial nutrition and hydration technologies from patients in a persistive vegetative state or an irreversible coma. 3.) If not, how long should the technology continue to be used for patients in this state?: one year, 5 years, 20 years, 50 years? 4.) And, who would pay the billions of dollars, which this would cost? 5.) If, on the other hand, removal of the technology is ethical, under what conditions would it be done and by whom?

Without a doubt Mrs. Schiavo was incompetent. She had been in a coma-like state for almost 15 years. In 1990 she suffered a cardiac arrest. She was found unconscious by her husband. He called 911 and at the hospital no cardiac activity showed on the electrocardiogram. Her heart was re-started but she had already suffered severe hypoxic brain damage. She was attached to ANH technology because she could not swallow. Over the years the artificial nutrition and hydration technology kept her alive. Her condition was diagnosed as persistent vegetative state. She was alive, she had sleep and awake cycles, but she had no cognitive or volitional capacities, no communication or relational capability. She did not experience the environment and did not respond to stimuli.

Terri Schiavo's medical diagnosis was confirmed by Dr. Ron Cranford, a recognized expert on PVS, and by several respected neurologists sent by The

American Neurological Association. But her parents disagreed with their medical assessment. They believed that she recognized them, and responded to them. From four hours of videotape they extracted a few seconds of images in which she seemed to be responding to stimuli. The parents also believed that they were the surrogate decision-makers. They contacted their own doctors who supported their claims.

When Mrs. Schiavo's husband, who for several years had been in a new relationship, ordered the removal of the ANH technology, the parents challenged his decision to withdraw the technology. Mr. Schiavo claimed that he was carrying out Terri's stated wish not to kept alive under the condition. The case was taken to court which recognized him as surrogate and his decision to withdraw the technology was supported by a court order. The parents in response appealed to Jeb Bush, the Governor of the state of Florida. After a wild legislative session, an emergency edict was issued by the legislature ordering reinsertion of the ANH technology. The case was returned to court and finally ended in the Supreme Court where the husband and the husband's decision prevailed.

Because of the ongoing media attention to this case, persons all over the U.S. had a chance to engage in bioethical reflection. Terri Schiavo is now as well known as Karen Ann Quinlan and Nancy Cruzan. Every American had a chance to debate competency evaluation, surrogate decision making, and the ethics of death and dying. What is not quite so clear is whether the debate was conducted with objectivity and truthfulness.

Looking at this case, is there any doubt that medical practice today, especially at the end of life, has become much more complicated. Doctors, nurses and other professionals in the clinical setting have to be aware of this complexity and understand how to respond ethically.

One issue raised by this case was that of Living Wills. Terri was a young woman when the accident happened and had no formal advance directive. If she had had one, there could still have been a debate about the meaning of phrases in the directive like, "no extraordinary measures", or "if there is no hope of recovery." The document would likely have specified the interventions that she would not want if death were "imminent." But when is death "imminent"? And couldn't persons change their mind, once they arrive at a previously hardly imaginable condition?

The Terri Schiavo case helps us to see a concrete instance of how medical practice has become much more complicated. Complexity and conflict today are especially intense when dying follows a decision to withhold or withdraw a treatment. Then complexities and the conflicts and the disagreements are everywhere.

Patients, for example, can disagree with themselves, saying one thing in a living will and then later on (when faced with death) changing their opinion. Family members certainly can disagree when the dying patient is incompetent and they are left with the decision-making responsibilities. The disagreements among family members are frequent and serious: for example, the difference between Terri Schiavo's parents and her husband.

Disagreements include physicians. Dr. Ron Cranford, a specialist in persistent vegetative state, diagnosed Terri Schiavo with PVS but a physician contracted by Terri Schiavo's parents disagreed. Physicians can also enter into disagreements with the family, especially when there is a fear of being prosecuted for following a particular family decision. Consequently, many cases of dying patients are moved to court. There is disagreement even among hospitals where patients are treated. Some hospitals stand for high-tech, continuing aggressive treatment, while others focus on more humane non-technical care of the dying.

Reflected in the Schiavo case there is deep religious disagreement. Disagreement exists between orthodox Jews and Reformed Judaism. Widespread disagreement exists among Protestants. There is even a difference between Vatican based Theologians Academic and Catholic moral theologians. During the long public debate, even The Pope stepped in declaring that artificial nutrition and hydration is not a treatment but rather a form of care, which can never be withheld or withdrawn. In so doing he contradicted a centuries-old Catholic moral teaching that patients may withhold or withdraw any medical intervention which is futile or burdensome.

The Terri Schiavo case shows that clinical conflicts and disagreements have now entered the political setting. Disagreements and conflicts developed between legislative and executive and judiciary branches of government. Republican legislative/executive interests preferred the continuation of life even during the dying process. The judiciary however gave preference to patient or surrogate autonomy and privacy.

All the differences and disagreements were reflected in the language used to describe the case. For those against withdrawing nutrition and hydration technology, withdrawal was talked about as *starving*, *killing*, *execution*. For those in favor of withdrawal, it was talked about as *respect for privacy*, *respect for autonomy*, *humane dying*.

There was disagreement even among ethicists. Vitalists focused on sanctity of life as the one dominant ethical principle. For others, respect for patient autonomy and privacy, as well as life in a more personal sense, were all relevant values. There was also disagreement between those who prefer withdrawing and withholding futile treatment in order to provide for a humane death, and those preferring physician-assisted suicide and euthanasia.

Finally there was great cultural disagreement and diversity: between those persons and organizations inclined to punish or reward politicians, and persons willing just to discuss and dialogue about the issues; those who rely on how a person looks for their moral judgments, and those who trust medical data even in the face seemingly contradictory visual images.

All the divisions and disagreements that we just listed are reflected in the legal world. There are traditional laws which are based on traditional wisdom that permit the withholding or withdrawing of medical technologies. Texas, California, and Virginia have laws that permit doctors and health-care ethics committees even to overturn patient or surrogate decisions to continue interventions which are futile. On the other hand, there are new laws being proposed by the Christian right which would turn the legal perspective around on issues of death and dying. In Alabama, for example, there is a proposal to prohibit all withdrawing and withholding of artificial nutrition and hydration. In Kansas, a law has been proposed requiring that all decisions to withdraw artificial nutrition and hydration which are made by surrogates, be taken to court.

That law has already passed the House in Kansas. In Missouri, there is a proposal to prohibit all withdrawal of nutrition and hydration, technologies. In Michigan, there is a proposal to bar spouses who have an affair from making a decision about artificial nutrition and hydration for his/her partner.

The point of citing the Schiavo case is to help medical professionals to become aware of the new complexities and the need for new caution. The context of medical practice has changed over the years and in order to be a responsible medical professional today, one must be aware of the changes. There is a need to look carefully at the present complexities. There is a need to appreciate the importance of medical history. Doctors today must realize that the only way to respond in a safe way to complex cases is to start with a careful consideration both of the medical facts and then to focus on the goals or objectives of medical practice.

More and more medical cases today, like the Schiavo case, are moved from a private doctor-patient relationship to a public legal context. More and more frequently medical issues are decided by the courts and are widely reported in the press. The newspaper accounts often reflect a certain hostility toward physicians. Physicians are often portrayed as self serving. Medicine is portrayed as just another business serving not the good of others but the selfish interests of doctors. This is a sad development. Inevitably there has to be an economic dimension to medical practice. Doctors like all other human being have to receive payments for what they do. Serious damage however occurs when money becomes the be all and end all of medical practice.

Besides being targeted in newspaper stories, physicians have also been targeted by outside economic interests. Advocates for these outside economic interests were successful in having U.S. courts strike down a long-standing proscription against physician advertising. Professionals by definition serve basic needs in society and therefore did not advertise like businesses. Outside economic interests however wanted to use competition among doctors as a way of lowering medical costs. They also wanted to break down the social deference given to doctors as medical professionals. In order to do so they set out to undermine the medical professional's claim to high ethical virtues. In the court case to permit advertising by doctors, lawyers argued that physicians are just another commercial group promoting their own selfish interests. Their arguments reflected a hostility toward the medical profession and they were successful.

Given the present cultural climate it is important to emphasize the fact that medicine is not a business. And medical practice is not just a job. In order to resist the cultural forces trying to undermine medicine as a profession, physicians first must be aware of circumstances in which they live and practice. Medical education and professional medical associations have to take steps to control selfish conduct. Physicians who use medicine for their own selfish interests are as much a treat to the medical profession, as priests who take advantage of their social status to satisfy sexual cravings are a threat to the priestly profession. They violate the basic obligation to work to realize one or more of the goals of medicine.

Today it is more and more important for all physicians to keep in mind the components of a true professional, especially the ethical components.

In medieval times, the Knights Hospitallis were nobles who cared for patients and were treated with great respect. But then they came under attack. Their power and authority to care for patients were threatened. What happened? They lost their ethical nobility; the charity and self sacrifice which characterized their medical care. They lost their high medical ethics. They lost everything. This piece of medical history is important. From it we can learn that when the power and authority of medical persons come under threat, there are serious consequences.

Medicine survived as a profession in Classical Greece, in Ancient Rome and in the first European cultures; it survived in pre-feudal, agricultural and industrial societies; and it can survive in today's economic climate, but not without a struggle.

Physicians as Professionals

Defensable ethical practice begins with an awareness of what it means to be a professional. The word professional comes from a deponent Latin verb: *profiteo*r, *profiteri*, *professus sum*, which means to make a public promise, to declare publicly a commitment to serve others. Professionals promise to provide help which is considered crucial for human beings and for humane societies. The three classical professions are priesthood, law, and medicine. All three are in danger today and therefore it is appropriate to review the characteristics which make someone a professional.

1.) Professionals promise to provide essential public services for the good of others. 2.) Aspiring to do professional service is considered a vocation, a calling rather than a job. A calling requires an inner commitment of the whole person. 3.) A prolonged, specialized university training is a pre-requisite for entering a profession. The university-based education includes both theoretical knowledge and practical skills. 4.) Control over entering a profession is through licensing. One must have a license to practice a profession. 5.) License Boards and Admission Boards are made up of members of the profession. 6.) Laws having to do with a profession are influenced by the profession itself. 7.) Those who pay for professional services do not control or have authority over the services provided. 8.) Professionals enjoy autonomy in the provision of services. 9.) Professions compose their own ethical codes and standards of practice. 10.) Professionals operate according to high ethical standards and with high inner moral requirements. To be a true medical professional is to be committed to a high ethics.

Autonomy, university level of education, setting the profession's own ethical standards, are all characteristics which deserve special attention. They are definitive of a profession and all are threatened. Society grants professional privileges to physicians in exchange for his or her publicly declared ethical commitments, his or her altruism, and rejection of self-serving behaviors. Society grants autonomy, respect, independence and decent financial compensation to medical professionals in exchange for their doing what is best for others rather than for themselves: i.e. for being persons of high ethical ideas. Ethics and medicine are essentially linked. They have always been. Ethical components are at the core of what it means to be a medical professional and a good doctor.

Being a good clinician is comparable to being a good parent. Parenting and ethics are linked for the same reasons that medical practice and ethics are linked. Without ethical parents who care for a child, the child will be severely damaged for life. Without ethical clinicians who care for patients, the same severe damage will result.

The freedom and respect which traditionally society granted to medical professionals today is threatened. There are increasing pressures from commercial interests to control what medical professionals do. More and more frequently, physicians are treated more like employees than like independent professionals. Doctors today working in hospitals or in state-run clinics or in clinics attached to industries can be treated as morally neutered technicians rather than independent professionals. Doctors in these settings are defined by their technical skills rather than by the high ethical ideals of a profession. And they are either given orders about how to practice or their practice is controlled to the smallest details by rules and laws.

Instead of being responsible for one's moral conduct, rules of conduct are more and more frequently imposed on the physician from outside. In fact it is often assumed to be the case that if doctors are to behave ethically, the ethical standards have to be imposed from outside. Increasingly one hears calls for laws which impose controls on what doctors can do. The self-imposed and self-generated ethics which gives medicine its professional status is ignored. To say that a professional ethic is self imposed rather than imposed from outside, does not at all imply an egocentric or selfish morality. The self imposed ethic of a medical professional is altruistic and unselfish. It is rooted in the structure of the relationship between a person who is ill and the person educated to heal: the doctor-patient relationship. Its core ethical value is commitment to help others and not to do harm.

The freedom, respect, ethical independence, and monetary benefits historically enjoyed by the medical professional were never total. Society granted generous benefits to professionals in response to the way professionals carried out their promised public service. The autonomy, the social respect, the financial rewards, are all dependent upon the practice of an ethics centered on meeting the needs of others. Without this ethics, the whole structure of professionalism collapses.

When physicians come together in meetings, it is to be expected that they share scientific information, medical data, new medical treatment possibilities, etc. All this is required to maintain a professional licence. It is, however, equally important to spend some time on the essential ethical dimensions of the profession. Without maintaining high ethical standards physicians are not true professionals.

Traditional Ethical Standards

The high ethical standards associated with medical practice are captured in the earliest historical statement of medical ethics, The Hippocratic Code. "• I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice. • I will neither give a deadly drug to anybody if asked for it, nor will I make a suggestion to this effect. • In purity and holiness I will guard my life and my art. • Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slaves. • What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself holding such things shameful to be spoken about. • If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot."

This historical ethical code has less and less influence on day-to-day practice of contemporary physicians. It gets little attention in medical education. It plays little more than a ritual role; e.g., recitation at medical school graduation ceremonies. Some medical school educators never refer either to the code or to the goals of medicine and consequently neither plays the role which it should in ethical medical practice.

Where then, does a contemporary professional ethics come from? How does the physician today figure out right from wrong in clinical situations? Where are the ethical rules, policies, and directives for everyday practice? How can they be effectively applied when today's society is no longer united by commonly held ethical values?

There is no disagreement about the basic ethical principle of medical practice, beneficence; act in the physical, psychological, social best interest of the patient. But there can be questions and disagreements about what is in the patient's best interest. In case of disagreement, what is the relationship between the authority of the physician and the patient's autonomy? Are there some concepts that could be used to help the physician form his or her judgment about the patient's best interest and then to defend that judgment in case of conflict and disagreement?

The concepts presented here for consideration are intended to help the doctor to do ethics in a clinical sitting. They are intended to provide a way to bring the most important ethical considerations into view and then to apply them. The concepts attempt to bring some order to the different elements that require consideration when the clinician has to do the right thing and cannot spend hours or weeks in reflection. They are: 1.) Objectives of Medicine, 2.) Informed Consent, 3.) Quality of Life, 4.) External Factors. The easiest cases or easiest ethical decisions are those in which one or another of these components is decisive and weighs the decision heavily in one direction. We will look at just the first two.

The Goals and Objectives of Medicine

Ethical decision making for patients begins with a careful determination of indications for or against a particular medical intervention. Ethical decision-making in effect begins where medicine itself begins: i.e., diagnosis based on objective data and an assessment of the risks and benefits of different treatment possibilities. Ethical concerns emerge when following diagnosis, questions remain about the risk/benefit assessment or about the benefit of an intervention in the long run. In order to be ethically acceptable, a medical intervention has to accomplish one of the goals of medicine: 1.) To Restore Health, 2.) To Relieve Symptoms, 3.) To Improve Impaired Function, 4.) To Preserve Life.

The last goal, the preservation of life, is not an independent objective because it is valid only when at least one of the first three goals is realizable. As we see from the Schiavo case, many contemporary ethical problems are created by technologies which are capable only of preserving life when none of the other goals of medicine are achievable.

Terri's life could have been prolonged for many decades but who could pay for such maintenance and who would benefit? Decades later, she would still be on the ANH technologies, her cerebral neurons would not be restored and therefore she could neither think nor choose. She would experience neither pleasure nor pain nor human relations. Only her brain stem would function so she could only breathe and sleep. Does the ANH technology which prolongs her vegetative life have to be kept in place until she dies attached to the technology? Can the withdrawal of a life preserving technology be recommended by a physician when it prolongs life, but accomplishes none of the other goals of medicine? If none of the first three goals of medicine are realizable, then withdrawal is justified. Not withdrawing the technology would amount to prolonging the dying process.

If a patient is dying, the moral requirement is never to prolong the dying process. The relevant consideration in such a case would be the distinction between prolonging life and prolonging death. If a pathology is progressive and irreversible, and the patient is both dysfunctional and debilitated, continuation of interventions would be prolongation of the dying process. Prolongation of dying is neither medically nor ethically defensible.

As we know from Schiavo and other highly publicized cases, dying can be prolonged for years amid mountains of complexities. There can be disagreement about a diagnosis, about the patient's quality of life, and even about the meaning of a reasonable effort in medicine (in the sense of an effort supported by science and clinical experience). Admittedly, something completely unexpected may happen (e.g., a miracle) but that possibility alone is not an acceptable justification for continuing interventions by a professional physician practicing scientific medicine. In fact, even an intervention which accomplishes one of the first three objectives of medicine may be withdrawn or withheld if it is judged by the patient to be *extraordinary*; i.e. too costly, too painful, too burdensome, in some sense unhelpful.

The decision to withdraw a technology which will result in the patient's death, must be made with care. It can, however, be supported either by an inability to accomplish goals of medicine or by the historical ethical distinction between *ordinary* and *extraordinary* treatment. Ordinary and extraordinary refer not to the medical treatment but to the way in which a treatment is experienced by the patient. Today, ordinary is talked about as *proportionate* and *extraordinary* as *disproportionate.* Any treatment that is futile or experienced by the patient as too costly, too painful, too risky, etc., qualifies as *extraordinary* or *disproportionate* and may be withheld or withdrawn. Death which follows is different from either active euthanasia or assisted suicide.

Informed consent

The doctrine of informed consent creates many dilemmas because it tries to balance very different values: on one side, beneficence (health or well-being); on the other, autonomy (or self-determination). Most of the ethical commentary on informed consent and a majority of the court cases deciding consent questions have focused on the physician's responsibilities to disclose information and to keep the medical setting free of coercion. (Cf Chapter 6 court cases: Natanson and Canterbury*)*. But more and more frequently, clinical questions referred to an HEC are not about either disclosure or undue influence on patients. Rather, HECs are consulted because of questions about the competence of a patient to give an informed consent.

Despite the work done to date, the competency question remains unsettled. What should the standard for competence be in order to ensure valid consent or refusal of consent to medical procedures? How can an HEC help clarify questions and doubts about patient capacity to consent or refuse consent? To be acceptable, any standard of competence must meet several important objectives. It must incorporate the general guidelines set out in legal decisions; it must be psychiatrically and philosophically sound; it must guarantee the realization of ethical values on which the consent requirement is based; and it must be applicable a clinical setting.

Some lawyers would prefer to turn every question about patient competency into a question for legal council and court involvement. This self-serving claim would make the delivery of health care impossible by turning almost every treatment decision by very sick patients into a legal case. Health care has to be delivered efficiently by health care professionals who must provide adequate disclosure of information to patients, protect them from coercion, and evaluate their competency. If and when problems or doubts arise, an HEC should be ready to assist in determining competency, which remains a clinical rather than a legal judgment. It is part of what a health care professional does in the course of humane treatment; it is not something that requires legal intervention and certainly not court involvement. Competency tests must be available for use by health care professionals.

In practice some tests seem too lenient and expose patients to serious harm. Others seem too stringent and turn almost all seriously ill patients into incompetents, thereby depriving them of nights and dignity. The solution proposed here is based on no single standard, but works out a sliding scale for competency. Accordingly as the medical decision itself (the task) changes or the context in which the patient must decide becomes more dangerous, the standards of competency to perform the task and confront the threat also change.

Competency Assessment

As long as a patient does or says nothing strange and acquiesces to treatment recommended by the medical professional, questions of competency do not arise. Questions are raised usually when the patient refuses treatment or chooses a course of action which in the opinion of a health care professional threatens his or her well-being. Either consenting to treatment or refusing consent rnay raise a suspicion of unreasonableness or irrationality in the sense of losing contact with one’s lived reality. More careful evaluation is then called for before a final determination of competency is made. A patient’s rationality is not something separate from his or her competency. Competency refers to making a judgment that is appropriate, given the context, situation and condition of the patient. Competency is not like height or weight, something independent of human relationship. Rather it refers to the very rational ability to realize or take into account the medical reality one confronts. Health care professionals are the indicated persons for making this judgment, but they may need HEC help.

Competency assessment usually focuses on the patient's mental capacities, specifically the mental capacities to make a particular medical decision. Does this patient understand the reality which she confronts and what is being disclosed about that reality? Can this patient come to a decision about treatment based on that understanding? How much understanding and rational decision-making capacity is sufficient for this patient to be considered competent? Or how deficient must this patient's decision-making capacity be before he or she is declared incompetent? A properly performed competency assessment should eliminate two types of error: preventing competent persons from deciding their own treatments, and failing to protect incompetent persons from the harmful effects of a bad decision.

The assessment process leads to a decision about a decision. A good clinical-based competency determination must balance the different and sometimes competing values of rationality, beneficence, and autonomy. Rationality or reasonableness is an underlying assumption in competency determinations. In an emergency we presume that a rational person would want treatment, and the informed consent requirement is set aside. But rationality cannot be assumed in non-emergency settings. A particular medical setting establishes certain expectations about what a reasonable person would do, and these expectations play an important role in competency determinations.

The patient's medical well-being (beneficence) also has to be considered in assessing competence. The same laws that establish the right to give or refuse informed consent express concern about protecting patients from the harm that could result from serious defects in decision-making capacity. Finally, a competency assessment must respect the value of autonomy. Patients must be permitted to determine their own fate, and a decision cannot be set aside simply because it differs from what other persons think is indicated. It is perfectly reasonable to make decisions about medical treatment based on one's own life values and quality-of-Iife assessment.

A Sliding-Scale Model

How should the medical professional in charge (usually a physician) proceed when considering a patient's competence? The model proposed here posits three general categories of medical situations; in each category, as the consequences flowing from patient decisions become more serious, competency standards for valid consent or refusal of consent become more stringent. Psychiatric pathologies most likely to undermine the mental capacities required for each type of decision are listed in the tables below. As psychiatric pathologies become more severe, they are more likely to undermine competent clinical decision-making of any sort. But if the decision being made is so dangerous as likely to cause a patient's death, then less severe psychiatric disorders would be sufficiently debilitating to undermine the delicate and demanding mental maneuvers required to justify an apparently bizarre decision. Unusual people do make unusual clinical decisions, and they must be able to explain and defend these choices in order to be accepted as competent choices.

