

# Elements necessary for informed consent in patients with schizophrenia

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## Abstract

In this paper we want analyze informed consent theory as applied to schizophrenia. To that end, we identify the necessary elements for a process to be autonomous, voluntary and reported in sufficient quality and quantity, and for delegation of decision making authority. Finally, we analyze the exceptions that are accepted, in both medical praxis and legal norms, for medical intervention without the patient's consent: urgency, patient's waiver to be communicated, therapeutic privilege, and incapacity to make decisions.

**Keywords:** Informed consent. Schizophrenia. Patients-personal autonomy.

## Resumo

### Elementos necessários ao consentimento informado em pacientes com esquizofrenia

Neste artigo se pretende analisar a teoria do consentimento informado aplicada à esquizofrenia. Para tanto se apresentarão os elementos necessários: que seja um processo autônomo, voluntário, informado em quantidade e qualidade suficiente e que a pessoa tenha competência para tomar decisões. Finalmente, analisamos as exceções aceitáveis, tanto ao nível da *práxis* médica como de normativa jurídica, para realizar uma intervenção médica sem o consentimento do paciente: urgência, renúncia do paciente a ser informado, privilégio terapêutico e incapacidade para tomar decisões.

**Palavras-chave:** Consentimento informado. Esquizofrenia. Pacientes-autonomia pessoal.

## Resumen

### Elementos necesarios al consentimiento informado en pacientes con esquizofrenia

En este artículo queremos analizar la teoría del consentimiento informado aplicado a la esquizofrenia. Para ello, exponemos cuáles son los elementos necesarios: que sea un proceso autónomo, voluntario, informado en cantidad y calidad suficiente, y que la persona tenga competencia para tomar decisiones. Finalmente, analizamos las excepciones que se aceptan, tanto a nivel de *praxis* médica como de normativa jurídica, para realizar una intervención médica sin el consentimiento del paciente: urgencia, renuncia del paciente a ser informado, privilegio terapéutico e incapacidad para tomar decisiones.

**Palabras-clave:** Consentimiento informado. Esquizofrenia. Pacientes-autonomía personal.

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Declara não haver conflito de interesse.

Informed consent (IC) is the requirement to obtain an autonomous authorization of a person to be treated in a medical intervention or to participate in clinical research, having been previously informed. It is a communicative process but not a formal requirement based on a simple signature. It must not be understood as an isolated fact but as a process which is an integral and continued part of decision making.

To be able to talk about informed consent the process has to be reasonable, reasoned and dialogued, making references to the proposed diagnosis, prognosis, aetiology and therapy. It is about giving the patient the opportunity of taking part of the decision making. Besides, it must not be understood as an isolated and punctual fact but as a readjustment process according to the person's progression. Because of this reason, the IC has to be conceived in a *revisable and changeable* way. We are talking about, therefore, a model of shared decision making<sup>1</sup>.

In the specific case of mental health, during psychiatric interviews the professional and the patient usually talk about which the positive and negative effects of the pharmacological treatment and/or the electroconvulsive therapy are. Particularly, unfavourable reactions or the effectiveness of the treatment are mentioned. With that, it is opened the opportunity to inform the patient again about how to take the medication or even the possibility of changing the dose and/or the drug.

In this sense, the United Nations (UN) in their *Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care*, 1991, in their 9<sup>th</sup> article, propose that the *treatment and caring of each patient is based on a plan prescribed in an individual way, examined with him, periodically revised, changed if appropriate and applied by professionally qualified personal*<sup>2</sup>.

In this way, what is intended is a continued assessment of the evolution of the symptomatology, of the deficiencies that presents in the different areas (cognitive, behavioural, etc.) of the unfavourable reactions of the treatment. Therefore, given the fact that it is not easy to find which drug is the most appropriate to the patient's clinical profile, it is usual to find in schizophrenia cases of morbid pathology: distress, depression, toxics consumption, etc<sup>3</sup>, and because every person tolerates drugs in different ways, a periodic revision is needed about the effectiveness of the treatment. If there is not a symptomatology improvement, a therapeutic

change is needed, either increasing or decreasing the dose, changing the type of drug or trying other tracts. In those cases, the IC will be done again telling the patient why the treatment has to be changed, what is wanted with this change, how and when this treatment will be made and which unfavourable reactions it can lead to.