A number of assumptions underlie the use of a sliding scale or variable standard rather than one ideal competency test. First, the objective content of the decision must be considered so that competency determinations remain linked to the decision at hand. Second, the value of reasonableness operates at every level. When people sit down to play chess, certain expectations are created even though no particular decisions are required. If, however, one player makes peculiar moves, the other will have to wonder whether his partner is competent or knows what he is doing. Something similar is assumed in the patient-physician partnership. Third, the reasonableness assumption justifies some paternalistic behaviour. A surrogate is authorized by this model to decide what is best for the patient who is incompetent. In more cases than a patient-rights advocate would prefer, the patient's decision is set aside in favour of reasonableness and beneficence. The clinical values of patient well-being are balanced with the libertarian values of autonomy and the transcultural value of common sense.

Easy, Effective Treatments

Standard No. 1. The first and least stringent standard of competence to give a valid consent applies to medical decisions that are not dangerous and are objectively in the patient's best interest. Even though these patients are seriously ilI, and therefore impaired in cognitive and volitional functioning, their consent to an effective, safe treatment is acceptable so long as the patient is aware of what is going on. *Awareness*, in the sense of being in contact with one's situation, satisfies the cognitive requirement of informed consent. The patient in effect understands what is happening. *Assent* to rational expectations satisfies the volitional component. Consent in effect takes the form of knowingly going along or not resisting. When an adult goes along with what is considered appropriate and rational, then the presumption of competent decision-making holds. Higher standards for capacity to give a valid consent to this first type of medical intervention are superfluous. Why insist on some abstract ideological requirement when the patient's decisional behaviours show every sign of being in contact with reality, being informed, and being free?

Consider the following two examples. Betty Campbell, a 25-year-old secretary who lives alone, has an accident. She arrives at the hospital showing signs of mild shock and suffering from the associated mental deficiencies. Her consent to blood transfusion, bone-setting, or even to some minor surgery need not be questioned. Even though there is no emergency, if she is aware of her situation and assents to receiving an effective, low-risk treatment for a certain diagnosis, there is no reason to question her competence to consent. To insist on an abstract standard which would make her incompetent and require seeking a surrogate to make the sane decision is foolishness.

Phil Randall's situation is quite different. The 23-year-old veteran, who has been addicted to drugs and alcohol, is on probation and struggling to survive in college. When Phil stops talking and eating for almost a week, his roommate summons a trusted professor. By this time Phil is catatonic, but the professor manages to get him on his feet and accompanies him in a police car to the state hospital. The professor explains to Phil the advantages of signing in as a voluntary patient, and Phil signs his name to the admission form which authorizes commitment and initial treatment. His consent to this first phase of therapy is valid because Phill is sufficiently aware of his situation to understand what is happening, and he assents to the treatment. Later on, when his condition improves, another consent may be required, especially if a more dangerous treatment or a long-term hospitalization is required. The next decision will require a higher level of competence because it is a different type of task.

Having a lenient standard of competence for safe and effective treatments eliminates the ambiguity and confusion associated with phrases like "virtually cornpetent", "marginally competent," and "competent for practical purposes". Such phrases are used to excuse the common sense practice of holding certain decisions to be valid even though patients are considered incompetent by some abstract standard, which ignores what the patient has actually decided and the type of decision called for. The same modest standard of competence should apply to a dying patient who refuses to consent to treatments that are burdensome or futile. Such would be a paradigm case of the "refusal-of-ineffective-treatment" category.

Most of the patients who would be considered incompetent to make treatment decisions under this first category are legally incompetent. Patients who use psychotic defenses that block both awareness of their situation and any decision-making ability fall outside the wide first criterion. Even children who have reached the age of reason can be considered ethically competent to mate some health care decisions.

Authors such as Alexander M. Capron, Willard Gaylin and Ruth Macklin support lowering the age of competency to make some medical decisions. The President's Commission also endorses a lower-than-legal age of competence. Health care professionals, however, cannot ignore the law and must obtain the consent of the child's legal guardian. But if a minor is competent or partially competent, there is good reason to involve him or her in the decisionmaking process.

Less Certain Treatments

Standard No. 2. If the diagnosis is doubtful, or the condition chronic; if the diagnosis is certain but treatment is more dangerous or not quite so effective; if there are alternative treatments, or no treatment at all is an alternative, then a different type of task is involved in making an informed treatment decision. Consequently, a different standard of competence to perform this task is required. The patient must be able to understand the risks and outcomes of the different options and then be able to make a decision based on this understanding. In this setting competence means ability to understand the treatment options, balance risks and benefits, and come to a deliberate decision. In other words, a higher standard of competence is required than the one discussed previously because the reality which a patient faces is a more demanding one to cope with. Let me give some examples of this second type of situation and the corresponding competency standards.

Antonio Marachal is a retired steel worker who has been hospitalized with a bad heart valve. Both the surgeon and his family doctor recommend an operation to replace the valve. Mr. Marachal understands what they tell him but is afraid of undergoing the operation. He thinks he will live just as long by taking good care of himself. His fear of surgery may not be entirely rational, but the option he prefers is real, and there is no basis for considering his refusal to be incompetent. Antonio is afraid and somewhat pessimistic, and these subjective states influence his refusal of what is every day more common surgery. But these emotional weaknesses do not undermine his competency because they lead him to a determination that falls within the range of reasonableness. Medical statistics alone do not determine rationality. Antonio's decision reflects Antonio's quality-of-life preferences, not his incompetence.

Or consider Geraldine Brown, a 40-year-old unmarried woman who is diagnosed as having leukemia. Chemotherapy offers a good chance for remission, but the side effects are repugnant amid frightening to her. After hearing and understanding the diagnosis, alternatives, risks, and prognosis, she refuses chemotherapy, deciding instead to follow a program that centers on diet, exercise, medication, and sorne natural stimulation of her immune system. Objectively, the standard medical treatment is preferable to what she decides, but informed consent joins objective medical data with subjective personal factors such as repugnance and burden and quality-of-life preferences. A decision one way or the other is reasonable, and a person who can understand the options and decide in light of them is competent even if he or she decides against statistical cultural standards.

Although ability to understand is not the same as being capable of conceptual or verbal understanding, some commentators assume that the two are synonymous in every case. Many would require that patients remember the ideas and repeat what they have been told as a proof of competence. Real understanding, however, may be more a feeling matter. Following an explanation, the patient may grasp what is best with strong feelings and convictions and yet be hard pressed to articulate or conceptualize an understanding or conviction. To set up an abstract, present or absent, standard of competence which involves some objective standard of understanding is to force complex clinical realities into a procrustean bed that only rationalists feel comfortable in. And yet, researchers continue to test out one or another objective rational standard for informed consent capacity.

Competence as capacity for an understanding choice, besides being reconciled with many different types of decisional behaviours, can also be reconciled with a decision to let a trusted physician decide which is the best treatment. Such a choice (a waiver) may be made for good reasons and represent a decision in favor of one set of values (safety or anxiety reduction) over another (independence and personal initiative). As such, it can be considered an informed consent and create no suspicion about competence even though the patient in such a case refuses to jump through any of the rationalistic hoops set up by a single competency standard advocate.

Ignorance or inability to understand, however, does incapacitate a person for making this type of decision. This is especially so when the ignorance extends to the options and persists even after patient and careful explanation. Patience and care may sometimes require that more than one person be involved in the disclosure process before a person is judged incompetent to understand. An explanation by someone from the same ethnic, religious, or economic background may also be necessary.

Dangerous Treatments

Standard No. 3. The most stringent and demanding criterion for competence is reserved for those treatment decisions that are very dangerous and run counter to both professional and public rationality. Here the decision involves not a balancing of what are widely recognized as reasonable alternatives or a reasonable response to a doubtful diagnosis, but a choice that seems to violate reasonableness. The patient's decision now appears irrational, indeed life-threatening. And yet, according to this model, such decisions can be considered respectable as long as the person making them satisfies the most demanding standards of competence. The patient's decision in this new situation is a different type of task than the others we have considered. As such, different and more stringent criteria of capacity are appropriate.

Competence in this context requires an ability on the part of the decision-maker to appreciate the risky and indeed life-threatening reality he or she is confronting. Appreciation requires the highest degree of understanding, one that grasps more than just the medical details of the illness, options, risks, and treatment. To be competent to make apparently irrational and very dangerous choices, the patient must appreciate the implications of the medical information for his or her life. Competence here requires an understanding that is both technical and personal, intellectual and emotional.

Because such decisions contravene public and intercultural standards of rationality, they must subjectively be both reflective and self-critical. The competent patient must be able to give reasons for the decision which show that he/she has thought through the medical issues and related this information to his/her personal values. The patient's personal reasons need not be scientific or publicly accepted, but neither can they be purely private nor idiosyncratic. Their intelligibility may derive from a minority religious or philosophical view, but they must be coherent and follow the logic of that belief system. This toughest standard of competence demands a rationality that includes verbalization, consistency, and the like. Some examples will illustrate.

Bob Cassidy, an 18-year-old high school senior and a outstanding athlete, is involved in an automobile accident which has crushed his left foot. Attempts to save the limb are unsuccessful, and infection threatens the boy's life. Surgeons talk to his parents *who* immediately give permission for amputation of the leg below the knee. Since Bob is legally no longer a minor, however, his consent is required for the surgery, but he refuses. "If I cannot play sports, my life is meaningless", he says. First the doctors try to talk to him, then his parents, and finally some of his friends. But he refuses to discuss the matter. When anyone comes to his room he simply closes his eyes and lies motionless. "If they cannot make my foot as good as before, I want to die," he tells them. "What good is it to live with only one leg? Without sports I can't see anything worth living for". From a psychiatric perspective, Bob is using unhealthy coping behaviour to handle his situation. He refuses to consider the irnplications of what he is doing and shows signs of being seriously depressed. No arguments or justifications are offered to counter the indications of immaturity and mild emotional illness. For these reasons he is judged to be incompetent for the task he presumes to undertake.

Charles Kandel is a Jehovah's Witness who refuses a blood transfusion after a bad accident at his job. He is not yet in shock, but will shortly be in danger of death. His wife and family support his refusal and pledge to help care for his children. The doctor asks Charles if he fears judgment from God if blood were given against his will. He is adamant, explaining to the medical group that he has lived his life by these beliefs, knows the possible consequences, and holds eternal life to be more important than life here on earth. His decision is very different from Bob Cassidy's, even though in each case a young man will likely die for refusing an effective and medically common procedure. Mr. Kandell meets the high standards required for such a decision and should be respected as a competent refusal.

A patient need not have a serious psychiatric pathology in order to be considered incompetent to make such serious decisions. In fact, common depression and neurotic fixations are enough to undermine the cognitive and conative functioning required for this demanding task. On the other hand, not every mental or emotional disturbance would make the patient incompetent. A certain amount of anxiety, for example, accompanies any serious decision. A patient may suffer some pain, but this would not necessarily impair a decision to refuse treatment. Even a degree of reactive depression may not incapacitate a patient for this type of task. But any mental or emotional disorder that compromises appreciation and rational decision-making would make a person incompetent. Persons, for example, who are incapable of controlling their destructive behaviour cannot be considered competent to make medical decisions that have destructive features. Consequently, a patient who is hospitalized for a self-inflicted injury would not be considered competent to refuse a lifesaving treatment. And dangerous decisions that are inconsistent with lifelong personal values again would create a strong suspicion of being products of incompetence.

The paradigm case of consent to ineffective treatment occurs when one decides to engage in a high-risk drug trial unrelated to one's own illness.

<table>
<tr><th colspan="6">**A Sliding Scale Model for Competency**</th></tr>
<tr><td colspan="6">STANDARD No. 1 - Easy, Effective Treatments</td></tr>
<tr>
<td>A. *Incompetent*
unconscious
severe retardation
small children
total disorientation
severe senile dementia
autism
psychotic defenses:
denial of self and situation
delusional projection</td>
<td>Consent</td>
<td>effective treatment for acute illness
diagnostic certainty
high benefit/low risk
limited alternatives
severe disorder/major distress/immediately life-threatening</td>
<td>Refused</td>
<td>ineffective treatment</td>
<td>B. *Competent*
children (10 and above)
retarded (educable)
clouded sensorium
mild senile dementia
intoxicated
conditions listed under #2 and #3 (A & B)</td>
</tr>
<tr><td colspan="6">Competency Standards
Minimal Requirements:
1. *Awareness:* orientation to one's medical situation
2. *Assent:* explicit or implied</td></tr>
<tr><td colspan="6">STANDARD No. 2 - Less Certain Treatments</td></tr>
<tr>
<td>A. *Incompetent*
severe mood disorders
phobia about treatment
mutism
short term memory loss
thought disorders
ignorance
incoherence
delusion
hallucination
delirium
conditions listed under #1 (A & B)</td>
<td>Consent or refused</td>
<td colspan="2">chronic condition/doubtful diagnosis
uncertain outcome of therapy for acute illness
balanced risks and benefits:
possibly effective, but burdensome
high risk, only hope</td>
<td colspan="2">B. *Competent*
adolescent (16 and above)
mildly retarded
personality disorders
narcissistic, borderline and obsessive
conditions listed under #3 (A & B)</td>
</tr>
<tr><td colspan="6">Competency Standards
Median Requirements:
1. *Understanding:* of medical situation and proposed treatment
2. *Choice:* based on medical outcomes</td></tr>
<tr><td colspan="6">STANDARD No. 3 - Dangerous Treatments</td></tr>
<tr>
<td>A. *Incompetent*
indecisive or ambivalent over time
false beliefs about reality
hysteria
substance abuse
neurotic defenses:
intellectualization
repression
dissociation
acting out
mild depression
hypomania
conditions listed under #1 and #2 (A & B)</td>
<td>Consent</td>
<td>ineffective treatment</td>
<td>Refused</td>
<td>effective treatment for acute illness
diagnostic certainty
high benefit/low risk
limited alternatives
severe disorder/major distress/immediately life-threatening</td>
<td>B. *Competent*
above legal age
reflective and self-critical
mature coping devices
altruism
anticipation
sublimation</td>
</tr>
<tr><td colspan="6">Competency Standards
Maximum Requirements:
1. *Appreciation:* critical and reflective understanding of illness and treatment
2. *Rational decision:* based on relevant implications including articulated beliefs and values</td></tr>
</table>

Objections to the Sliding Scale

Certain objections to this sliding scale notion are easy to anticipate. Libertarian thinkers will see it as justifying paternalistic behaviour on the part of physicians and diminishing the patient's discretion to do whatever he or she prefers no matter what the consequence. True, by these standards some patient decisions would not be respected, but competency was originally required and continues to be needed in order to set aside certain dangerous and harmful decisions. This model provides guidelines to determining which patient decisions fall within the original purpose for a competency requirement. On the other hand, the sliding scale provides a justification even for decisions that are considered to be irrational. Instead of limiting freedom, it safeguards patient autonomy while balancing this value with well-being.

Admittedly, in standard no. 1 the outcome, which is beneficial to the patient, plays a role in establishing the rationality of the decision and the competency of the decision-maker. The President's Commission rejected a standard based on outcome because only the physician can determine outcome, and if outcome constitutes the only test of a competency, then competence is a matter of doing what the doctor thinks best. But outcome is not the standard of competence in this model. Rather it is an important factor in only one class of medical decisions. In other decisions patients may competently go against medical assessments of outcome. In fact, a decision that leads to an outcome that professionals and non-professionals alike would consider the most unacceptable -unnecessary death- can be considered a valid and competent option according to this model because it balances rationality, autonomy, and quality-of-life assessments of medical benefit.

Objections will also be raised against standard no. 3, the most stringent for judging competence. If patients must understand thoroughly and make a rational decision in order to be considered competent, then too many people will be considered incompetent. Consequently, the medical delivery system will be clogged with surrogate decision-making, and many patients will be robbed of dignity and self-determination. But the most stringent standard in this model requires just such capacities for competence, but only in cases where the patient has most to lose from his or her choice. If patients in category three suffer a decline in autonomy (and they do because some decisions will not be respected), this is balanced by a gain in beneficence and rationality.

Balancing Values

A balancing of values is the cornerstone of a good competency assessment. Rationality is given its place throughout this model. Not only does the sliding scale reflect a rational ordering of things, but reasonableness is an underlying assumption for each standard of competence. Maximum autonomy, however, is also guaranteed because patients can choose to do even what is not at all beneficial (participate in an experiment which has little chance of improving their condition) or refuse to do what is most beneficial. Finally, beneficence is respected because patients are protected against harmful choices, when these are more the product of pathology than of self-determination. HEC members can use the model to help families and physicians work out a carefully defensible strategy for handling difficult patients and difficult decisions.

Conclusion: competency judgments and professional status of Medicine

Competency determination of a patient is a metaphor for a doctor's own competency. To do competency determinations in subtle and complex situations, tests the academic sophistication and moral character of a physician. To evaluate competency, the doctor must have an intellectual grasp of complicated aspects of human decision-making. The physician must also have a critical grasp of his/her own biases, e.g. pro aggressive treatments to the end vs. pro palliative care and aid to accomplish humane dying. In order to carry out the competency evaluation, a doctor also needs a solid ethical character because he/she is grappling with life and death decisions for vulnerable persons who need empathy, care and protection.

To make competency evaluations the doctor must have both respect for patient autonomy and training in assessment of the psychiatric aspects of the patient. He/she must also be very aware of the goals of medicine. Besides all the above mentioned complexities, physicians are responsible for the public image of physicians as protectors of patients and pursuers of patient benefit. It is in delicate life and death situations with compromised and vulnerable patients that the high professional status of the physician is either witnessed or smeared.

If doctors cannot be trusted to evaluate patients and then to do what is most respectful and most beneficial for them, that will mark the end of medicine as a profession.

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ASSESSING THE DECISION-MAKING CAPACITY OF PATIENTS: AN UNRESOLVED ISSUE

Pablo Simón

Assessing the decision-making capacity of patients: an unresolved issue

It can be argued that assessing capacity is one of the key issues still to be resolved by the general theory of informed consent, and this despite the fact that in the USA it was identified as a cause of concern almost 30 years ago, at the start of the modern era of informed consent in clinical practice, inaugurated by the case of *Canterbury vs. Spence* in 1972.

Informed consent is nothing more nor less than a model of the clinical relationship which arises from introducing the notion of the psychological and moral autonomy of individuals into the classical model of the doctor–patient relationship, a model which had until then been based exclusively on the idea of beneficence.

This development – the inclusion of the principle of autonomy in the clinical relationship – has revitalised debate about how such autonomy should be understood within the context of sociopolitical relationships in modern societies. As Victoria Camps rightly argues, in general what has prevailed is an individualist, liberal or negative version of autonomy: the "right to be left alone", as opposed to notions of autonomy which stress a more collective, republican or positive understanding[1]. For this more collective version, exercising autonomy cannot entail simply disposing of the moral ties which bind us to those around us, to those with whom we are seeking to construct a shared project of society, to those with whom we identify as fellow *citizens*. And so, according to Camps, individual autonomy must be properly articulated with our shared public responsibility to construct more humane societies.

This is an opinion which I share. Indeed, I have always argued for a model of informed consent which does not simply limit itself to the defence of patient autonomy. The model of informed consent I have proposed is one which insists that the taking of decisions is the result of a deliberation process involving both patient (autonomy) and professional (beneficence) within a social framework which defines what is harmful (non-maleficence) and what is unjust (justice)[2]. The patient must therefore accept that his private wishes can-

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[1] Camps V. *La voluntad de vivir*. Barcelona: Ariel, 2005. pp. 107-130.

[2] Simón Lorda P, Júdez Gutiérrez J. Consentimiento informado *Med Clin (Barc)* 2001; 117:99-106.

not be limitless but are constrained by a social framework which is public and collective, even if it is not fixed and immutable.

In any event, whether in its negative or positive version, it is clear that at least three conditions must be met if patients are to exercise their autonomy as individuals:

- They must act voluntarily: that is, free from "external" coercion.
- They must have sufficient information about the decision to be taken: that is, regarding the purpose of the decision, the risks, the benefits and potential alternatives.
- They must have capacity: that is, they must have a series of psychological aptitudes – cognitive, voluntary and emotional – which enable them to understand, evaluate and process the information satisfactorily, to take a decision, and to express that decision.

Needless to say, the content of these conditions may vary depending on whether we are using a negative or positive version of autonomy and, with regard to capacity, we will also see that it is impossible to completely disregard social assessments.

In any event it is important to distinguish between autonomy and capacity, because it is possible that, when a patient takes a decision which is not really autonomous, this is due not to a problem of capacity but to one of information or will. In other words, we cannot have autonomy without capacity, but we can have capacity without autonomy.

This having been said, it can be clearly seen that the aim when assessing patient capacity is the same as for any diagnostic test: to avoid both false positives and false negatives.

- False negative: treating a patient who is actually competent as if he is incapable of taking his own decisions, and preventing him from deciding for himself. This involves denying him the right to exercise his autonomy and his rights as a patient, and causing him unnecessary moral damage.
- False positive: treating a patient who is actually incompetent as if he were capable of taking his own decisions. This may cause unnecessary damage

to the patient's health or even to his life, because the patient is not taking a truly autonomous decision.

Which is more serious from an ethical perspective: a false positive or a false negative? It is impossible to give a definite answer to this question, for the simple reason that any answer involves value judgements[3]. For those who believe that the worst thing you can do is to violate somebody's autonomy, a false negative will always be far more serious than a false positive. And the opposite is true for those who believe that protecting people from harm is more important than respecting their autonomy.

For this reason it is important to stress that, as in all clinical judgements, the judgement of a patient's capacity is the result of a probabilistic, pragmatic decision rather than being a matter of scientific certainty. As a consequence, none of the scripts, tools or protocols for assessing capacity can ever be a "Holy Grail", the magic solution which will answer all of our questions and resolve all of our concerns. When we use such devices, we must accept the possibility of scientific, technical and ethical mistakes.

This should not prevent us from searching for the most sensitive and specific tools for assessing capacity. Indeed, there would appear to be an urgent need for this. A recent British study into the prevalence of incapacity in adult patients admitted to a London hospital, using the MacCAT-T, detected figures of around 30%[4]. But most striking of all is the fact that many of these patients were deemed to be capable by their doctors.

The terminological issue: capacity and competency

One of the reasons why doctors have problems with the issue of capacity is because both legal texts in Spain and foreign literature – usually from the USA and Canada – tend to be somewhat unclear in their use of terms and concepts.

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[3] DeMarco JP. Competence and Paternalism. *Bioethics* 2002;16(3):231-245.

[4] Raymont V, Bingley W, Buchanan A, David AS, Hayward P, Wessely S et al. Prevalence of mental incapacity in medical inpatients and associated risk factors: cross-sectional study. *Lancet* 2004;364:1421-7.

If one reads the North American literature on this subject, one will often find two different terms being used: “competency” and “capacity”. Let us consider what they mean:

- “Competency” is a legal term, and it means the legal recognition of the psychological aptitude to take certain decisions. The equivalent term in Spanish law would be “legal capacity”.
- “Capacity” is a psychological, clinical term. It defines the psychological aptitudes necessary for the taking of a given decision here and now. This is what doctors, psychiatrists and psychologists evaluate, as do lawyers. The equivalent term in Spain would be “de facto or natural capacity”, sometimes also referred to as “competency”.

As we can see, they are two sides of the same coin: one cannot occur without the other.

However, in the English-language literature both terms are often used interchangeably, in a similar way to what occurs with the words “ethical” and “moral”, which are sometimes used as synonyms and sometimes not. Sometimes the author identifies this fact, but often it has to be deduced from the context.

In the United Kingdom, the term used is “capacity”, as established by the Mental Capacity Act of 2005, the law which currently regulates the evaluation of capacity and the taking of decisions with those who lack capacity. The draft version of the “Code of Practice” on how it will work is currently undergoing public consultation[5].

Although the law regulating informed consent in Catalonia (Act 21/2000) still uses the term “competencia”, the current trend in Spain is moving away from this. This is because, in the Spanish legal framework, the term has connotations which do not apply well to the taking of decisions by patients. As a result, the more legally precise term “capacidad” is coming into general use.

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5. Available at http://www.dca.gov.uk/consult/codepractise/consultation0506.pdf

The capacity to which we are referring is the "capacity to act". In other words, it refers to the internal conditions which enable a person to effectively exercise his or her rights and obligations. And, as we have already seen, these conditions take two forms: "legal capacity to act" and "de facto or natural capacity to act". Or what are referred to in English as "competency" and "capacity", respectively.

The relationship between the two is complex, as we have already mentioned, because practical and legal capacity always go hand in hand. Whenever a person's practical capacity is affected, their legal capacity is also undermined. It is important to know whether this restricted capacity is temporary or permanent. In common clinical contexts, it is more usual for us to consider potentially temporary situations. However, in some clinical fields – such as psychiatry or geriatrics – the incapacity may become permanent.

When differentiating between these situations for practical purposes, discussion tends to employ the negative forms of these terms. So people talk of:

- "Incapacity": the lack of de facto or natural capacity here and now, as a result of which the subject temporarily loses his legal capacity. For example, a patient in an alcohol-induced coma, with severe hypercapnic encephalopathy or one who is simply under general anaesthetic and therefore unconscious.
- "Incapacitated": the permanent lack of legal capacity, because a judge has issued an incapacitation ruling, usually as a result of a mental illnesses which impairs the individual's reason permanently and not just in a particular situation.

In Spain, Act 41/2002 on the autonomy of patients draws this distinction in article 9, paragraph 3, where it states that informed consent must be "consent by representation" in three situations: where the patient is "incapable", where the patient is "incapacitated" and where the patient is a "minor". This paragraph therefore adds two more concepts to those of "incapable" and "incapacitated".

The first of these is "consent by representation" which is the kind of consent which must be given when somebody is not in a position to give consent for himself: that is, when the person does not have "capacity" in a general sense. In these cases, it is not that the clinician can act without giving information or requesting consent, but rather that, in addition to involving the patient as far as is possible, there is another person involved in taking decisions: the representative. It is important to emphasize this because doctors often tend to assume that, if a patient is incapable, then they are the ones who should assume control of the situation and decide unilaterally.

The other important concept is that of the "minor". The question of informed consent in the case of minors is possibly one of the most complex and controversial issues, and also one of the issues which causes most concern to doctors[6]. However, we will not address this issue explicitly here.

One important point to bear in mind is that we must always assume that patients (or at least adults) possess their (natural) capacity unless there is an incapacitation ruling to the contrary. As a result, it is a patient's incapacity which has to be demonstrated, not the patient's capacity, which he is assumed to possess. Where doubt exists, the assumption of capacity must prevail.

Who can and should assess the assumed incapacity of patients?

As doctors, assessing the capacity of our patients is something we have always done. However, it should be noted that something with such serious legal repercussions as simultaneously restricting and protecting the rights of patients had no legislative basis until the approval of Act 41/2002, and in particular articles 5.3 and 9.3.a. Notaries, by contrast, have explicitly had this power and responsibility under civil law for decades.

It is also important to note that Act 41/2002 only grants this function to "doctors" and not to other types of health professional, such as nurses or clinical psychologists. And the authority and responsibility is held "by the doctor who is caring for the patient" or by the "doctor in charge". Of course, before deciding on the possible incapacity of a patient, a doctor may ask another specialist to assess

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[6] Gracia D, Jarabo Y, Martín Espíldora N, Ríos J. Toma de decisiones en el paciente menor de edad. M*ed Clin (Barc)* 2001; 117:179-90

him. But the final responsibility is the doctor's and cannot be delegated to "the psychiatrist" or "the psychologist". These specialists only have an advisory role.

When does the assumed incapacity of a patient have to be assessed?

The fact that a doctor thinks it necessary to assess a patient's capacity in order to seek to detect potential areas of incapacity does not necessarily indicate a paternalistic attitude. Rather, such a decision is usually an expression of responsibility and respect towards the patient.

There are at least four situations which should set alarm bells ringing with regard to the possibility that the patient is incapable:

- The patient has undergone a sudden change in his usual mental state. These changes may be due to psychiatric problems or to physical changes such as hypoxia, infection, medication, metabolic disorders, etc.
- The patient rejects a treatment which is clearly indicated in his case, and is unable to explain his reasons clearly or bases these on excessively irrational ideas and assumptions.
- The patient readily accepts the performance of very invasive, uncomfortable or dangerous procedures, apparently without weighing up the risks and benefits.
- The patient has a previously identified, underlying neurological or psychological disorder, which may cause temporary states of incapacity.

How do we assess a patient's assumed incapacity?

When doctors ask how to evaluate a patient's capacity, they instinctively turn to the law to see what it has to say. The unpleasant surprise is that the law has nothing specific to say. At most it says that a patient is capable of giving informed consent when he has sufficient "understanding" and "will". But the legislation does not establish any objective criteria or practical method for measuring such things. When, for example, a judge wishes to clarify such situations, he calls upon expert witnesses to give an opinion. These are usually forensic scientists or psychiatrists. What is surprising is that these specialists do not have any standardized procedure for evaluating such issues either, or at least not one which is applicable in the context of clinical decision-making. Their assessments of capacity are usually the result of combining diagnostic tools such as tests, scales, etc., which have usually been designed for other purposes, with a subjective clinical assessment based on examination and interview. For their part, notaries, who also have both the power and the duty under civil law to perform such assessments, similarly lack any standardized procedure for doing.

Spanish doctors, who have been performing de facto "assessments" of their patients' capacity, also lack tools which have been specifically developed for this function. They do so using a mixture of common sense and professional experience which, while they allow physicians to muddle through in difficult situations, are scarcely sustainable in the long term.

The only option is to look at what others have done and undertake a rigorous, conceptual, cross-cultural assessment of the tools they have developed. It would also be good if, once these tools had been validated, they could be incorporated into the computer applications used to manage patient medical records. This would encourage both the use of such tools and the appropriate recording of the results.

In March 1977, three authors at the Western Psychiatric Institute and Clinic at the University of Pittsburgh in the USA published what could be seen as the first study which was explicitly dedicated to the problem of assessing capacity, in the *American Journal of Psychiatry*. In their article they reviewed the capacity *tests* which were used in everyday practice, whether in a legal context or in a clinical context, primarily that of psychiatry[7]. What they called "tests" were what we refer to today as criteria for assessing capacity, and how we determine this remains an open question (TABLE 1).

These criteria are widely known and referred to. However, less attention has been paid to the fact that this study also raised a question which continues to be a focus of debate today: the role of the type of clinical decision in assessing capacity and establishing the necessary standards for compliance with these criteria.

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7. Roth LH, Meisel A, Lidz CW. Tests of competency to consent to treatment. *Am J Psychiatry* 1977;134:279-284.

Loren, Roth and Meisel argued that two factors were particularly closely related to such assessments: the risk/benefit balance of the proposed treatment, and whether the patient was "accepting" or "rejecting" treatment.

To express this interdependence they used a "2x2" matrix (TABLE 2). This expressed the idea that, in situations where patients give their consent to a course of treatment with a low risk/benefit balance, health professionals tend to use more flexible capacity criteria. By contrast, where patients reject a course of treatment with a low risk/benefit balance, the criteria tend to be more demanding. The situation is reversed for treatments with a high risk/benefit balance: less demanding criteria are applied to the rejection of such treatments than to their acceptance. Here, clearly, is the seed of what we will come to know as the Sliding Capacity Scale.

In this way, this early study identified the three basic questions around which all subsequent discussion of capacity assessment has revolved:

- Determining the mental areas to be assessed: criteria.
- The standards which these criteria must meet and, above all, whether these standards vary or not according to the complexity of the clinical decision to be taken: Sliding Capacity Scale.
- The design and validation of standardized assessment tools or protocols which can be applied in practice.

We shall consider each of these issues in turn[8].

The criteria for assessing capacity

As we have seen, the first review of the criteria for assessing capacity occurred within the framework of North American psychiatry and, more specifically, in the context of forensic psychiatry. This was to remain the dominant framework throughout the 1980s, until neurologists also became involved in analyzing the issues.

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[8] Some of what follows has already been developed in Simón P. *El consentimiento informado.* Madrid: Triacastela, 2000. p.277-313

The psychiatric perspective

In the years following the publication of Roth, Meisel and Lidz's study in 1977, one of their colleagues at the Western Psychiatric Institute and Clinic at Pittsburgh, the psychiatrist Paul S. Appelbaum, began to take an interest in the issue of capacity and informed consent, particularly in the field of mental illness. In 1979 Appelbaum published an article considering the problem of how to assess the capacity of psychiatric patients to give their consent to voluntary hospitalization[9]. This theoretical study was followed in 1981 by an empirical study of the issue[10]. This second study is interesting because it constitutes one of the first attempts at considering the practical problems of capacity assessment.

Concern with the practical difficulties of assessing capacity in health care led Appelbaum to publish, also in 1981, a study of this issue with Loren H. Roth[11]. The article was addressed above all to psychiatrists, prophetically warning that these specialists would become increasingly involved in assessing the capacity of all sorts of patients at the request of their doctors in the years to come, with the consequent legal repercussions.

But the most interesting contribution to the issue of criteria and standards for capacity assessment came from Appelbaum and Roth the following year, 1982, in a study of the capacity of individuals to give their consent to research[12]. The authors began by identifying the failure of ethics to address the question of the capacity of human research subjects. Not even the National Commission into the ethical issues around research had made any significant proposals in

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[9] Appelbaum PS, Bateman AL. Competency to consent to voluntary psychiatric hospitalization: a theoretical approach. *Bull Am J Psychiatry Law* 1979;7:390-9.

[10] Appelbaum PS, Mirkin SA, Bateman AL. Empirical assessment of competency to consent to psychiatric hospitalization. *Am J Psychiatry* 1981;138(9):1170-6.

[11] Appelbaum PS, Roth LH. Clinical issues in the assessment of competency *Am J Psychiatry* 1981;138(11):1462-7. In July 1982 the same journal published a case study where the authors returned to this problem. Roth LH, Appelbaum PS, Sallee R, Reynolds II CF, Huber G. The Dilemma of Denial in the Assessment of Competency to Refuse Treatment. *Am J Psychitry* 1982; 139(7):910-913.

[12] Appelbaum PS, Roth LH. Competency to consent to research: a psychiatric overview. *Arch Gen Psychiatry* 1982;39:951-8

this regard. This led them to put forward proposals which, although originally focused on research, could logically be extended to the field of health care.

Appelbaum and Roth started by suggesting that the criteria of capacity be divided into four groups, as shown in TABLE 3, with the requirements becoming gradually more demanding. As can be seen, the authors suppressed the second criterion proposed by Roth, Meisel and Lidz, the one regarding "the reasonableness" of the decision taken by the patient. But they also introduced two innovations in their explanation of the criteria: a) they suggested a series of "relevant psychiatric aspects" which could interfere with or influence the satisfaction of each of the criteria; and b) they identified the problems of empirical assessment and went on to sketch out some suggestions regarding the examination of patients in a sub-section for each criterion headed "assessing capacity".

The influence of this article was enormous. Although other authors have also contributed to this area, these four criteria have become essential and have been used in the construction of simple decision-making algorithms[13]. In fact, these four criteria constitute the basis of one of the most thoroughly validated clinical capacity assessment procedures, the *MacArthur Competence Assessment Tool*, designed by Thomas Grisso and Paul S Appelbaum (TABLE 4). The authors set out the first draft of this tool in an article in the *New England Journal of Medicine* in 1988, which treated these four criteria as essential to any assessment of capacity[14].

In the United Kingdom, the Mental Capacity Act of 2005 requires three of the capacity criteria, but replaces the fourth – appreciation – with information retention.

The neurological perspective

At the end of the 1980s, some people began to argue that the analysis of the psychological elements of decision-making had led to the neglect of the underlying biological condition. According to this perspective, those neurological

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[13] Miller SS, Marin DB. Assessing Capacity. *Psychiatric Emergencies* 200;18(2):233-242.

[14] Appelbaum PS, Grisso T. Assessing patient's capacities to consent to treatment. *NEJM* 1988; 319(25):1635-8.

deficits which affect mental activities may render a patient incapable of taking decisions in a way which is at least as significant as any purely psychic changes, if indeed such changes exist independently of neurological deficits. In other words, according to these authors, if psychiatrists should be closely involved with the assessment of capacity then the role of neurologists is every bit as important.

According to Michael P. Alexander – one of the earliest advocates of this position – an individual's capacity depends on performing three steps before taking a decision[15]. Firstly, the individual must recognize that he is being asked to take a deliberate decision. To do this, the individual must have the following systems intact: a) the neocortical mechanisms which allow him to communicate with the outside world by processing complex information, and b) the limbic system which enables the individual to add a basic volitional and emotional element to his responses.

The second step is to be able to activate all the neurosensory mechanisms which enable the individual to process information and to issue responses. There are basically four of these mechanisms: a) review of similar past experiences; b) obtaining new information; c) arithmetical, visual, emotional etc. processing of all the above information; d) maintenance of expectations regarding the outcome of the decision and its possible emotional consequences.

The third step is the practical implementation of the decision, and this may be external (a specific action or decision) or internal (reassessing and restarting the process).

According to Alexander, in order to perform these three steps satisfactorily, the individual must maintain the following seven mental activities at an adequate level: 1) Attention; 2) Memory; 3) Language; 4) Spatial perception; 5) Calculation, communication etc.; 6) Reasoning; and 7) Emotional and affective activity.

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15. Alexander MP. Clinical determination of mental competence. *Arch Neurol* 1988;45:23-6.

A person with severe aphasia, for example, may have a neocortical disorder which causes a language deficit which prevents him from performing the first and second steps. By contrast, someone with frontal lobe syndrome will often suffer from disorders which will prevent him from performing the third step. But most important of all, according to Alexander, is the fact that many patients whom he had assessed for capacity and in whom he had identified sufficiently severe deficits for them to be deemed incapable, had been found capable using the criteria and standards described in the previous section.

At the start of the 1990s, three other authors – Freedman, Stuss and Gordon – insisted above all on the cognitive activities necessary to exercise capacity properly, leaving to one side the affective components[16]. They argued that these activities are the four included in TABLE 5, and that they should be assessed with regard to the following five activities: a) *attention*; b) the *comprehension* of basic information relating to the type of decision at issue; c) the *retention* of the information; d) the *expression* of wishes; e) *perception* and *reason* with regard to the questions being discussed.

However, in reality this approach does not differ greatly from the four criteria put forward by Appelbaum and Grisso, and this may be why these are the criteria which have become an essential point of reference.

The most significant aspect of all these contributions is the correct identification of the fact that capacity assessment cannot be merely *psychiatric* but must also attend to the *neurological* area. This was so clear that subsequent attempts to elaborate specific capacity assessment protocols or studies of how such assessments are performed in daily clinical practice would compare the results with tests which examined this area, such as the Folstein mini-mental state examination[17].

In fact, the only Spanish attempt to elaborate a procedure for assessing capacity, the “Sitges Document” discussed below, takes a fundamentally neurological approach to the issue, perhaps because it is designed for patients with dementia.

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[16] Freedman M, Stuss DT , Gordon M. Assessment of competency: the role of neurobehavioral deficits. *Ann Intern Med* 1991;115:203-8.

[17] See, for example, Cohen L, McCue JD, Green GM. (1993).

The standards of capacity and discussion of the "Sliding Competency Scale"

The debate in the North American literature regarding the degree of compliance with the different capacity criteria which individuals must achieve in order to be considered capable or incapable has been dominated by the debate around the concept of the "Sliding Competency Scale", developed and defended by James Drane[18], and by Allen Buchanan and Dan Brock[19,20].

For the advocates of the concept of the sliding scale, capacity is directly related to the specific clinical decision to be taken. Difficult clinical decisions which involve a complex risk-benefit analysis such as deciding not to undergo a chest X-ray to study a haemoptysis in a patient who smokes require a higher level of capacity. By contrast, a simple clinical decision such as that of a person with stable, complication-free diabetes to provide a blood sample would require a lower level of capacity.

The concept of the Sliding Scale starts, therefore, with the notion that establishing an individual's capacity involves identifying a cut-off point or level on a continuous line which goes from total incapacity to total capacity. The theory of the Sliding Scale argues that this cut-off point is not fixed but moveable, and that it shifts according to the complexity of the decisions to be taken. As a result, capacity is not "symmetrical" but "asymmetrical". In fact, Drane refers to three levels or degrees of difficulty of decisions. At Level I, the easiest decisions, most people would be considered capable, while at Level III, which refers to very complex decisions, many people would be deemed incapable.

This proposal has generated significant debate, although generally more of an academic than a clinical nature[21,22,23]. The main argument against is that, in

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[18] Drane JF. The many faces of competency. *Hastings Cent Rep* 1985 Abr; 17-21.

[19] Buchanan A, Brock DW. Deciding for others. *The ethics of surrogate decision-making*. New York. Oxford University Press, 1989.

[20] Buchanan A. Mental capacity, legal competence and consent to treatment. *J R Soc Med* 2004;97:415-20.

[21] Wilks I. The Debate Over Risk-Related Standards of Competence. *Bioethics* 1997; 11: 419-20

[22] Cale GS. Risk-Related Standards of Competence: Continuing the Debate Over Risk-related Standards of Competence. *Bioethics* 1999; 13: 131-48.

[23] Wilks I. Asymmetrical Competence. *Bioethics* 1999; 13: 154-9.

some way, it reintroduces a paternalist restriction on the exercise of autonomy by individuals, because the assessment of what constitutes a "difficult" decision depends on a risk-benefit analysis carried out by people other than the individual concerned, typically doctors. As we noted earlier, the different positions are related to the importance assigned to false positives and false negatives in any procedure to assess capacity, and therefore depend upon a value judgement[24].

Tools for assessing capacity in a clinical context

The current situation in the English-speaking world

If, during the 1980s, debate focussed on criteria and standards for the assessment of capacity, during the 1990s the design of clinical tools or protocols for assessing capacity has come to the fore. The current decade appears to be continuing in the same vein, although with a shift towards comparative research into different assessment protocols, and attempts to identify the fastest, simplest and most reliable instrument.

Elsewhere I have described some of the protocols introduced during the early 1990s[25]. Here, I will outline the main developments in the literature since the mid-1990s. The first thing we should note is that research in this field is very closely linked to three areas of medicine: psychiatry/psychology, geriatrics, and neurology, which acts as an intermediary between the first two areas. This research has occurred within the context of two types of activity: clinical decisions (diagnostic and therapeutic) and participation in research projects[26,27]. Most of this research has been conducted among elderly patients, in particular those with dementia[28], and psychiatric patients, in

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[24] DeMarco JP. Competence and Paternalism. *Bioethics* 2002;16(3):231-245.

[25] Simón P. *El consentimiento informado*. Madrid: Triacastela ,2000. p.302-309.

[26] Moser DJ, Schultz SK, Arndt S, Benjamin ML, Fleming FW, Brems CS et al. Capacity to provide informed consent for participation in schizophrenia and HIV research. *Am J Psychiatry* 2002;159(7):1201-7.

[27] Pinals DA , Appelbaum PS. The history and current status of competence and informed consent in psychiatric research. Isr *J Psychiatry Relat Sci* 2000;31(2):82-94.

[28] Kim SYH, Caine ED, Currier GW, Leibovici A, Ryan JM. Assessing the competence of persons with Alzheimer's disease in providing informed consent for participation in research. *Am J Psychiatry* 2001;158:712-7.

particular those with schizophrenia[29] and, to a lesser degree, those with depression[30].

There have also been important developments in another area, albeit one which is closely related to the others: that of forensic medicine. The aim here has been to develop procedures to assess capacity both in civil and criminal cases. The former generally involves incapacitation procedures and assessing the capacity of witnesses to give evidence, while the latter involves determining the responsibility of the accused.

Practical assessments of capacity have used three types of tool, as follows:

1. Neuropsychological tests, such as the Mini-Mental State Examination, the Weschler Adult Intelligence Scale (WAIS), etc. The problem with these tests is that they have not been specifically designed for this task. However, they have a very important role to play in research into the assessment of capacity and also fill a gap as complementary assessment systems in practical settings.
2. General protocols for assessing capacity, which we will discuss in more detail below.
3. Specific protocols for assessing capacity. These assess capacity in relationship to specific tasks or procedures. For example, the Hopkins Competency Assessment Tool (HCAT)[31] and the Health Care Proxy Guidelines (HCP)[32] basically assess the capacity to complete a living will which operates as a durable Power of Attorney[33]. The Competence

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[29] Jeste DV, Depp CA, Palmer BW. Magnitude of impairment in decisional capacity in people with schizophrenia compared to normal subjects: An overview. *Schizophrenia Bull* 2006;32(1):121-8.

[30] Appelbaum PS, Grisso T, Frank E, O'Donnell S, Kupfer DJ. Competence of depressed patients for consent to research. *Am J Psychiatry* 1999;156(9):1380-4.

[31] Janofsky JS, McCarthy JS, Folstein MF. The Hopkins Competency Assessment Test: A brief method for evaluating patient's capacity to give informed consent. *Hosp Community Psychiatry* 199;43(2):132-6.

[32] Mezey M, Teresi J, Ramsey G, Mitty E, Bobrowitz T. Decision-making Capacity to execute a Health Care Proxy: development and testing guidelines. *JAGS* 2000;48:179-187.

[33] However, the HCAT is beginning to be used as a general indirect competency assessment tool. Lucha PA , Kropcho L, Francis M. Acute pain and narcotic use does not impair the ability to provide informed consent: Evaluation of a competency assessment tool in the acute pain patient. *American Surgeon* 2006;72(2):154-7.

Interview Schedule (CIS) assesses the capacity to consent to or refuse electro-convulsive therapy[34]. And the Evaluation to Sign Consent (ESC)[35] and the California Scale of Appreciation (CSA)[36] assess the capacity to agree to participate in a research project.

Below we will focus on general protocols. These can be classified into three groups, as follows[37,38]:

1. Interview scripts: These are simple lists of questions suggested to doctors as being suitable for use when assessing capacity during a clinical interview[39]. Instructions are not given about how to evaluate the responses.
2. Tests or protocols: Consist of structured or semi-structured interview scripts which include a system for evaluating responses, usually by means of numerical scores.
3. Protocols with scenarios: These are protocols which use hypothetical scenarios rather than exploring capacity with regard to the actual, specific decision to be taken.

Protocols which incorporate marking systems are of most interest, whether they use hypothetical scenarios or not. TABLE 6 shows the six most important protocols at present.

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[34] Bean, G., Nishisato, S., Rector, N. A., & Glancy, G. (1996). The assessment of competence to make a treatment decision: An empirical approach. *Canadian Journal of Psychiatry*, 41, 85–92.

[35] Deronzo EG, Conley RR, Love R. Assessment of capacity to give consent to research participation: State of the art and beyond. *J Health Care Law Policy* 1998;1:66-87. The form is available at: http://www.dhmh.state.md.us/oig/irb/pdf/attachment6-2006.pdf (Visited on 14 May 2006).

[36] Saks, E. R., Dunn, L. B., Marshall, B. J., Nayak, G. V., Golshan, S., & Jeste, D. V. (2002). The California Scale of Appreciation: A new instrument to measure the appreciation component of capacity to consent to research.

[37] *American Journal of Geriatric Psychiatry*, 10, 166–174 37Sullivan K. Neuropsychological assessment of mental capacity. *Neuropsychology Review* 2004;14(3):131-142.

[38] Tunzi M. Can the patient decide? Evaluating patient capacity in practice. *American Family Physician* 2001;64(2):299-306.

[39] Finucane P, Myser C, Ticehurst S. “Is she fit to sign, doctor?” Practical ethical issues in assessing the competence of elderly patients. *Med J Aust* 1993;159:400-3.

The two best reviews of the pros and cons of capacity assessment protocols in the literature are probably those by Edward Sturman[40] and Jennifer Moye et al[41]. On the basis of their analysis, the current situation would appear to be as follows:

1. Deficits in *understanding* and *reasoning* detected by the protocols correlate closely with the deficits detected by commonly used clinical tests for neuropsychological assessment. The relationship is weaker for *expressing a choice* and, above all, *appreciation*. This is no doubt due to the fact that the degree of abstraction and personalisation required for this criterion is not adequately assessed by neuropsychological tests. The California Scale of Appreciation (CSA) was expressly designed to assess this issue in the context of participation in research projects.
2. There is a correlation between tests of cognitive impairment, such as the mini-mental, and capacity assessment tests, above all with regard to the understanding criterion, but this relationship has to be investigated more thoroughly.
3. A correlation has been detected between the results of the capacity tests and other variables such as, for example, prior experience of taking similar health-related decisions, level of socialisation[42] or socioeconomic status. The type of illness also appears to be a significant variable which influences the results[43]. In the case of psychotic patients, the severity of the negative symptoms appears to be related to the reduction of capacity, but the same is not true of positive or depressive symptoms[44]. Recently it has been found that a

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[40] Sturman ED. The capacity to consent to treatment and research: A review of standardized assessment tools. *Clinical Psychology Review* 2005;25:954-74.

[41] Moye J, Gurrera RJ, Karel MJ, Eldestein B, O'Connell C. Empirical advances in the assessment of the capacity to consent to medical treatment. Clinical implications and research needs. *Clinical Psychology Review* 2006 (in press).

[42] Allen RS, DeLaine SR, Chaplin WF, Marson DC, Bourgeois MS, Dijkstra K, Burgio LD. Advance Care Planning in Nursing Homes: Correlates of capacity and possession of advance directives. *Gerontologist* 2003;43(3):309- 17.

[43] Palmer BW, Dunn LB, Appelbaum PS, Mudaliar S et al. Assessment of capacity to consent to research among older persons with schizophrenia, Alzheimer disease, or diabetes mellitus: comparison of a 3-item questionnaire with a comprehensive standardized capacity instrument. *Arch Gen Psychiatry* 2005;62(7):726-9

[44] Palmer BW, Jeste DV. Relationship of individual cognitive abilities to specific components of decisional capacity among middle-aged and older patients with schizophrenia. *Schizophrenia Bull* 2006;32(1):98-106.

short training session designed to improve the skills of schizophrenic patients before assessing them with a capacity test leads to better test results[45].

4. There are studies of the reliability of the results of these protocols, but they are insufficient. The psychometric properties are not well known[46]. Studies of concordance between the different tests or protocols are inconclusive. In general, concordance between the results for understanding is higher than for other criteria, while concordance for appreciation is lowest[47]. There are no good studies of test-retest reliability, in particular with regard to healthy subjects who in principle are not subject to possible fluctuations in capacity as a result of their illness. There is a need for more studies of concordance between observers, because although the results here appear to be good they are sometimes contradictory[48,49].
5. Research into the validity of protocols encounters a methodological problem which is very difficult to resolve: the absence of a "gold standard" which makes it possible to estimate the sensitivity and specificity of tests. The most widely used standard is assessment by trained, experienced health professionals, such as forensic scientists, psychiatrists or geriatric specialists.
6. Most of these studies are based on small sample sizes, which limits the validity of the results, partly because the complexity of the construct entails methodological designs with multiple tests, making it difficult to recruit large numbers of subjects.

These six points make it difficult to establish one protocol as absolutely superior to another. Despite this, there is a tendency in the literature to consider the McCAT as the leading protocol both for taking treatment decisions

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[45] Moser DJ, Reese LR, Hey CT, Schultz SK, Arndt S, Beglinger LJ, Duff KM, Andreasen NC. Using a brief intervention to improve decisional capacity in schizophrenia research. *Schizophrenia Bull* 2006;32(1):116-200.

[46] Zapf PA , Roesch R. An investigation of the construct of competence: A comparison of the FIT, the MacCat-CA and the MacCat-T. *Law and Human Behaviour* 2005;29(2):229-252.

[47] Moye J, Karel MJ, Azar AR, Gurrera RJ. Capacity to consent to treatment: Empirical comparison of three instruments in older adults with and without dementia. *Gerontologist* 2004;44(2):166-75.

[48] Marson DC, McInturff B, Hawkins L, Bartolucci A, Harrell LE. Consistency of physician judgments of capacity to consent in mild Alzheimer's disease. *JAGS* 1997;45:453-7.

[49] Cairns R, Maddock C, Buchanan A, David AS, Hayward P, Richardson G, Szmukler G, Hotopf M. Reliability of mental capacity assessments in psychiatric patients. *BR J Psychiatry* 2005;187:372-8.

(McCAT-T) and for taking decisions with regard to clinical research (McCAT-CR)[50]. However, there is clearly a need for additional research to further explore the issues identified above and to answer the new questions which are already being raised[51]. For example, is it possible to design protocols which are shorter, more straightforward and quicker to apply than those which currently exist? If we have to accept that the "gold standard" consists of expert assessments, then what criteria do these experts have to meet in order to be considered as such?[52] How should we respond to the ethical problem raised by the possible incapacity of research subjects to consent to participate in research projects into capacity assessment protocols?[53]

The current situation in Spain

In Spain, as far as I am aware, there are no validated capacity assessment protocols. The nearest thing we have is the "Sitges Document"[54]. This was the result of a study conducted using the Delphi consensus method by a multidisciplinary group of experts in the broad field of dementia (geriatricians, neurologists, social workers, psychologists, lawyers, etc). The purpose of the study was to establish the basic criteria to use when assessing the capacity of individuals with dementia to take decisions in six different spheres: decisions which affect their own health (S), decisions about whether to participate in research (I), decisions relating to their financial situation (P), decisions regarding their own non-employment related activities (A), other personal decisions (O) and, finally, decisions about other people for whom the individual has a non work-related responsibility (T).

1. The 16 criteria selected have a very neurological focus, as can be seen from TABLE 7. Each criterion is assessed for each patient, who is

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[50] Casarett DJ. Assessing Decision-Making Capacity in the Setting of Palliative Care Research. *J Pain Symptom Management* 2003; 25(4):S6-S13.

[51] Appelbaum PS. Decisional capacity of patients with Schizophrenia to consent to research: taking stock. *Schizophrenia Bull* 2006;32(1):22-25.

[52] Kim SY. When does impairment become decisional incompetence. Ethical and methodological issues in capacity research in schizophrenia. *Schizophrenia Bull* 2006;32(1):92-97.

[53] Saks ER, Dunn LB, Palemr BW. Meta-consent in research on decisional capacity: A "Catch-22". *Schizophrenia Bull* 2006;32(1):42-46.

[54] Boada M, Robles A, editores. Análisis y reflexiones sobre la capacidad para tomar decisiones durante la evolución de una demencia: «Documento Sitges». Barcelona: Glosa, 2005. Available from the website of the Spanish Society for Neurology. http://www.sen.es/ (Visited on 15 May 2006).

assigned one of the following scores: 1 Normal; 2 Slight impairment; 3 Moderate impairment; 4 Serious impairment; 5 Function abolished.

2. The standards are established using two measures:
   a. Firstly, in each decision-making context two levels of difficulty are identified, according to the degree of complexity of the decision to be taken: "Major level" (M) and "minor level" (m).
   b. Secondly, using the Delphi procedure, scores from 1 to 5 are assigned for each criterion and each type of decision, according to the maximum alteration. The result is the double-entry matrix shown as TABLE 8.
3. Practical assessment of capacity is based on neuropsychological assessment based on the tests normally used to study patients with dementia. The authors have very helpfully tabulated which of the 16 criteria can be examined with each test or scale. The most effective is the CAMDEX battery, which can be used to assess 15 of the 16 proposed criteria.

The strengths and weaknesses of the "Sitges Document" are self-evident, and indeed the authors themselves highlight what these are:

"It should be clear that the results are arbitrary in so far as they derive from the subjective opinion of individuals, even if these individuals are experts who have arrived at a consensus. We would need to translate these judgements into practice, using a controlled sample of individuals, applying objective methods which would allow us to assess the validity of the tables and to determine how they should be adapted. At the very least, we hope that our efforts will provide a basis for such research and will contribute to defence of the right to decide, essential as it is to participation in social activities."

Conclusion: the long road ahead

The final conclusion to be drawn from everything we have considered is that assessing the decision-making capacity of patients remains an area where there are more questions than answers. And if this is true in the English-speaking world, then the situation in Spain is far more worrying. There is an urgent need for rigorous assessment studies which provide Spanish doctors and researchers with tools which enable them to assess the capacity of patients and research subjects. In this regard, by way of a conclusion, I would like to make ten practical suggestions:

1. That there should be a rigorous transcultural validation of the MacCAT-T and the MacCAT-CR in Spain. This involves validating the capacity criteria of understanding, appreciation, reasoning and expressing a choice.
2. This validation should be performed with sample sizes large enough to be statistically valid.
3. The validation should compare healthy and ill subjects, at least for patients with dementia, schizophrenic patients and patients suffering from chronic illness. A distinction should also be drawn between patients who are hospitalised and outpatients.
4. This validation should compare the results of the MacCAT with the results of other psychiatric or neuropsychological tests. In elderly patients the Mini-Mental State examination should be used for this purpose, and in patients with dementia the CAMDEX should be used.
5. That for this validation the "gold standard" should consist of doctors with specific training in capacity assessment. In order to avoid overloading patients or trial subjects, this assessment could be carried out by assessing video recordings of interviews in which the MacCAT and neuropsychological tests are applied.
6. It is important to include measures of reliability, test-retest and concordance between observers, and of the psychometric properties of the MacCAT.
7. It is important to ensure that the whole research project is conducted on a sound ethical basis, and that the problem of obtaining informed consent is resolved.
8. Subsequently, investigation into capacity assessment tools should be extended to minors, as this is likely to be a source of increasing conflict in the future.
9. Another area which should be developed rapidly, as soon as we have a validated standard protocol like the MacCAT, is investigation of abbreviated versions of the tools which allow faster but equally reliable assessments.
10. None of the above will be possible if we do not improve the general training of doctors and legal experts with regard to the assessment of capacity in a clinical context. I have made specific mention of the legal profession because, while it is true that Spanish doctors in general suffer from a significant and worrying lack of knowledge in this area, the situation of legal experts in general is not much better. And this is an area where it is essential that these two groups work together.

Table 1. Competency tests according to Roth, Meisel and Lidz (1977)

COMPETENCY TESTS
(Roth, Meisel and Lidz - 1977)

1. The patient is capable of expressing a choice.

This test proposes a set of minimum requirements in order for a patient to be declared competent. The patient only has to show that he or she is in favour of or against the diagnostic or therapeutic procedure proposed. The quality of the patient's decision is therefore not evaluated in any way, and a simple "yes", "no" or "you decide, doctor" is sufficient.

2. The patient makes a "reasonable" decision.

According to this test, the patient is competent if he or she takes a decision which could be considered "correct" or "responsible". This is a decision which would be taken by a "reasonable" person who found him or herself in the same position as the patient. The emphasis is therefore on the outcome of the patient's decision-making process rather than on the mere existence of the decision itself or the manner in which this was reached.

3. The patient takes a decision based on "rational" motives.

This test, unlike the preceding one, seeks to evaluate the "quality" of the patient's reasoning process rather than the outcome. The aim is to detect those decisions which could be the result of a mental illness affecting the subject's reasoning.

4. The patient comprehends the risks, benefits and alternatives of the treatment (including non-treatment).

According to this test, a patient's decision-making process does not necessarily need to be "rational" or produce a "reasonable" outcome. But what is essential for the patient to be considered competent is a sufficient degree of comprehension of the information needed to take the decision, even if the patient gives a different value to each element of this information than the doctor.

5. The patient genuinely understands all the relevant aspects of the decision to be taken and gives genuinely voluntary and informed consent.

This is a more complex test, which only establishes the capacity or otherwise of the subject by analysing how the patient has understood the situation in which he or she finds him or herself, the relevant information and how he or she has evaluated this information to reach a decision. This is a demanding test which requires the doctor to analyse the decision-making process carefully.

[Taken from Roth LH, Meisel A, Lidz CW. Tests of Competency to Consent to Treatment. *Am J Psychiatry* 1977; 134(3):279-284].

Table 2. Factors which, according to Roth, Meisel and Lidz, influence selection of competency test

	RISK / BENEFIT BALANCE	
DECISION	FAVOURABLE	UNFAVOURABLE
CONSENT	Competency Test LOW	Competency Test HIGH
REJECTION	Competency Test HIGH	Competency Test LOW

[Taken from Roth LH, Meisel A, Lidz CW. Tests of Competency to Consent to Treatment. *Am J Psychiatry* 1977; 134(3):279-284.]

Table 3. The four competency evaluation criteria of PS Appelbaum and Loren Roth (1982)

COMPETENCY CRITERIA	**TYPICAL SIGNS**	**SIGNIFICANT PSYCHIATRIC ASPECTS**
1. The subject expresses a choice (Expressing a choice)	- Expresses consent. - Expresses positive interest in participating in the trial - Cooperates satisfactorily - Answers questions.	- Muteness: catatonic state or severe depression - Mania or catatonic agitation - Psychotic thought disorders - Clear ambivalence: schizophrenia, obsessive states.
2. The subject genuinely understands the most important aspects of the trial (Understanding)	- Has sufficient cognitive capacity - Understands the nature, risks and benefits of the procedure - Understands alternatives, and the advantages and disadvantages of each - Knows he/she has to take a decision - Knows who and where he/she is, what the informed consent form is and what it means to sign it - Understands the consequences both of participating and of not participating.	- Level of intelligence. IQ (mental deficiency, organic changes) and ability to lead a normal life (chronic mental illness) - Linguistic abilities - Level of attention and orientation - Memory capacity - Effects of brain damage and alcohol.

COMPETENCY CRITERIA	TYPICAL SIGNS	SIGNIFICANT PSYCHIATRIC ASPECTS
3. The subject rationally handles the information in an adequate manner (Reasoning)	- Has good judgement - Is rational and correctly evaluates reality - Can take decisions appropriately.	- Illusions and hallucinations - Alterations to thought processes - Anxiety, euphoria, agitation - Extreme phobias, panic - Obsessive concerns - Extreme passivity and dependency.
4. The subject correctly understands his or her situation (Appreciation)	- Is aware of situation, both cognitively and emotionally - Is aware of the consequences of consent or rejection - Knows who he/she is and the reasons for giving consent - Has a mature understanding of the implications of the different options - Adequately assesses what information is relevant in order to reach a decision - As a result of all the above, is able to realise: + that he/she has a problem which matches the trial requirements + that the trial has research objectives, not just therapeutic ones + that both researchers and non-researchers may participate in care + that the treatment may be randomised, double-blind, with placebo, etc.	- Denial regarding: + existence or seriousness of illness + research nature of trial + possibility of improvement with and without participation in trial + trial methodology - Capacity for abstract thought affected by: + low IQ + limited education + psychosis + physical brain damage - Psychotic alterations: + distortions + projections + nihilism + desperation/abandonment.

[Taken from Appelbaum PS, Roth LH. Competency to consent to research: a psychiatric overview. *Arch Gen Psychiatry* 1982;39:951-8..]

Table 4. Criteria and scores for MacCAT-T

CRITERION	SUB-CRITERION	PS	TS
Understanding	Understanding of illness	0-2	
	Understanding of treatment	0-2	**0-6**
	Understanding of risks and benefits	0-2	
Appreciation	Of situation of illness	0-2	**0-4**
	Of general purpose of treatment	0-2	
Reasoning	Logical-sequential	0-2	
	Logical-comparative	0-2	
	Predictive (consequences arising from possible choices)	0-2	**0-8**
	Internal consistency of choice process	0-2	
Choice	Expresses a decision	0-2	**0-2**

PS : Partial Score for each sub-criterion
TS: Total Score possible for each criterion

Table 5. Cognitive areas relevant for an adequate evaluation of a patient's competency according to Freedman, Stuss and Gordon

COGNITIVE AREAS OF COMPETENCY (Freedman, Stuss & Gordon)	
Attention	
Language	• Spontaneous language • Comprehension of verbal information • Reading comprehension • Writing
Memory	• Short-term • Long-term
Frontal Lobe Functions	• Awareness • Reasoning

Table 6. The most important general protocols for assessing capacity

NAME	ABBREVIATION	AUTHOR	COUNTRY	YEAR	TYPE	SCORE
Aid to Capacity Evaluation	ACE	Etchells et al[1]	Canada	1999	Semi-structured interview	YES
Capacity Assessment Tool	CAT	Carney et al[2]	USA	2001	Structured interview	YES
Capacity to Consent to Treatment Instrument	CCTI	Marson et al[3]	USA	1995	2 scenarios and interview	YES
Decision Assessment Measure	DAM	Wong et al[4]	UK	2000	Semi-structured interview	YES
Hopemont Capacity Assessment Interview	HCAI	Edelstein[5]	USA	1999	2 scenarios and interview	YES
MacArthur Competence Assessment Tool	MacCAT -T * MacCAT –CR MacCAT -CA	Grisso & Appelbaum[6,7]	USA	1998	Semi-structured interview (1 scenario in the CR version)	YES

* The MacCAT exists in three versions: "T" (Treatment) for clinical treatment decisions; "CR" (Clinical Research), for participation in research projects; and "CA" (Criminal Adjudication), for the adjudication of responsibility.

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1. Etchells E, Darzins P, Silberfeld M, Singer PA , McKenny J, Naglie G, et al. Assessment of patients capacity to consent to treatment. *Journal of General Internal Medicine* 1999;14:27–34. This protocol is available at http://www.utoronto.ca/jcb/disclaimers/ace.htm (Visited on 15 May 2006)
2. Carney MT, Neugroschl J, Morrison RS, Marin D, Siu AL. The development and piloting of a capacity assessment tool. *The Journal of Clinical Ethics* 2001;12:17–23.
3. Marson, DCCody, HA, Ingram KK, Harrell LE. Neuropsychological predictors of competency in Alzheimer's disease using a rational reasons legal standard. *Archives of Neurology* 1995;52:955–9.
4. Wong JG, Clare ICH, Holland AJ, Watson PC, Gunn M. The capacity of people with a mental disability to make a health care decision. *Psychological Medicine* 2000;30:295–306
5. Edelstein B. *Hopemont capacity assessment interview manual and scoring guide*. Morgantown, WV: West Virginia University, 1999.
6. Grisso T., Applebaum PS. *Assessing competence to consent to treatment*. New York: Oxford University Press, 1998.
7. Appelbaum PS, Grisso T. *MacCAT-CR. Mac Arthur Competence Assessment Tool for Clinical Research*. Sarasota (FL – USA):Professional Resource Press;2001.

Table 7. Neurological aspects which intervene in decision-making and configure capacity criteria, according to the "Sitges Document".

Neurological aspects which intervene in decision-making

1. Level of awareness (Nc)
2. Perception of stimuli (Pc)

Cognitive functions

    3. Attention (At)
    4. Gnosias (Gn)
    5. Language: comprehension (L-C)
    6. Language: expression (L-E)
    7. Calculation (Cc)
    8. Episodic memory of recent events (Me)
    9. Autobiographical episodic memory (Ma)
    10. Spatial orientation (Oe)
    11. Constructive praxis (P-C)

12. Executive functions (Fe)
13. Abstract reasoning (Ra)
14. Motivation – self-control – introspection (MAI)
15. Spontaneous invention (Ie)
16. Affectivity – emotional state (AE)

Table 8.
The "Sitges Document" scoring matrix

	SM	Sm	IM	Im	PM	Pm	AM	Am	OM	Om	TM	Tm
Level of awareness (Nc)	2	2	1	2	1	2	1	2	1	2	1	2
Perception of stimuli (Pc)	3	3	3	3	3	3	2	3	2	3	2	3
Attention (At)	2	3	2	3	2	3	2	3	2	3	2	3
Gnosias (Gn)	3	4	3	4	2	3	2	3	2	3	2	3
Language: comprehension (L-C)	3	4	3	3	3	3	3	3	3	4	3	3
Language: expression (L-E)	3	4	3	3	3	3	3	4	3	4	3	3
Calculation (Cc)	5	5	5	5	2	3	3	4	3	4	3	4
Episodic memory of recent events (Me)	3	3	2	3	2	3	2	3	2	3	2	3
Autobiographical episodic memory (Ma)	3	3	3	4	2	3	3	3	3	4	3	3
Spatial orientation (Oe)	4	5	4	5	3	4	3	4	4	4	3	4
Constructive praxis (P-C)	5	5	5	5	4	5	3	4	4	5	3	5
Executive functions (Fe)	2	3	2	3	2	3	2	3	2	3	2	2
Abstract reasoning (Ra)	2	3	2	3	2	3	3	3	2	3	2	2
Motivation – self-control – introspection (MAI)	2	3	2	2	2	3	2	2	2	3	2	2
Spontaneous invention (Ie)	2	3	2	3	2	3	2	2	2	3	2	2
Affectivity – emotional state (AE)	2	3	2	3	2	3	2	3	2	3	2	2

Left-hand column: neurological aspects which intervene in decision-making.

Top row: types of decision of greatest interest, classified by category. SM: decisions which have a major influence on subject's health; Sm: decisions which have a lesser influence on subject's health; IM: major decisions regarding participation in research; Im: lesser decisions regarding participation in research; PM: major decisions regarding finances; Pm: lesser decisions regarding finances; AM: major decisions regarding subject's non-employment activities; Am: lesser decisions regarding subject's non-employment activities; OM: major decisions about self not covered by above; Om: lesser decisions about self not covered by above; TM: major decisions about others for whom subject has a non-employment responsibility; Tm: lesser decisions about others for whom subject has a non-employment responsibility.

Scores: unified scale from 1 to 5, 1: normal; 2: slight impairment; 3: moderate impairment; 4 serious impairment; 5 function abolished.

PANEL DISCUSSION

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Evaluation of capacity in the elderly. Instruments

The evaluation of capacity should occur within the context of a comprehensive geriatric assessment which includes clinical, psychological, functional and social aspects. The psychological assessment analyses cognition, state of mind, personality, anxiety, and quality of sleep.

It may be that with regard to decision-making capacity, what is essential is to identify problems in cognitive function and, to a lesser degree, emotional state.

The cognitive examination analyses the following areas:

- Personal, spatial and temporal orientation.
- Memory: both of recent and distant events, and immediate memory, which is the most important for comprehension.
- Concentration and attention span.
- Language, perception and psychomotor functions.
- Abstract thought.

Traditionally, quick examination scales are used in daily work with elderly patients. These are standardised instruments which can be applied quickly and are not intrusive for the patient. They evaluate different areas of the higher functions, and are relatively independent of the evaluator's judgement. As a result, they ensure greater objectivity than an unstructured interview.

The best-known scales are:

- Folstein's Mini-Mental State Examination
- Lobo's Cognitive Mini-Exam

- Memory Impairment Screen
- Dementia Rating Scale
- 7 minute test
- Set Test
- Pfeiffer's Test.

Folstein MF, Mini Mental State. A practical method for grading the cognitive state of patients for the clinician. *Journal of Psychiatric Research*, 1975;12(3):189-198.

Administration time: 10 minutes

General cut-off score for elderly: 24/30

Sensitivity: 89.8 %

Specificity: 83.9 %

Predictive value (-): 97.8 %

Wrongly classified patients: 15.1 %

Sometimes the short examination is not sufficient, and in these cases a full neuropsychological examination has to be carried out by an experienced professional.

With regard to the emotional state, there are also relatively simple instruments which aid assessment. The most widely known of these is Yessavage's *Geriatric Depression Scale*. In addition, an interview aimed at identifying depressive symptoms such as sadness, helplessness, insomnia, changes in eating patterns, isolation, ideas about death etc. is almost always desirable.

Finally, when one is considering evaluating a patient's capacity, it is important to identify the causes of this assumed incapacity and to assess whether the incapacity is treatable. It is also necessary to identify communication problems such as speech disorders or hearing difficulties which could have a significant impact on the examination. And, of course, we have to start from the basis of respect for the individual and the assumption that everyone is capable unless the contrary has been shown to be the case.

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Capacity, beliefs and mental disorder[1]

Recognition and respect for patients' capacity or competence have become a key part of the clinical relationship, and basing the clinical relationship on this spells the end of traditional paternalism. Every competent individual is free to decide regarding his body or behaviour, so long as this does not harm the rights of others. Once an individual's capacity has been established, nobody can make decisions for him or prevent him from exercising his autonomy. This is one of the most important operating principles of a liberal, free, democratic society in which values can be contested but not imposed.

Basic individual rights cannot entail duties, and I therefore cannot agree with the statement that we have duties which may limit our autonomy for the good of the community. As a result, we can respect Jehovah's Witnesses when they argue that transfusion is sinful and, as a result, cannot support blood donation, even though this is desirable for other citizens.

If we look at the wording of the constitutions of democratic societies, we see that they identify few duties, and sometimes when such duties are established this is not done correctly. This is the case with article 35 of the Spanish Constitution, which talks both of the right to work and of the duty to work. It is obvious that this duty cannot be enforced, otherwise what would happen to those who live without working? Should they be pursued? If a right to ownership is established, should those who live from rental income be pursued? The only duty which can be imposed is the duty to respect the rights of others and pay one's taxes. In other words, in a liberal society paying your taxes and not destroying street furniture, with everything else being governed by the rights of others, for example, the right to be a doctor, and the duty to practice in the correct manner would then derive from the duty to respect the rights of others, in this case, of patients.

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[1] Published subsequently, in Catalan, in *Bioètica & Debat.* 2006, 45; 8-10.

So the rights inherent to our condition as individuals do not entail duties, except where the rights of others may be violated. We have recognised the right to life, but not the duty to conserve it. Prescribing this duty would allow the recently banished medical paternalism in through the back door. In the clinical relationship, in my opinion, the situation is best summed up by the maxim that a competent patient cannot necessarily decide what is to be done to him, but he can decide about what is not to be done to him.

The clinical states which limit a patient's capacity are restricted to those situations in which reason is diminished. In summary, we can say that capacity is reduced in cases where judgement is damaged as a result of psychosis, or is dulled or distorted by serious mood disturbances (mania and depression); in personality disorders, judgement tends not to be damaged. Capacity is reduced in those disorders where assessment of reality is altered either temporarily or permanently. I will return to this issue shortly, but firstly I would like to consider the issue of depression because this is where the assessment of capacity can be become more complicated.

I believe that depression is the clinical situation which poses most problems for the diagnosis of capacity, because clinical depression is often confused with other situations. I understand depression to be a clearly defined disorder which is distinct from the states of sorrow, grief and sadness with which it can be confused. The great writers don't usually confuse these states and, as a rule, rather than talking of depression, refer more accurately to sadness, grief or sorrow. A clinical example of what I am talking about is provided by the case of Ramon Sampedro, the subject of the 2004 film, *The Sea Inside*, winner of the Academy Award for Best Foreign Language Film. Like any man or woman in his situation, he may be sad, demoralised, unhappy, in a bad mood, miserable or with feelings of helplessness, but he is not necessarily depressed if we understand the term "depression" to refer to a well-defined set of symptoms. Sampedro, according to all the available information, was not depressed even though he may have been upset or even distressed. In these situations capacity is unaffected. It is therefore very important to establish a proper diagnosis of depression and not to confuse depression with grief, distress, dismay, gloominess, sadness or sorrow. At the same time, we should also be aware that these states may be modified as a result of taking medication.

It is also very important to remember that being overwhelmed, confused or disoriented may temporarily prevent a person from reasoning properly. However, these states can be influenced to a degree, unlike in the case of depression. When a person is very distressed and overwhelmed it is necessary for doctors to involve the patient in a productive dialogue rather than simply giving orders in an inflexible manner. However, such a productive dialogue may be impossible with a patient who is delirious or depressed. A patient with a well-established depression is not interested in dialogue; rather, he is impervious or indifferent to it. The patient "isn't there, isn't himself", as I was told by a depressed person who, at the same time, reasoned perfectly well while also feeling that he had lost a vital, essential, substantial part of himself.

We feel that reasoning is correct when the ideas formulated accord with those accepted in a given community, even if others may find these absurd. This is the situation which occurs when a mother supports the genital mutilation of her daughters. Those of us who support laws based on human rights and respect for individual autonomy find such practices abhorrent and believe they should be outlawed, but at the same time we have to accept that the reasoning of a mother who forces her daughter to undergo such mutilation is not diminished, because she holds ideas which are shared with the rest of her community, even if we do not share them. However, if someone says that dialysis can be dangerous or can poison us, their reasoning is impaired because this view does not correspond to the evidence provided by science and accepted by everyone and, as a consequence, people who say such things are not deemed to have capacity. When someone says that when blood leaves the body, as happens in dialysis, the process is dangerous, contradicting the medical or scientific evidence, he may suffer from paranoia, but if he says that the practice is prohibited then he may not be. The paranoid make judgements about reality itself, not just about reality as they experience it, including religious beliefs, but observable reality.

Fear can lead to refusal of treatment, but dialogue with the medical team, doctors and nurses usually changes the situation. Being afraid is completely different to paranoia, because a person who is afraid is not making a judgement about what exists, but rather about how he feels about it or what he wants to do. As a result, his reason is not affected and, despite the fear, he remains rational. In such situations, it is possible to engage in a fruitful dialogue with the patient, and to help him to regain his calm.

A very different situation arises when a person with an opinion regarding medical treatment refers not to clearly established facts but to opinions of an ideological nature, in other words to assessments of reality. This is what we see when ideas of a religious or magical nature are invoked, such as happens in the case of genital mutilation. When and how do we distinguish between an ideology which is religious in nature and thus respectable, and an ideology which has neither a rational nor a religious basis? In my opinion, although a religious ideology may contain ideas and assessments which strike some of us as irrational, the person who holds to this ideology behaves in a manner which is generally rational and his ideas can very well be shared by others. This is the case with the Jehovah's Witnesses or the Amish; with the strict prohibition against working on the Sabbath or eating shellfish established by Judaism; the prohibition against drinking alcohol or eating pork for Muslims, and other beliefs and practices of this type. The woman who believes that dialysis is toxic is displaying evidence of a reasoning deficit because her claim is not one which can be shared by ordinary people. However, if this person told us they had just founded a religion the situation might be different. Of course, not everyone can found a religion. Psychotic individuals cannot found religions because the thoughts of psychotic individuals are idiosyncratic and very peculiar, and do not take others into account. Religious fantasies may strike those who do not share them as highly irrational, but they are distinguished from clearly irrational or delirious outpourings because they can be shared by many people, can be accepted and, above all, do not interfere with the ordinary life of the community which accepts or respects them.

The point I am making here with regard to religious ideas is that consent cannot be restricted to or conditioned by the so-called common good or a supposed collective right in an abstract manner, but can only depend on the individual good. We do not accept that a notion of the common good should lead us to respect the decision of parents who, in the case of the Jehovah's Witnesses, do not agree to give a transfusion to a child aged ten or eleven and, as a result, we do not recognise their claims. On a similar basis, nor do we accept the mutilation of girls, even if the community believes and has established that leaving a girl untouched will bring her all sorts of misfortune. If there was a religion which forbade vaccination, we would be unable to accept this precept precisely because this would go beyond the rights of the individual concerned and could harm others who have the same rights. Finally, we might argue that while we do not have the right to have a mother who is alive, we do have the right for our mother not to transmit smallpox to us, or any other serious transmissible disease which could be prevented. Our mother may go climbing, putting her life at risk if this is what she prefers, but she does not have the right to reject vaccination because this rejection could put another's life at risk.

When the Bioethics Committee of Catalonia considered whether it should be compulsory to request the consent of a pregnant woman before performing a test for the presence of HIV antibodies, I took the line, which was not widely shared, that the woman's consent should not be formally requested in this case. We do not have the right to prevent the performance of the test precisely because possible serious damage to the child limits the autonomy of the mother. As a result, a patient's rights and autonomy, unconditional for the individual, come to an end when another can be harmed.

With regard to capacity assessment scales for patients, I believe that doctors will accept their use where this does not constitute a form of abuse and a kind of torture because, depending on the nature of the scale, administering it may involve treating parents without due respect. A carefully designed scale which does not overwhelm the patient can be helpful because it can contribute to the establishment of an objective judgement of the diagnosis of incapacity. These scales, in my opinion, should evaluate logical thought which does not deny the evidence; attention; the capacity not to be distracted; the faculty of prediction and a reasonable concern with one's own interests as opposed to the indifference which may occur, for example, in cases of depression.

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1. Care as an ethical touchstone

The application of an approach based on bioethical principles or human rights means placing the individual at the centre of health care. No doubt everyone with an interest in bioethics would agree with this statement. However, its ethical scope is unclear unless we seek to identify what it means in clinical situations and in the context of caring for patients, health service users and their families. Bioethics requires us to re-evaluate and rethink the manner and form of interpersonal relationships between health professionals and users, recognising the individual being treated or cared for as the moral actor. In this context, health professionals are an essential source of information if the individual is to understand, decide, choose and act. As a result, when we seek to assess a person's competency to decide, we need to stop and analyse the communication which takes place and the relationship which has been established, in order to be sure that the individual is provided with adequate support to allow him to achieve the highest possible level of competency. My understanding is that the "problem of the competency of individuals" is not one to be resolved purely by the use of measurement tools, which to a greater or lesser degree represent an atomised view of the individual and do not point the way forward. By contrast, I would argue that tackling "the problem of competency" entails seeking to view the individual in a more global, integrated and holistic way, as I will explain below.

Nursing Care proposes a paradigm which is based on the notion that people can deal with their problems if they get the right help. Caring involves helping the individual to maintain and develop as much autonomy as possible, while recognising that everyone has their own particular way of living and of developing their health. As a result, Caring gives priority to the actual situation and context of the individual. In addition, as part of the process of caring the nurse understands that individuals take decisions about their health in crisis situations which may require more or less significant changes and which generally entail a greater degree of dependency on others than is usual. For this reason, Care is both individual and global, and it assesses health requirements and relationships from the perspective of participants.

There are many theories and models of Caring which seek to explain the phenomenon. One of these is Madeleine Leininger's theory of "Culture Care: Diversity and Universality", which I will outline briefly. Her theory includes concepts and constructs which are related to the social structure, the environment and language, to discover and obtain knowledge based on the culture supported by the individual's "world". One of the key features is the idea that culture determines and the patterns and lifestyles which influence people's decisions, as a result of which it is essential that these offer information and guidance to health professionals. This theory helps the nurse to discover and document the world of the person she is caring for, using emic viewpoints, knowledge and health practices, together with an ethics based on professional knowledge. In this way, clinical judgement guides actions and decisions in a way which is consistent with the cultural modes and specific life of each person. The relationship between health professional and care recipient is an intercultural encounter in which two "worlds" seek to share their experience and knowledge. The idea can be illustrated by the following simple example:

A 73-year-old woman is prescribed a spray by her doctor to treat her first acute asthma attack. She is told "use this". When the woman sees that the device is a spray, she uses it as an air freshener.

Is this woman incompetent to understand the proposed treatment and to follow it correctly? Should we, as a result, talk to a family member, if there is one, so that he or she can administer the treatment? Is non-compliance with the treatment due to the person's incapacity? The focus of nursing care helps us to remain alert and not to misinterpret ways of understanding, of taking decisions, of performing actions as the result of a person's incompetence. Instead, it helps us to reformulate instructions more clearly.

It is worth asking whether we can also help the individual to implement his or her decisions, even where these differ from the course proposed by health professionals, as the following example shows:

A 22-year-old man with spinal cord compression requiring surgery refuses treatment, citing his belief in non-intervention and his rejection of many of the claims of western medicine. He signs a voluntary discharge form and leaves the hospital.

An approach centred on Caring and on the importance of respecting people's lifestyles would lead us to realise that the patient's refusal of surgery meant he was not given any information or education regarding his needs: for example, safety measures with regard to possible cranial hypertension, position, potential problems of swelling, the consistency of food, dietary exclusion and prevention of constipation etc. This information would certainly have helped him to be more capable and competent to deal with his situation.

Often it is children or partners who, for a variety of reasons, believe that their relatives are incapable when they become ill and are required to take decisions. The more difficult the decision, the more likely it is that a family member will speak on behalf of the ill person. Here, too, Caring allows us to understand the need of family members for help and their own potential to understand the scope and importance of not reducing the individual's autonomy in decision-taking.

An 83-year-old patient is admitted for major respiratory difficulties and is diagnosed as having tuberculosis. His daughter requests that her father is not informed directly, and proposes that she be the one to give consent because her father was seriously ill from tuberculosis and nearly died when he was young, and lost several friends and acquaintances to the disease.

Is this person incompetent to receive the information? As a result, is it better for him not to know about what is happening and about the help which is now available? Should he continue to be afraid of tuberculosis or should the doctor ignore the daughter's information and inform the patient in order to obtain consent for treatment? Should the nurse lie when administering the medication? If we advocate a care which is centred on the actual situation of the individual, then the fear expressed by the daughter is a vital piece of information, not in order to limit the capacity of her father but to handle the diagnosis with particular sensitivity so as to ensure that it is properly understood, while we also help the daughter to relate to her father without undermining his capacity.

These examples highlight the importance of considering health care FOR and FROM the perspective of the individual, with the assessment of competence as one more instrument for getting to know who we are treating and caring for, and which should be used to provide information which does not only measure capacity.

In this sense, assessment helps us towards a better understanding of the patient, and to plan our professional actions more carefully, to tailor them to patients, and to make the necessary time available, if possible. The assessment should also seek to answer questions such as: Do we know what factors promote understanding of the clinical information? Do we create an atmosphere of trust and transparency which makes the individual feel secure and therefore helps him to understand his situation? Are we able to identify factors which have played a key role in the patient's life and which may influence his understanding? In which contexts is the information provided? And so on.

2. The importance of intuition and verification

This is a tricky matter, because our entire professional system increasingly defines competency in terms of scientific evidence. But sometimes this does not take account of the human factor. Intuition based on experience and prior knowledge is often a useful tool for good health professionals who know what is happening as a result of their proximity to the person they are caring for, without necessarily requiring objective data. It is difficult to demonstrate, but it happens. R. Alfaro, one of the first nurses to study the process of nursing, the application of scientific method to planning and implementing nursing care, stressed the need not to ignore this intuitive knowledge which allows us to identify critical situations before they arise, and sometimes to predict what might happen.

The objection raised to intuition is that it is subjective and is just another name for "common sense". Intuition should not be confused with psychological identification with a patient's situation. Our emotions can lead us to understand situations as if we were experiencing them directly and so prevent us from maintaining the distance we need if we are to understand the other. This is an obvious risk in any human relationship, and all the more so when suffering and pain are involved. However, intuition is not based either on emotion or on preconceived value judgements, as is the case with common sense, but rather on pre-conscious knowledge acquired from previous experiences which leave an imprint and means that in similar situations the intuitive individual has more background to enable them to understand what is happening: for example, when you know that something is not right even if you don't know why. Proximity is an important element which helps us to get to know people and to intuitively know what could happen, if the health professional is self-aware enough to be able to differentiate between what she thinks she has seen and what the individual has expressed.

This is not to disparage objectivity or empirical data, but rather to seek to reformulate them by drawing on other sources and other mechanisms with which to approach individuals and situations. For example, such approaches can be important when dealing with patients with high levels of dependency and verbal communication problems. Do we give sufficient value to information from non-verbal communication? Do we seek to verify our intuitions or do we just dismiss them as irrational? Do we unconsciously use judgements based more on the options available to health professionals than on the needs expressed by the individual?

Of course, we must seek to test our intuitions by asking the same question as we would ask of scientific evidence. Is what I think is happening what is really happening, or is just what I am able to see or even what I want to see? The danger of seeing what one wants is not restricted to intuition but also applies to positivist knowledge.

Team work

It may be that as nurses we have not done a good job of explaining our professional growth of recent decades, it may be that doctors find it hard to renounce their hegemony over medical power. Perhaps this only happens in certain cases, where nurses find comfort in a supposed moral neutrality which makes the doctor responsible for the whole of the care process, or perhaps there are specific doctors who do not accept that patients' health needs today are far more diverse and greater and are not restricted to medical issues. Leaving aside many observations one might make, this approach to working is of benefit to nobody, least of all to the patient and his family. Just as scientific progress has increased our knowledge of the biological aspects of illness and revealed the need for new medical specialisms which used to be covered by general medicine or surgery, it has also increased our knowledge of patients' health needs, self-care, habits and beliefs, about the processes of grieving and adaptation to illness or loss, etc. As nurses, we investigate care and how it is delivered, relationships, management models, etc. We have more and more evidence about the best approaches to take, and the contribution of nursing care to the quality of care and the outcomes obtained is becoming clearer and clearer. As a result, I believe that care dynamics must change, focusing on the patient, the health service user and his family.

Like the opinion of the doctor, care is an essential element, not only when assessing competence but also in promoting it when looking after a person who is thought to be incompetent or someone whose level of comprehension is unclear. The nurse's extensive knowledge of her patient, his situation, his family, his needs, lifestyle and motivations is absolutely essential. Furthermore, Care which is centred on the needs of life helps to increase the individual's competence because it helps him to lead his life in a way which takes account of his health needs. Nursing knowledge and medical knowledge together largely constitute the minimum shared moral basis of good team work. Both doctors and nurses are under an ethical obligation to work together, and all the more so in situations where there is reasonable doubt as to an individual's capacity or competence.

Team work refers to a form of organisation and management based on care units. I agree that the law establishes that doctors are responsible for assessing competency, but doctors and nurses must work together, sharing knowledge and responsibilities both from a legal and from an ethical perspective.

3. The institutional level

Finally, I would like to offer a brief, critical consideration regarding the institutional approach which has introduced bioethical modifications as if it were dealing with legislation. In bioethics, legal standards do not legalise acts which already occur in our healthcare culture, but instead introduce a set of standards of behaviour which require a change in professional conduct. It is impossible to consider the autonomy of individuals and their level of competency other than on the basis of Human Rights, Bioethical Principles, respect for the individual, etc. I believe we run the risk of depriving the legislation of its ethical value by applying it without first considering its meaning, without considering the technical and human knowledge we bring to it, or the time that this new kind of relationship demands.

When implementing bioethical standards, institutions have placed all the weight of the change on health professionals, relying on their sensitivity and on their individual efforts. However, there is a need for specific support combined with the provision of the resources health professionals need if they are to be able to improve the work they do. Assessing a person's competency is not any easy process, it cannot always be done quickly and in an abbreviated form, and it cannot be performed by direct care professionals alone. How can we develop communication skills in order to improve our work in the area of competence and provide relevant information which reflects the existing health organisation? How can we avoid declaring a person incompetent because of the difficulty of assessing him in a calm, considered manner? How can we avoid declaring a person incompetent instead of modifying the environment to make it more protective? How can we establish a process to assess a person's competency if there is no ongoing relationship? How can we establish ethical commitments as a part of team working by proposing ethical criteria for assessing the quality of care? How can we ensure we have the time required for all of this? There have been no pre-implementation or follow-up studies in care units with regard to Rights and Principles, and there is rarely any clear institutional planning process to promote and enable this. There is an increasing need for ethical criteria to be supported by health management and organisation, and not to rely solely on professionals in direct care.

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Drawing up ethical guidelines, recommendations and protocols is one of the recognised functions of Care Ethics Committees. Indeed, I would say this is their principal function, as there is evidence that their other two functions (the analysis of individual cases and training) are of less importance and are the focus of less activity.

Recognising this reality is important, because it helps to focus the committee on the job of drawing up, disseminating and assessing these guidelines. The consultative function, which usually involves a small number of cases, would be strengthened if the policy of producing guidelines was effective, and the same is true of the training function, because this could reflect the issues addressed by the guidelines.

The Ethics Committee of the Parc Taulí Health Corporation already has a number of documents of this type. Among others, these cover such issues as the rejection of treatment, confidentiality, non-resuscitation orders, etc, together with one addressing today's issue: capacity assessment. Why have we drawn up this guide in particular? The reasons are the following:

- Guides have to respond to the need to resolve real, practical problems. These may differ from centre to centre. For us, this was a problem which had arisen on several occasions, and we needed to find a practical solution.
- Capacity is one of the requirements for the exercise of autonomy, and we all know that the emergence of this principle has been one of the engines powering the expansion of bioethics. If we need to preserve the autonomy of patients, we must be capable of analysing the requirements which underpin it, and one of these is capacity.

The document was drawn up following a well-established process: an interdisciplinary group including members drawn from outside of the ethics committee was set up, a literature review was carried out, etc. It is worth noting that one of the problems we faced was the lack of models which explicitly address this issue.

It is not enough simply to produce a document of this sort. That is clear. You have to disseminate it, explain it and apply it. We used the usual mechanisms to disseminate it (intranet, internal magazine, general sessions etc.). A series of specific training seminars were also attended by over a hundred health staff. However, this is always a work in progress, and one which must be continuously reviewed.

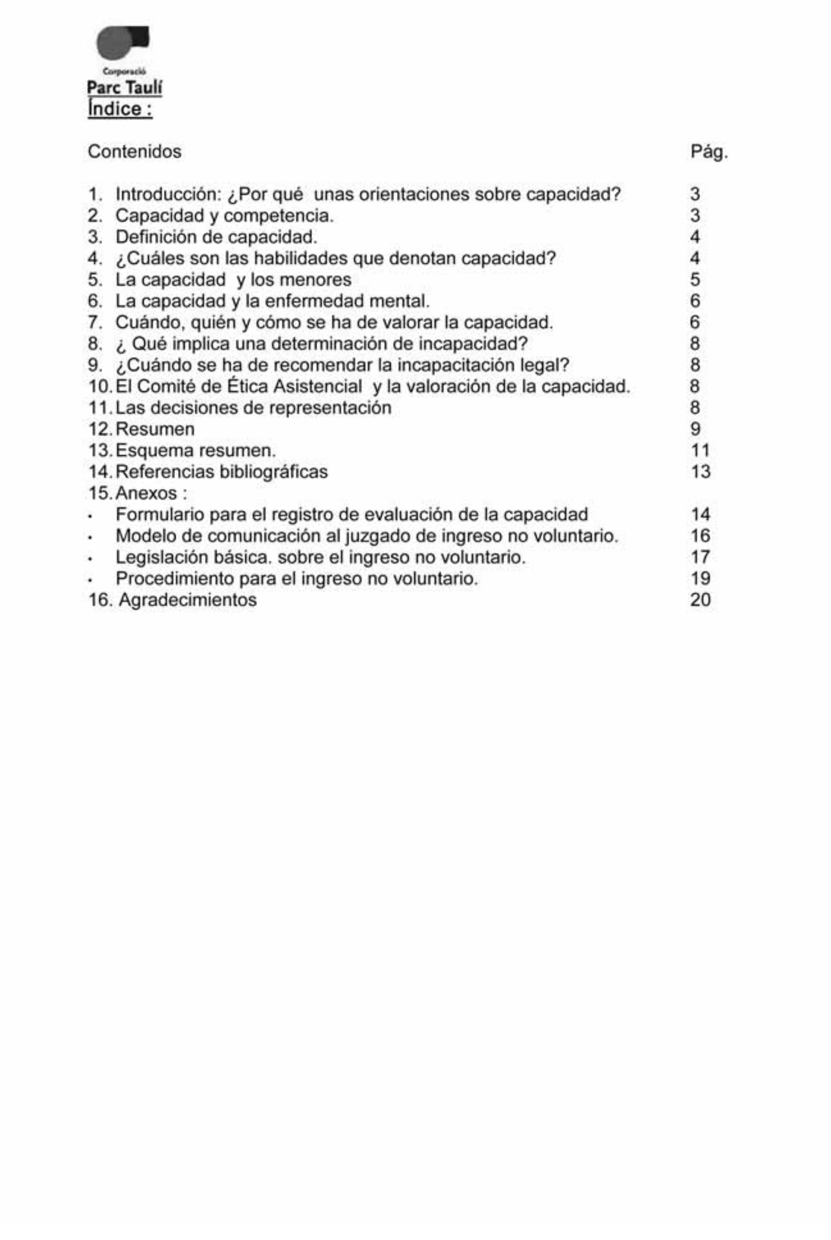
Our experience, after several years, is that the *Guide for the assessment of capacity* is an essential tool and is very useful in dealing with individual cases, in drawing up other documents upon which this topic has a bearing, and in setting out our "knowledge" and "agreements" with regard to this issue. Agreements and goals of this sort are fundamental because they enable us to make progress in our discussion of how they are to be achieved.

Corporació
Parc Taulí

Orientaciones para evaluar la capacidad

Comité de Ética Asistencial

Sabadell, Abril de 2003



Corporació
Parc Taulí

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Introducción: ¿Por qué unas orientaciones sobre capacidad?

La capacidad es uno de los requisitos del proceso de consentimiento informado junto a la información, la voluntariedad y la autenticidad. El cumplimiento de estas cuatro condiciones garantiza una toma de decisión autónoma y los profesionales sanitarios tienen la obligación moral y legal de respetar y promover la autonomía. Esto último está claramente reconocido en la legislación vigente, tanto nacional como internacional de nuestro entorno, así como en los diferentes códigos deontológicos profesionales. Pese a todo ello no existe un consenso sobre los criterios, estándares y protocolos para evaluar la capacidad, situación que puede provocar incertidumbre en la práctica clínica. Para paliar esta deficiencia se han elaborado las presentes "Orientaciones" que son normas institucionales para mejorar la calidad asistencial en este aspecto concreto.

La utilidad de una guía de esta naturaleza queda resaltada por dos regulaciones legales recientes :

- La *Llei 21/2000, de 29 de desembre, sobre els drets d'informació concernent la salut i l'autonomía del pacient, i la documentació clínica*, al ocuparse del derecho de autonomía de los pacientes (art. 7.2) atribuye al médico la responsabilidad de apreciar la competencia o capacidad del paciente para prestar su consentimiento sobre las actuaciones médicas procedentes.
- La *ley 41/2002 de 14 de Noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica* la cual se expresa en parecidos términos en su artículo 5.3.

De tal manera que, por expresa previsión legal, será el criterio del médico responsable (integrado con el de todos los profesionales sanitarios que compongan el equipo asistencial) el que sirva para determinar, en función del estado físico o psíquico del paciente, sí éste se encuentra o no, en aquel momento, en situación de competencia o de capacidad suficiente para adoptar las decisiones correspondientes o para hacerse cargo de su situación.

Este documento tiene la finalidad de orientar a los profesionales sanitarios en aquellos supuestos conflictivos o en los pudieran surgir dudas sobre la capacidad del paciente, a los efectos de facilitar la decisión relativa a sí el consentimiento informado ha de ser prestado en aquel caso por el propio paciente, o se ha de acudir, una vez constatada su incapacidad o incompetencia, al representante para que lo sustituya a dichos efectos.

Por otro lado, tampoco debe olvidarse que la citada Ley prevé (en su art. 7.3) que, apreciada la incapacidad del paciente para adoptar decisiones sobre su tratamiento médico, se pueden llevar a cabo las actuaciones indispensables desde el punto de vista clínico a favor de su salud, sin necesidad de recabar ningún consentimiento sobre ellas.

2. Capacidad y competencia

Frecuentemente capacidad y competencia son utilizadas como sinónimos. En nuestra tradición jurídica se suele utilizar más el término capacidad con dos acepciones:

- la capacidad de obrar de hecho implica la presencia de determinadas habilidades, fundamentalmente psicológicas, de la persona para gobernar los hechos y las obligaciones de que es titular (en este caso la toma de decisiones sanitarias). Siempre se refiere a situaciones concretas (una toma de decisión específica). Es el tipo de capacidad de mayor interés para los conflictos que se producen en el ámbito sanitario. En este documento nos referiremos a ella con el término **"capacidad".**
- la capacidad de obrar de derecho o "legal" hace referencia al reconocimiento legal de la potestad del sujeto para ejercer eficazmente sus derechos y deberes. Como norma general, se presume capacidad de obrar legal plena a las personas mayores de 18 años. La capacidad legal sólo puede ser modificada mediante sentencia judicial que requiere un proceso de incapacitación regulado por el Código Civil. La declaración de incapacitación conlleva el nombramiento de un representante. En este documento nos referiremos a ella con el término **"capacidad legal".** En la situación específica de las

decisiones sanitarias, como se verá más adelante, este tipo de capacidad de presupone a partir de los 16 años.

3. Definición de capacidad

Por principio, todo sujeto mayor de edad (ver el apartado especialmente dedicado a los menores), es legalmente capaz, pero esta capacidad legal no es suficiente a todos los efectos ni en todo momento, desde el punto de vista de su autonomía de voluntad en relación con las decisiones relativas a su salud. Es decir que aun gozando de la presunción legal de capacidad, puede encontrarse en una situación de incapacidad para decidir sobre su salud, esta situación de incapacidad se caracteriza por un estado del individuo definido por " *déficits funcionales juzgados como suficientemente graves para que no puedan dar respuesta a una toma de decisión específica teniendo en cuenta las consecuencias potenciales* " (definición extraída de: GrissoT, Appelbaum PS. Assessing competence to consent to treatment . A guide for physicians and other health professionals . Nueva York : Oxford University Press , 1998)

Independientemente de la definición antes expresada hay que tener en cuenta los siguientes aspectos a la hora de tratar la capacidad :

- No hay una incapacidad general, sino que es específica para cada tipo de tarea o de decisión.
- La capacidad puede variar en el tiempo y hay que intentar restaurarla para tratar de incorporar al sujeto en la toma de decisión.
- La exigencia de capacidad ha de ser proporcional al tipo de decisión (Ej. se ha de exigir mayor capacidad para rechazar un tratamiento de soporte vital que para el rechazo de otro tratamiento que no tenga esta consideración).
- Aun apreciada la incapacidad del paciente se ha de procurar su participación, tanto como sea posible, en la toma de decisiones.
- Las decisiones relativas a la salud de un paciente incapaz han de ser lo más objetivas y racionales posibles a su favor y en respeto de su dignidad personal.

4. ¿ Cuáles son las habilidades que denotan capacidad?

A continuación se enumeran una serie de habilidades cuya ausencia permitirá sospechar la incapacidad (en buena medida seguimos la propuesta de Grisso y Appelbaum).

1. Habilidad para **comprender** la información relevante en la situación en cuestión (por ejemplo someterse a una intervención quirúrgica, a una transfusión, etc...). No basta con la aseveración de que ha comprendido, sino que hay que verificarla. Presupone un proceso cognitivo y está relacionada con el nivel de inteligencia. Esto último es muy importante pues hay que adecuar el lenguaje al nivel de inteligencia y/o educativo de cada paciente. La comprensión puede verse afectada por desórdenes psiquiátricos como la esquizofrenia o la depresión ; Del mismo modo puede suceder con trastornos neurológicos o por la sordera o efectos secundarios de algunas medicaciones.

2. Habilidad para **apreciar la "significación"**:implica "contextualizar" la información a la propia situación, "hacerla suya" teniendo en cuenta sus valores y creencias. Su falta se asocia con la negación y la falta de "insight" (comprensión). Implica evaluar las razones de por qué elige un determinado curso de acción, razones que han de tener significación para su situación en particular.
   Es fundamental aquí la valoración de las consecuencias, en qué medida las considera y pondera.

3. Presencia de **razonamiento**: presupone la existencia de un mínimo proceso lógico a la hora de abordar la decisión, que podría seguir el siguiente guión:
   - La consideración del problema a tratar (focalizar el tema).
   - La consideración de las diferentes alternativas existentes.
   - La consideración de las consecuencias posibles a las diferentes alternativas y su probabilidad de ocurrencia.

- La evaluación final.

  En buena medida, sí no totalmente, la presencia de este apartado supone también los dos anteriores, aunque aquí se hace más hincapié en el proceso cognoscitivo de orden lógico de deliberación.

4. La habilidad para **expresar** una elección, la cual no forzosamente ha de ser en forma verbal. Sin embargo la interpretación de esta habilidad ha de ser unívoca. Sin la expresión de una elección es imposible entrar a valorar las otras habilidades. Por el contrario, como única habilidad tampoco tiene valor. En resumen: su falta implica la incapacidad, pero su presencia no significa la capacidad.

5. La capacidad y los menores

La consideración del menor como sujeto pleno de titularidad de derechos y el reconocimiento de una capacidad progresiva para ejercerlos se halla ampliamente respaldado por argumentaciones de carácter ético y psicológico que han tenido su correlato en nuestro marco legal. El sustrato de las primeras es una consecuencia tanto del pluralismo moral de nuestras sociedades como del conocimiento del desarrollo moral (esencialmente a través de Piaget y Kohlberg). Entre las normas legales que sustentan esta posición se hallan en diversos artículos del Código Civil (Título VII de las relaciones paterno-filiales), La Ley Orgánica 1/1996, de 15 de Enero (de Protección Jurídica del Menor), así como la Constitución Española en su artículo 39.4.

Las decisiones relativas a cuestiones de salud concernientes a los denominados derechos personalísimos que, en la medida de que existan habilidades para ello, se han de ejercer por el menor. El razonamiento de apartados anteriores (evidenciar la presencia de las habilidades señaladas) también se ha de aplicar a los menores de edad y no hay que partir del " a priori": *sí es menor, es incapaz.* La presencia de tales habilidades supone un proceso gradual que se inicia entorno a los 12 años y que, generalmente, culmina entre los 16 y 18 años. La capacidad no es, pues, un proceso de "*todo o nada*", sino progresivo. Este margen de edades está reconocido en diversas normas legales: en el Código Civil al tratar la mayoría de edad (18 años). También hay disposiciones específicas como Ley 21/2000, de 29 de diciembre, sobre los derechos de información concerniente a la salud y la autonomía del paciente, y a la documentación clínica (Parlamento de Cataluña) donde se establece el consentimiento a partir de los 16 años. De igual forma sucede con la Ley 41/2002 de 14 de Noviembre.

Teniendo en cuenta todo lo mencionado, como directrices concretas hay que tener en cuenta lo siguiente:

- A menores por debajo de los 12 años no se les ha de considerar capaces para la toma de decisiones sanitarias, lo cual no implica que se les haga partícipes, en la medida de lo posible, de proceso diagnóstico - terapéutico. En la misma situación se encontrarían los incapacitados legalmente. Esta propuesta se justifica en que a esta edad los menores no tienen las habilidades previamente reseñadas. Quienes tienen que tomar la decisión son entonces sus padres o tutores, teniendo estos la limitación que implica el ejercicio de la patria potestad, la cual se ha de aplicar en "beneficio" del menor. La consideración de beneficio o perjuicio se establece por consenso y en caso de disputa se ha de acudir al juez.
- En el intervalo entre los 12 y los 16 años se ha de valorar la competencia intelectual y emocional del menor para comprender el alcance de la concreta intervención o actuación que haya de realizarse sobre su salud, es decir se ha de indagar sobre las habilidades que denotan capacidad, de igual modo que con los adultos.
  El resultado negativo de la valoración sobre su capacidad implicaría que las decisiones corresponderían a los padres, sin perjuicio de que se habría de oír la opinión del menor al respecto.

  El resultado positivo del juicio sobre su competencia habilitaría al menor para consentir personalmente sobre el acto médico con relación al cual se le haya considerado competente para decidir

Sin embargo hay que tener presente lo siguiente:

- La elección de una alternativa por el menor que implique unas consecuencias que en nuestro entorno sociocultural se entiendan como claramente perjudiciales (un posible ejemplo sería el rechazo de una apendectomía o de una transfusión en presencia de riesgo vital) se ha de valorar muy prudentemente y, como criterio general, de forma restrictiva. En caso de producirse esta situación hay que ponerla en conocimiento de los responsables del ámbito y realizar una consulta al Comité de Ética Asistencial.
- Como se ha dicho anteriormente la exigencia de capacidad ha de ser proporcional a la importancia o "gravedad" de la decisión.

En nuestro ordenamiento legal se presupone la capacidad de los menores a partir de los 16 años para dar personalmente su consentimiento en el ámbito de su salud, excluyendo las decisiones relacionadas con los supuestos de interrupción voluntaria del embarazo, ensayos clínicos y práctica de técnicas de reproducción humana asistida. Lo cual les equipara a estos efectos a los mayores de edad, sin perjuicio de que se puedan plantear dudas sobre su capacidad, las cuales se habrían de resolver de acuerdo con las orientaciones de este documento.

Sin embargo, en el margen de edad entre los 16 y 18 años se ha de informar a los padres (o tutores) y la opinión de estos se ha de tener en cuenta para la toma de decisión correspondiente.

6.La capacidad y la enfermedad mental.

Frecuentemente se identifica incapacidad con enfermedad mental y viceversa. La asunción de este postulado es errónea, pues no *necesariamente* se ha de dar tal vinculación.

Es sabido que la presencia de determinadas enfermedades mentales puede alterar la percepción, la atención, la memoria y el razonamiento así como también otras habilidades afectivas y emocionales. La tarea del profesional de Salud mental consiste en evidenciar trastornos psicológicos y valorar en qué medida inciden sobre las habilidades exigidas para la capacidad. Algunos ejemplos son muy evidentes (ejemplos de enfermedades mentales que distorsionan la percepción de la realidad como pueden ser la psicosis o la dependencia alcohólica).

7. Cuándo, quién y cómo se ha de valorar la capacidad

7.1 ¿Cuándo?

La evaluación de la capacidad implica los prerrequisitos de conciencia y ausencia de riesgo vital inmediato (que imposibilite, por premura de tiempo, la evaluación).

En general, en todos aquellos supuestos en que a priori se planteen dudas sobre la capacidad del paciente, y especialmente en aquellas situaciones en que concurran circunstancias del tipo de las se exponen a continuación:

- Cuando en el ejercicio de la autonomía para la toma decisiones sanitarias se produzcan circunstancias que cuestionen las habilidades anteriormente mencionadas. Hay ejemplos muy evidentes como las psicosis , las demencias o la presencia de alteraciones orgánicas agudas tales como hipoxemia o dolor difícilmente controlable.
- Cuando se produzcan cambios súbitos en el estado mental también puede ser un indicador.
- Sin embargo lo más que más habitualmente lleva a cuestionar la capacidad es el **rechazo de tratamiento**, sobre todo en función de sus consecuencias (beneficio esperado).
- Cuando se propongan tratamientos de elevado riesgo y bajo beneficio.
- Como regla general, la participación en proyectos de investigación exige un alto grado de capacidad. Por lo anterior, cuando existan dudas sobre la conciencia, comprensibilidad, etc.. que puedan afectar a la capacidad del sujeto se tendría que justificar su entrada de aludiendo a las características propias del objetivo de la investigación.

7.1.1. El ingreso no voluntario: Un ejemplo de rechazo al tratamiento es el rechazo al ingreso cuando éste es un medio necesario para tratar al paciente. Cabe distinguir dos situaciones:

7.1.1.1. Enfermedad mental o trastorno psíquico: Una situación, frecuente en la praxis psiquiátrica pero no sólo limitada a este tipo de pacientes, es el rechazo al tratamiento cuando éste precisa de un ingreso. En el tratamiento de enfermedades psiquiátricas graves no es infrecuente la hospitalización del paciente y la oposición de éste al estar alterada su capacidad por la descompensación psicopatológica.

Esta situación está expresamente regulada en diversas normas legales, tanto estatales o autonómicas, que son las siguientes (su texto se reproduce en el Anexo 2):

- Ley 9/1998, de 15 de Julio , del Código de Familia de la Legislación Autonómica en Cataluña:
- Ley 1/2000 de 7 de Enero, de Enjuiciamiento Civil (BOE núm. 7, de 8-1-2000) . Artículo 763.

Las obligaciones derivadas de las normas anteriores son:

- La necesaria autorización judicial previa para el internamiento no voluntario, a excepción de la situación de urgencia en que se ha de solicitar en el plazo inmediato de las 24 horas siguientes. El mismo criterio rige para la autorización de tratamientos, durante el ingreso, que impliquen peligro de la vida o de la integridad física del enfermo. El juez cada dos meses revisa la situación de la persona, situación de la que han informar al juez periódicamente los facultativos responsables.
- Estas obligaciones también son válidas para los menores aunque estén sometidos a la patria potestad.

La notificación al juzgado de este tipo de situaciones se ha de hacer conforme al modelo que se reproduce en el Anexo 2.

7.1.1.2.Otras situaciones: Aunque las normas reproducidas con anterioridad se refieren al ámbito específico del enfermo psiquiátrico , también creemos que son válidas para cualquier otra situación en que el paciente se encuentre sea incapaz de hecho (un ejemplo frecuente pueden ser los enfermos con demencia) y sea imprescindible el ingreso. A tal efecto se tendrá que utilizar el mismo modelo de comunicación que aparece en el Anexo 2 (ver apartado 9).

En el Anexo 4 se puede ver el Procedimiento para el ingreso no voluntario (adaptado de Recomanacions per a l'ingrés no voluntari i la práctica terapèutica de mesures restrictives. Comitè de Bioètica de Catalunya. Març de 2002)

7.2. ¿Quién?

La valoración de la capacidad para la toma de decisiones sanitarias es obligación de los profesionales sanitarios fundamentada en su deber de preservar la autonomía y procurando el bien del enfermo (evitando que el enfermo incapaz se dañe).

Se ha de realizar de forma interdisciplinar, teniendo un papel relevante el médico responsable del paciente. Es esencial recoger la opinión de todos aquellos profesionales que tienen interacción con el enfermo, en especial las enfermeras por su especial proximidad y conocimiento de los pacientes.

De acuerdo a las consideraciones hechas en un apartado anterior, el psiquiatra puede colaborar en valorar sí la presencia de una alteración mental interfiere en el funcionamiento de las habilidades exigidas.

Es importante reconocer que la evaluación de la capacidad no es una responsabilidad, ni función exclusiva del profesional de salud mental.

7.3. ¿Cómo? Cuestionario-guía para evaluar la capacidad

Como se ha señalado en inicio no hay criterios, estándares o protocolos consensuados nacional o internacionalmente; sin embargo se han publicado algunos instrumentos o procedimientos que pueden ser de ayuda en la valoración de la capacidad. Hemos escogido dos de ellos (Aid to Capacity Evaluation y el Test MacArthur) para configurar el cuestionario-guía que aparece en el anexo. También se han tenido en cuenta, de forma especial, algunas consideraciones de la Escala Móvil de James Drane.

Antes de proceder a la evaluación de la capacidad hay que cuestionarse porqué se realiza, partiendo de la presunción de capacidad del paciente.

La cumplimentación de este cuestionario es **aconsejable para evaluar adecuadamente la capacidad.** Se aconseja conservar la evaluación realizada en la historia clínica del paciente con expresa mención de la conclusión en el curso clínico.

8. ¿Qué implica una determinación de incapacidad?

- Determinar que una persona es incapaz para tomar una determinada decisión es un hecho importante, pues la toma de decisiones sanitarias conciernen a los denominados derechos personalísimos de la persona. La determinación de incapacidad no exime del proceso de consentimiento informado y por ello se ha de nombrar un representante (ver apartado 11).

El representante elegido se ha de hacer constar expresamente en la historia clínica del paciente.

En caso de existir un documento de Voluntades Anticipadas se ha de tener en cuenta lo señalado por él. Se ha de adjuntar copia del documento en la historia clínica del paciente o se ha de hacer constar expresamente en la misma.

9. ¿Cuándo se ha de recomendar la incapacitación legal?

El proceso de incapacitación legal presupone que las condiciones de incapacidad se van a prolongar durante largo tiempo, en la mayoría de las ocasiones indefinidamente. Existen algunas enfermedades (demencias, por ejemplo) que en algún momento de su evolución generan una incapacidad del paciente para la toma de este tipo de decisiones. sí concurren estas circunstancias se ha de animar a la familia al inicio de un proceso de incapacitación legal. Se ha de tener en cuenta que el proceso puede ser largo, lo cual se ha de ponderar con el pronóstico del paciente. Mientras no exista una declaración judicial de incapacidad se ha de cumplimentar el formulario de evaluación de la capacidad, de forma obligada, y señalar expresamente en la historia clínica quién es el representante del paciente[*]. Después será necesario comunicarlo al Juez solicitando un tutor o defensor judicial.

Si no existe familia, lo cual puede ocurrir en algunas ocasiones en el ámbito socio-sanitario, el responsable de esta área actuará como guardador de hecho. Un documento interno, acompañado del formulario para la evaluación de la capacidad, ha de ratificar tal decisión. Para el inicio del proceso de incapacitación legal y/o mientras este se concrete, se han de seguir los mismos criterios señalados en el párrafo anterior

10. El Comité de Ética Asistencial(CEA) y la valoración de la capacidad.

El CEA puede ayudar en la valoración de la capacidad ante casos puntuales, su función es asesora y de facilitación de documentación. En este sentido hay que recordar que uno de los objetivos del CEA es velar por el respeto de los derechos y deberes de los pacientes y estas orientaciones intentan colaborar en este sentido.

11. Las decisiones de representación.

Una vez que se ha determinado que el paciente es incapaz hay que entrar en las llamadas "decisiones de representación". Para ello:

a) El primer criterio a utilizar es el de respetar la voluntad del propio paciente. Esta voluntad puede estar registrada o manifestada de diferentes formas. La más propia es aquella que se realiza a través del documento de voluntades anticipadas (del cual existe un modelo en nuestro centro), ya sea indicando cual es la voluntad del paciente o designando un representante en su lugar.

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[*] *Se utiliza este término aunque desde un punto de vista estrictamente jurídico es inadecuado. Desde esta perspectiva no existe represenntación legal ni representantes en tanto no hayan sido designados tras el correspondiente procedimiento de incapacitació y , en consecuencia, no es correcto referirse al "representante del paciente" ya que se trata de una situación previa a la declaración judicial de incapacidad. A pesar de todo lo mencionado entendemos que el término se puede utilizar en el sentido " de aquel que conoce mejor los deseos y/o valores del paciente".*

b) Si no es posible utilizar el criterio anterior, el segundo criterio es el de acudir al representante . Éste, lógicamente, tendría que ser aquel que mejor los deseos y/o valores del paciente. Este razonamiento nos lleva a identificar en los familiares, de forma habitual, a estos representantes. Así cabe respetar la línea de parentesco (de acuerdo a nuestra legalidad vigente) aunque éste no ha de ser un criterio absoluto).

c) Si no es posible acudir a los dos criterios anteriores, hay que intentar determinar los mejores intereses del paciente de acuerdo mediante un juicio intersubjetivo de los profesionales que lo cuidan y se enfrentan a esta situación. Para garantizar las máximas garantías de este proceso éste se ha de realizar en consulta al Comité de Ética Asistencial. Este procedimiento tratará de determinar que alternativas de tratamiento benefician más al paciente.

El orden de utilización de estos criterios es jerárquico, es decir, se ha de utilizar en primer lugar el primero, sí no es posible se ha de emplear el segundo y así sucesivamente.

Sin embargo pueden existir situaciones en donde nos podamos cuestionar alguno de los criterios anteriores. Alguna de estas situaciones son las siguientes:

- Cuando se determina que las familias (en sentido extenso del representante del paciente) no están cualificadas para decidir. Algunos argumentos para justificar esta posición podrían ser los siguientes: situaciones previas conocidas de abusos o daños hacia el sustituido, cuando pueda existir un conflicto de intereses que pueda perjudicar al paciente o que los representantes sean incapaces.
- Cuando las decisiones tienen consecuencias muy importantes. Por ejemplo que impliquen un acortamiento de la vida que puede ser evitado o que ocasionen pérdidas significativas de funciones fisiológicas o psicológicas.
- Cuando la decisión va en contra de la buena práctica asistencial (indicaciones del tratamiento).
- Cuando la decisión del representante no es coherente con los deseos previos del paciente.

En toda y cada una de estas situaciones se ha de consultar al Comité de Ética el cual valorará se es necesario acudir a alguna instancia legal.

12. Resumen

La capacidad es una de las **condiciones esenciales para ejercer la autonomía**, la cual se ha de respetar y promover en la toma de decisiones sanitarias.
Hay que diferenciar la "capacidad" de la "capacidad legal". La segunda se presupone en el caso de decisiones sanitarias a partir de los 16 años (salvo algunas excepciones). La primera se refiere a la **"capacidad de obrar de hecho"** la cual implica la presencia de determinadas habilidades, fundamentalmente psicológicas, de la persona para gobernar los hechos y obligaciones; en este caso de las decisiones sanitarias que le competan. Esta última es la que más nos interesa.

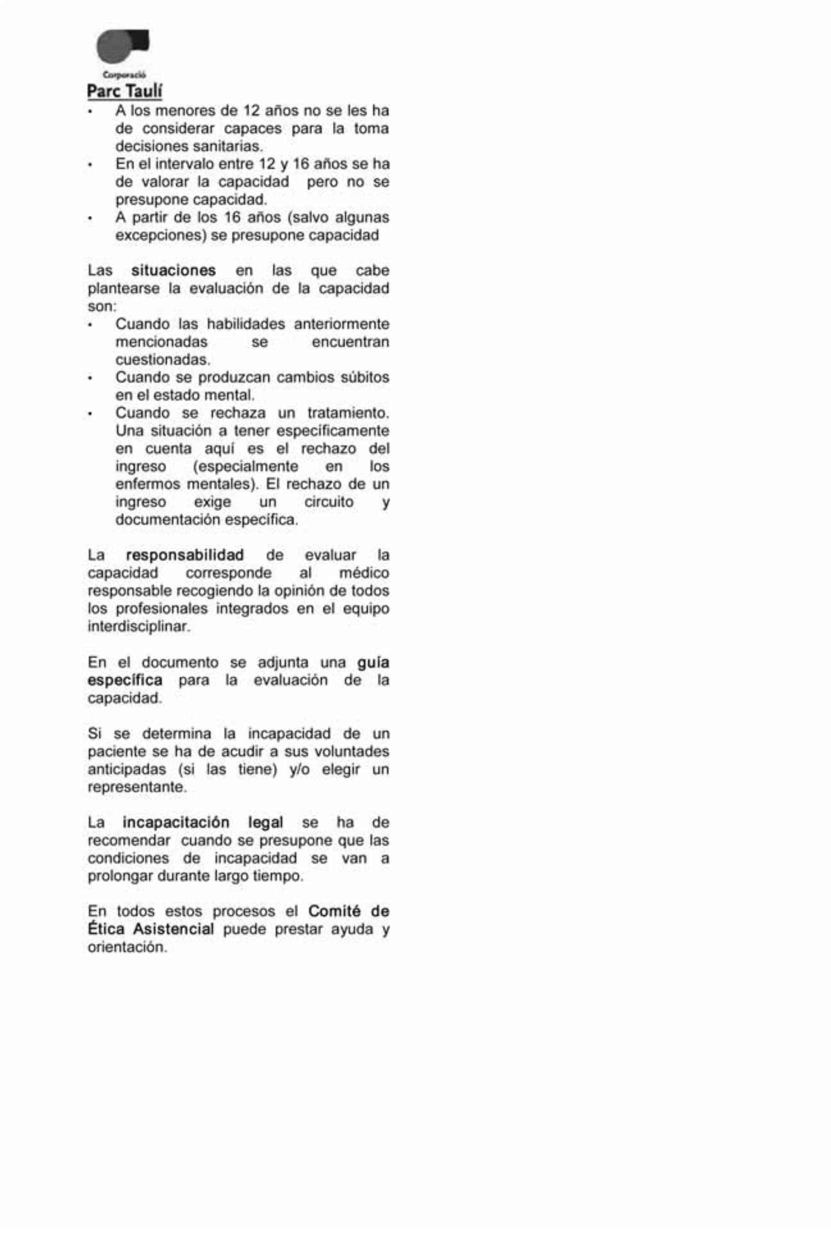
Se ha de partir del presupuesto de capacidad. Del mismo modo hay que tener en cuenta que:

- La capacidad puede variar en el tiempo y hay que intentar restaurarla.
- La exigencia de capacidad ha de ser proporcional al tipo de decisión .
- Aun apreciada la incapacidad del paciente se ha de procurar su participación, tanto como sea posible , en la toma de decisiones.
- Las decisiones relativas a la salud de un paciente incapaz han de ser lo más objetivas y racionales posibles a su favor y en respeto de su dignidad personal.
- No hay una incapacidad general, sino que es específica para cada tipo de decisión.

Las **habilidades a explorar para evaluar la capacidad** son:

- Comprensión de la información relevante.
- Apreciación de la significación.
- Presencia de razonamiento.
- Posibilidad de expresión de la decisión.

Los **menores** suponen un apartado especial, en donde hay que tener en cuenta lo siguiente:



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- A los menores de 12 años no se les ha de considerar capaces para la toma decisiones sanitarias.
- En el intervalo entre 12 y 16 años se ha de valorar la capacidad pero no se presupone capacidad.
- A partir de los 16 años (salvo algunas excepciones) se presupone capacidad

Las **situaciones** en las que cabe plantearse la evaluación de la capacidad son:

- Cuando las habilidades anteriormente mencionadas se encuentran cuestionadas.
- Cuando se produzcan cambios súbitos en el estado mental.
- Cuando se rechaza un tratamiento. Una situación a tener específicamente en cuenta aquí es el rechazo del ingreso (especialmente en los enfermos mentales). El rechazo de un ingreso exige un circuito y documentación específica.

La **responsabilidad** de evaluar la capacidad corresponde al médico responsable recogiendo la opinión de todos los profesionales integrados en el equipo interdisciplinar.

En el documento se adjunta una **guía específica** para la evaluación de la capacidad.

Si se determina la incapacidad de un paciente se ha de acudir a sus voluntades anticipadas (si las tiene) y/o elegir un representante.

La **incapacitación legal** se ha de recomendar cuando se presupone que las condiciones de incapacidad se van a prolongar durante largo tiempo.

En todos estos procesos el **Comité de Ética Asistencial** puede prestar ayuda y orientación.

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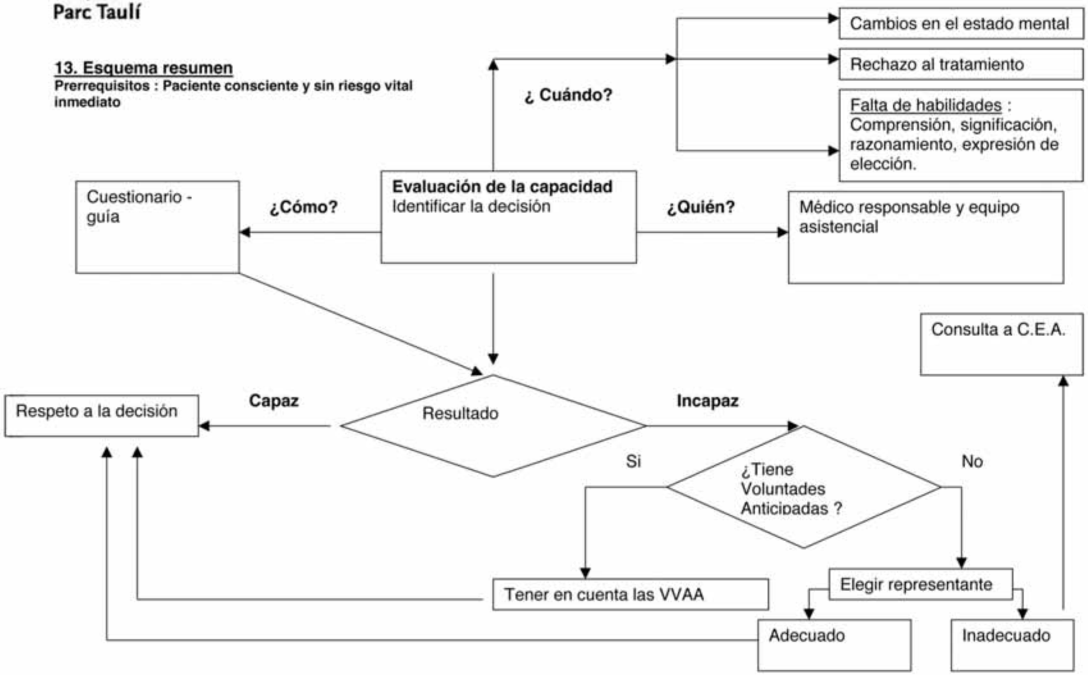
13. Esquema resumen

Prerrequisitos : Paciente consciente y sin riesgo vital inmediato



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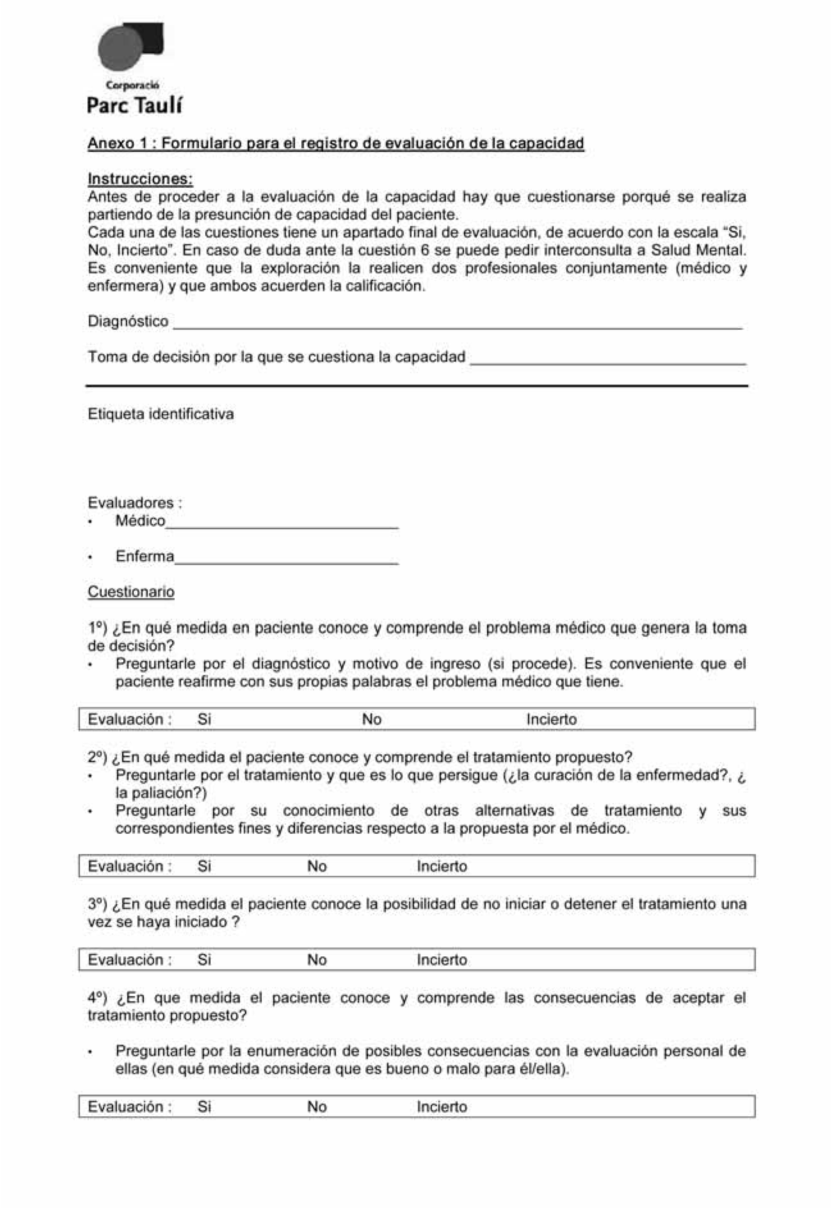

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Anexo 1 : Formulario para el registro de evaluación de la capacidad

Instrucciones:

Antes de proceder a la evaluación de la capacidad hay que cuestionarse porqué se realiza partiendo de la presunción de capacidad del paciente.
Cada una de las cuestiones tiene un apartado final de evaluación, de acuerdo con la escala "Si, No, Incierto". En caso de duda ante la cuestión 6 se puede pedir interconsulta a Salud Mental. Es conveniente que la exploración la realicen dos profesionales conjuntamente (médico y enfermera) y que ambos acuerden la calificación.

Diagnóstico ____

Toma de decisión por la que se cuestiona la capacidad ________________________

Etiqueta identificativa

Evaluadores :
- Médico__________________________

- Enferma__________________________

Cuestionario

1º) ¿En qué medida en paciente conoce y comprende el problema médico que genera la toma de decisión?
- Preguntarle por el diagnóstico y motivo de ingreso (si procede). Es conveniente que el paciente reafirme con sus propias palabras el problema médico que tiene.

Evaluación : Si No Incierto

2º) ¿En qué medida el paciente conoce y comprende el tratamiento propuesto?
- Preguntarle por el tratamiento y que es lo que persigue (¿la curación de la enfermedad?, ¿ la paliación?)
- Preguntarle por su conocimiento de otras alternativas de tratamiento y sus correspondientes fines y diferencias respecto a la propuesta por el médico.

Evaluación : Si No Incierto

3º) ¿En qué medida el paciente conoce la posibilidad de no iniciar o detener el tratamiento una vez se haya iniciado ?

Evaluación : Si No Incierto

4º) ¿En que medida el paciente conoce y comprende las consecuencias de aceptar el tratamiento propuesto?

- Preguntarle por la enumeración de posibles consecuencias con la evaluación personal de ellas (en qué medida considera que es bueno o malo para él/ella).

Evaluación : Si No Incierto

5º) ¿En que medida el paciente conoce y comprende las consecuencias de rechazar el tratamiento propuesto?

- Preguntarle por la enumeración de posibles consecuencias con la evaluación personal de ellas (en qué medida considera que es bueno o malo para él/ella).

Evaluación : Si No Incierto

6º) ¿En qué medida el paciente padece algún tipo de trastorno psiquiátrico y/o cognitivo que pueda afectar a la respuesta de las preguntas anteriores?

Evaluador externo: Si No Médico

- La presencia de enfermedades neurológicas puede ser importante.
- Existen diversos instrumento fiables para medir el deterioramiento cognitivo : Global Deterioraton Scale, Mini-Mental (las puntuación por debajo de ...... denotan déficits cognitivos importantes).

- Comentarios

Evaluación : Si No Incierto

Una vez realizadas las cuestiones anteriores hay que responder a la cuestión de sí es capaz o no el paciente para la toma de decisión concreta. Esta decisión se tiene que realizar de forma deliberativa por profesionales que cuidan al paciente (en sesión clínica por ejemplo).
A la hora de realizar esta evaluación hay que tener en cuenta la "importancia" de la decisión, la cual se puede calibrar en función de las consecuencias, de acuerdo a la regla siguiente: A mayores beneficios esperados y menores riesgos el estándar de capacidad ha de ser menor. El siguiente cuadro puede ser explicativo al respecto (extraído de J. Drane).

Nivel de capacidad Tipos de decisión	*Bajo*	*Medio*	*Alto*
Consentir	Tratamiento eficaz para enfermedad aguda Beneficio alto y riesgo bajo Alternativas limitadas Trastorno grave, sufrimiento intenso, amenaza vital inmediata	Enfermedad crónica /diagnóstico dudoso. Enfermedad aguda con tratamiento de resultado incierto Equilibrio entre riesgos y beneficios	Tratamiento incierto (que no existan evidencias de su eficacia)
Rechazar	**Tratamiento incierto (que no existan evidencias de su eficacia)**	**Enfermedad crónica /diagnóstico dudoso.** **Enfermedad aguda con tratamiento de resultado incierto** **Equilibrio entre riesgos y beneficios**	**Tratamiento eficaz para enfermedad aguda.** **Diagnóstico cierto** **Beneficio alto/ Riesgo bajo** **Alternativas limitadas** **Trastorno grave, sufrimiento intenso, amenaza vital inmediata**

¿Es el paciente capaz ? : Si No

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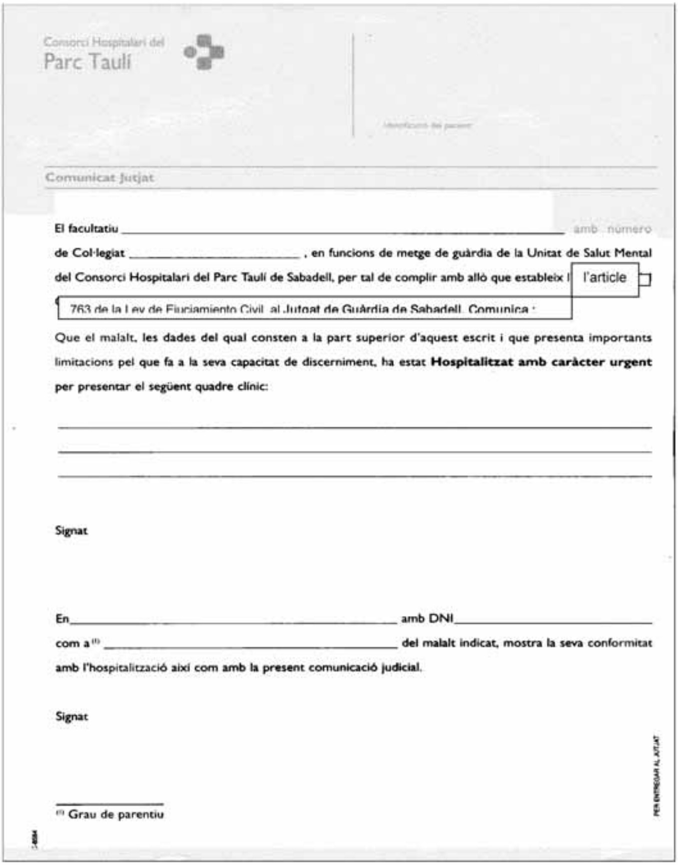
Anexo 2 : Modelo de comunicación al juzgado de de ingreso no voluntario



Consorci Hospitalari del
Parc Taulí

Identificació del pacient

Comunicat Jutjat

El facultatiu ______________________________ amb número **de Col·legiat** ______________ **, en funcions de metge de guàrdia de la Unitat de Salut Mental del Consorci Hospitalari del Parc Taulí de Sabadell, per tal de complir amb allò que estableix l** l'article ☐ 763 de la Ley de Enjuiciamiento Civil, al Jutgat de Guàrdia de Sabadell. Comunica :

Que el malalt, **les dades del qual consten a la part superior d'aquest escrit i que presenta importants** limitacions pel **que fa a la seva capacitat de discerniment**, ha estat **Hospitalitzat amb caràcter urgent per presentar el següent quadre clínic:**

____

____

____

Signat

En ______________________________ **amb DNI** ______________________

com a [1] ______________________________ **del malalt indicat, mostra la seva conformitat amb l'hospitalització així com amb la present comunicació judicial.**

Signat

PER ENTREGAR AL JUTJAT

---

[1] Grau de parentiu

Anexo 3 ; Legislación básica

- Ley 9/1998, de 15 de Julio , del Código de Familia de la Legislación Autonómica en Cataluña:

*"**Article 255. Autorització judicial i comunicació de l'internament***
1. L'internament d'una persona per raó de trastorn psíquic, qualsevol que en sigui l'edat, en una institució adequada i tancada requereix autorització judicial prèvia si la seva situació no li permet decidir per si mateixa. No es requereix aquesta autorització si per raons d'urgència mèdica cal l'adopció d'aquesta mesura, però en aquest cas el director o directora del centre on s'efectuï l'internament ha de donar compte del fet al jutge o jutgessa del partit judicial a què pertany el centre, en el termini màxim de vint-i-quatre hores. La mateixa obligació es produeix quan la persona voluntàriament internada es troba en una situació que no pot decidir lliurement per si mateixa la continuació de l'internament.
2. Un cop s'ha efectuat la sol.licitud de l'internament o s'ha comunicat l'internament, el jutge o jutgessa, després de fer l'exploració personal i escoltar el dictamen del facultatiu o facultativa que designi i l'informe del ministeri fiscal, ha d'acordar motivadament l'autorització o la denegació de l'internament o de la continuació d'aquest. El jutge o jutgessa, cada dos mesos, ha de revisar la situació de la persona internada.
En el cas que es pretenguin aplicar tractaments mèdics que puguin posar en perill la vida o la integritat física o psíquica de la persona afectada, hi és aplicable el que estableix l'article 219 per a aquests tractaments, i les funcions atribuïdes per l'article 219 al tutor o tutora, en aquest supòsit, són exercides pels familiars de la persona internada o, si no n'hi ha, pel jutge o jutgessa."

*"**Article 219. Autorització prèvia***
1. La persona titular de la tutela necessita autorització judicial per a:
a).Internar la persona incapacitada en un establiment adequat.
b).Aplicar a la persona incapacitada tractaments mèdics que fonamentalment puguin posar en greu perill la seva vida o la seva integritat física o psíquica.
Les mesures indicades per l'apartat 1 poden ésser preses sense autorització prèvia si el fet d'obtenir-les pot comportar un retard que impliqui un greu risc per a la persona tutelada, per a altres persones o per als béns. En aquest cas, s'ha de comunicar al jutjat que correspongui i al consell de tutela, si n'hi ha, la decisió adoptada, en el termini de vint-i-quatre hores, com a màxim."

- Ley 1/2000 de 7 de Enero, de enjuciamiento civil (BOE núm. 7, de 8-1-2000). Artículo 763:

Artículo 763. Internamiento no voluntario por razón de trastorno psíquico.
1. El internamiento, por razón de trastorno psíquico, de una persona que no esté en condiciones de decidirlo por sí, aunque esté sometida a la patria potestad o a tutela,, requerirá autorización judicial, que será recabada del tribunal del lugar donde resida la persona afectada por el internamiento.
La autorización será previa a dicho internamiento, salvo que razones de urgencia hicieren necesaria la inmediata adopción de la medida. En este caso, el responsable del centro en que se hubiere producido el internamiento deberá dar cuenta de éste al tribunal competente lo antes posible y, en todo caso, dentro del plazo de veinticuatro horas, a los efectos de que se proceda a la preceptiva ratificación de dicha medida, que deberá efectuarse en el plazo máximo de setenta y dos horas desde que el internamiento llegue a conocimiento del tribunal.
En los casos de internamientos urgentes, la competencia para la ratificación de la medida corresponderá al tribunal del lugar en que radique el centro donde se haya producido el internamiento. Dicho tribunal deberá actuar, en su caso, conforme a lo dispuesto en el apartado 3 del artículo 757 de la presente Ley.
2. El internamiento de menores se realizará siempre en un establecimiento de salud mental adecuado a su edad, previo informe de los servicios de asistencia al menor.

3. Antes de conceder la autorización o de ratificar el internamiento que ya se ha efectuado, el tribunal oirá a la persona afectada por la decisión, al Ministerio Fiscal y a cualquier otra persona cuya comparecencia estime conveniente o le sea solicitada por el afectado por la medida. Además, y sin perjuicio de que pueda practicar cualquier otra prueba que estime relevante para el caso, el tribunal deberá examinar por sí mismo a la persona de cuyo internamiento se trate y oír el dictamen de un facultativo por él designado. En todas las actuaciones, la persona afectada por la medida de internamiento podrá disponer de representación y defensa en los términos señalados en el artículo 758 de la presente Ley.

En todo caso, la decisión que el tribunal adopte en relación con el internamiento será susceptible de recurso de apelación.

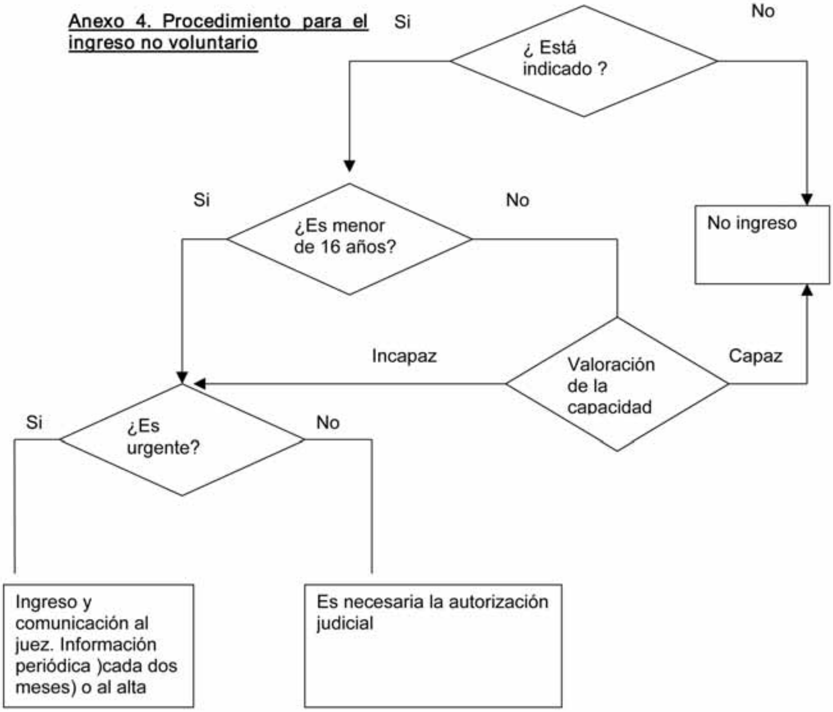
4. En la misma resolución que acuerde el internamiento se expresará la obligación de los facultativos que atiendan a la persona internada de informar periódicamente al tribunal sobre la necesidad de mantener la medida, sin perjuicio de los demás informes que el tribunal pueda requerir cuando lo crea pertinente.

Los informes periódicos serán emitidos cada seis meses, a no ser que el tribunal, atendida la naturaleza del trastorno que motivó el internamiento, señale un plazo inferior.

Recibidos los referidos informes, el tribunal, previa la práctica, en su caso, de las actuaciones que estime imprescindibles, acordará lo procedente sobre la continuación o no del internamiento.

Sin perjuicio de lo dispuesto en los párrafos anteriores, cuando los facultativos que atiendan a la persona internada consideren que no es necesario mantener el internamiento, darán el alta al enfermo, y lo comunicarán inmediatamente al tribunal competente.

Anexo 4. Procedimiento para el ingreso no voluntario



16.Agradecimientos

- A todos los miembros del CEA por su colaboración en la realización de este documento, en especial a aquellos que conformaron el grupo de trabajo para la elaboración de este documento (M. Carmona, C,Albert, G. Diestre, A. Mariné, y P. Hernando).
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- A J.A. Seoane (Doctor en derecho y Experto en Bioética Sanitaria. profesor de Filosofía del derecho en la Universidade da Coruña) por sus rigurosas y múltiples aportaciones.

SUMMARY

At this seminar we wanted to show how much work remains to be done and to stress that as health professionals we must raise our awareness of the issues. Showing respect towards our patients' desires at times may also involve analysing their competency to understand and decide; just as much as whether the patient is free to do so, and has the information required to do it properly. This is a difficult task, and one for which we are poorly prepared. And yet it is one which we must know how to perform, which we cannot treat as optional, but which forms part of our responsibility. In other words, it is one we must perform rationally, on the basis of thorough knowledge and applying a clear method. The documents contained here, of which the speakers gave an oral summary, represent a good start.

We wanted to begin with two people who have been closely involved with these issues. James Drane, one of the genuine pioneers in this area, explained its basis and its early stages; Pablo Simón, who has made the area a focus of study, discussed how it has developed and the prospects for the future. The papers were followed by a panel discussion which brought together several medical professionals who discussed their views of the problems encountered when applying these principles: we heard from a nurse, from a psychiatrist, and from a member of an ethics committee which has already taken practical steps in this regard.

James Drane's paper reminded us of the basis of this discipline. He has spent many years reflecting upon this subject, and his theoretical contribution, now accepted as a classic, seeks to encourage professionals to take their commitment more seriously. It is his belief that, if professionals do not act as they should, then their decisions easily outstep the framework of the clinical relationship where they should remain, and are exposed to the mercy of legal or administrative inclemency. Using the case of Terri Schiavo, a recent example in his country, he showed us to just what extremes things can go. He reminded us that professional responsibility, which he analysed in historical terms, must accept the patient's limits. Except that these limits may give rise to doubts about the competency of the person who sets them, even if that person is legally competent. How should we assess this? This is a difficult task and, with his famous Sliding Scale, James seeks to provide support to the inexperienced health professional. His aim is, above all, to help such professionals understand what we are talking about when we refer to competency, and to stress that this variability means we must take a case by case approach. The examples he gave us for each of the three levels were highly illustrative, and formed part of a very clear and practical presentation, with a stress on education rather than on regulation. Anyone can grasp and remember the general principles of how to apply such an approach, which I believe should be included in the training of medical professionals. All in all, a thought-provoking talk.

The discussion identified the paternalistic bias which means that it is the health professional who ultimately identifies the situation in which the decision is to be taken as more or less “difficult”, and who requires the patient to show (or demonstrate?) a greater or lesser degree of competency. Drane recognised this situation, and responded to it by appealing to responsibility.

Pablo Simón took us further, setting out the need for deeper consideration of the practical applications by providing valid instruments which are as sensitive and specific as possible. He argued that, in order to increase the genuine participation of patients, we have to reduce false negatives and false positives in our assessment of “capacity”, the term which he prefers to use. This was his stance in a terminological controversy which remains unresolved, even in the English-speaking world, and which was also explored during the discussion. Against this it was argued that, while the term *competency* has other meanings (for example, when we refer to the competency of a professional or a court) in the context of the patient it is clear that this refers to the patient’s *capacity*, to his de facto capacity, to his capacity to make decisions. In the context, the meaning is clear. So, when we refer to an incompetent patient there is no need to add anything else, while we do need to specify further if we refer to an incapable patient, as we would have to specify whether this judgement is legal or clinical. It is to be hoped that time and discussion, rather than judicial inertia, decide in favour of one or other term.

Pablo gave a very thorough account of practical attempts to assess de facto capacity, from the first efforts in psychiatry, neurology and geriatrics up to the present. He described the most significant contributions during recent decades with regard to assessment criteria and standards, and also considered tools and protocols used in clinical and research settings. This up-to-date, critical overview of the literature enabled us to identify both the target and the attempts to achieve it, and also how difficult it is to create the sort of simple but reliable instrument we need. The text Pablo has provided demonstrates why he is and will remain the leading authority to whom we in Spain will refer when working in this area.

Montserrat Busquets, speaking from her perspective as a lecturer in nursing, explained the central importance of care if we are to reach a realistic assessment of the world of the patient in all its dimensions, to ensure that we have the fullest and most integrated understanding of it possible. She reminded us that this vision, based as it is on the frequency and intimacy of the caring relationship, can be decisive in the assessment of patient competency, more so even than any instruments designed for this purpose. During the discussion she stressed that her aim was not to denigrate objectivity, the value of which she was keen to stress, but rather that team work should facilitate a better assessment of the situation by drawing on all of the knowledge about the individual which has been acquired to date. And it should be recognised that doctors often take decisions about the competency of their patients on the basis of little objective information and, unfortunately, based solely on partial knowledge which has not been checked or discussed with colleagues.

Rogeli Armengol, speaking as a psychiatrist, warned of the need to distinguish between those situations where the patient loses the capacity to make judgements about reality, such as is the case in psychosis, depression or severe mania, and which would be responsible for clear incompetence, and personality disorders or emotional states such as grief or sorrow, in which competency may be partially reduced but where this can be more easily reversed. The question always arises as to whether the help of a specialist should be used to help identify where the line lies between these states. Another interesting issue he raised was the need to distinguish between, on the one hand, the respectable irrationality of a belief shared by members of a given community and, on the other hand, the inexplicable, individual stance which we therefore in principle find less reasonable. In the discussion he pointed out the paradox which underlies this reality: that a bizarre position is more difficult to respect when it is new and individual and perhaps therefore more independent, than when it is shielded by a group which often demands uncritical acceptance. Does it make sense for us to request a competency assessment of those who simply refuse to accept a blood transfusion while we do not require one of those who claim to be Jehovah's Witnesses?

This brings us back to the note of caution we sounded at the start of the day when we noted that the simple fact of assessing somebody's competency is in itself an invasion of their privacy and that we must therefore have good reason for doing so and must proceed with great caution. Indeed, in his paper Rogeli warns of the danger associated with competency assessment instruments if they are misused.

During the discussion, in addition to this caution and these dangers, the public was surprised by the difficulty of ensuring that the instruments under discussion are rigorous but not rigid, can be customised while still allowing for comparisons between them, and increase the safety and autonomy of the patient rather than augmenting his submission and dependency.

Pablo Hernando, as a highly experienced member of a care ethics committee, presented a guide containing recommendations to address these fears by providing carefully considered support for clinical practice in the modern context, without being excessively complex, and which encourages a responsible approach which reflects many of the contributions to the seminar discussion. Indeed, it could also provide a model to help all of us to get started, to take the first step in our health centres; to follow the path outlined here. One thing is certain; that along the way we will meet again. And I hope that the journey includes opportunities to rest and to reflect upon whether we are travelling in the right direction, how we are performing, how we can improve the care we provide to our patients, the paradoxes we encounter, the risks we have identified, the help we can offer or receive. And I hope that in that event we are fortunate enough to receive the kind of hospitality we have enjoyed from the Víctor Grífols i Lucas Foundation and the Letamendi Foundation. And I also hope that we are able to enjoy the same companionship: both the colleagues whose presentations it has been my privilege to introduce and those who have come to enter into dialogue with them and whom I hope to meet again at our next event.

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Surgeon. Víctor Grífols i Lucas Foundation
Bioethics Advisory Committee of Catalonia.

LIST OF SPECIALISTS INVITED TO TAKE PART IN THE DISCUSSION

Salvador Altimir
Consultant Geriatrician at the Hospital Universitario Germans Trias i Pujol in Badalona

Rogeli Armengol
Psychiatrist and psychoanalyst. Psychiatry Service, Hospital General Vall d'Hebron in Barcelona

Montse Busquets
Lecturer in the Department of Nursing and Basic and Surgical Medicine at the School of Nursing at the University of Barcelona
Member of the Board of Trustees of the Víctor Grífols i Lucas Foundation

Pablo Hernando
Master in Bioethics. President of the Catalan Society for Bioethics
President of the Care Ethics Committee. Consorci Hospitalari del Parc Taulí

Jordi Trelis
Catalan-Balearic Society for Palliative Care

CHAIRMAN

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Surgery Service of the Germans Trias i Pujol University Hospital of Badalona and Vice-president of the Víctor Grífols i Lucas Foundation

Publications

Bioethics Monographs:

14. *Addressing the problem of patient competency*
13. *Health information and the active participation of users*
12. *The management of nursing care*
11. *Los fines de la medicina* (Spanish translation of *The Goals of Medicine*)
10. *Corresponsabilidad empresarial en el desarrollo sostenible* (Corporate responsibility in sustainable development)
9. *Ethics and sedation at the close of life*
8. *El uso racional de los medicamentos. Aspectos éticos* (The rational use of medication: ethical aspects)
7. *La gestión de los errores médicos* (The management of medical errors)
6. *Ethics of medical communication*
5. *Problemas prácticos del consentimiento informado* (Practical problems of informed consent)
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2. *Ethical and scientific standards in research*
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1. *Social Perceptions of Biotechnology*

Ethical Questions:

1. *¿Qué hacer con los agresores sexuales reincidentes?* (How to deal with repeat sexual offenders?)

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