The problem is when instead of conceiving it as a dialogic process it is perceived as a process based on a signature. In that case, its true value is lost, that is to say, the respect for the patient's autonomy. Victoria Camps states that *when the patient is shown a paper that he has to sign without too many previous explanations, what happens is that we have passed from a paternalistic clinical relationship to a simply contractual one*<sup>4</sup>. On his behalf, Marc Antoni Broggi<sup>5</sup> thinks that the practices which evidence more the oversight of the real objective of the IC, for the sake of a legal requirement, are: the delivery of the information in writing, replacing, with that, the dialogue; and the supremacy of the exhaustiveness of information above its comprehension.

## Elements of the informed consent

During the IC process the professionals have to verify the existence of a series of elements that are needed in order to be able to make an *informed consent* properly and not to simply *give consent to a medical process*. In this sense, it is needed the person to be *autonomous*, to be able to make the decision in a *voluntary* way, to be *informed in sufficient quantity and quality* and to have *competence* to make a decision.

### Substantially autonomous action

To Beauchamp and Childress<sup>6</sup> personal autonomy refers to the capacity of people to determine themselves, being exempt from intern and extern conditionings. There are two essential conditions regarding that: a) *freedom* – acting independently of the influences intended to control and, b) *being an agent* – to have de capacity of acting intentionally. Thereby, respecting autonomous decisions imply, at least, that people have opinions, that they can choose and act based on their own values and/or beliefs. On their behalf, Beauchamp and Faden, cited by Simón, think that *X acts autonomously if and only if he acts a) intentionally; b) comprehending what he does, and c) free of controlling influences*<sup>7</sup>.

**Voluntary**

The fact that the IC has to be a totally voluntary act has been one of its essential characteristics from its beginnings. In this way, the *Nuremberg Code* stipulates that IC has to be voluntary and informed. Also the Belmont Inform establishes that the consent has to have the following characteristics: information, comprehension and wilfulness. Therefore, the process has to be free, or rather, not conditioned nor forced.

Manipulation is another procedure through which a person can be forced and it consists of influencing him so that he acts in a certain way, having been informed in a biased or fraudulent way. It has to be clear that *persuasion*, which is not incompatible with wilfulness, consists of inducing or moving somebody with reasons in order him to think or do something, but being ultimately the person the one who decides in a free way. To Júdez and Simón<sup>8</sup> persuasion is a positive factor and it is of a big help for those patients who have difficulties with analysing benefits and risks among different options of treatment. The problem rests in knowing when persuasion finishes and when manipulation begins.

In patients suffering from schizophrenia persuasion is very important, because they can reflect lack of interest about things, attention problems, lack of *insight*, reason why they can think they do not need medication, etc. It is supposed, though, that they require support and motivation to be able to choose a concrete therapeutic line. In this way, the professional and the family play a crucial role for the patient to decide between an option or the other.

Now then, this persuasion must become coercion in situations in which the patient does not want any kind of medication because of its unfavourable reactions or when he lacks of consciousness of the pathology. This coercion is justified legally, psychopathologically and ethically, to avoid attitudes that can damage themselves or the others, worsening the symptomatology, among others. A clear example of that is the involuntary outpatient treatment<sup>9</sup>. Therefore, even IC in this way is not "voluntary", we believe it is, *prima facie*, justifying why it is being put at risk his own life and the others'.

**Enough quantity and quality of information**

For a person to be able to decide if he accepts or rejects a treatment, or if he takes part in a clinical test, it is necessary to be correctly informed. In the informative process four aspects take part: a) What

information give?; b) How to give it?; c) To whom? And; d) In which context give it in writing?.

- **What information to give?**

It is obvious that in emergency and/or dangerous situations there will be no time to elaborate the IC; however, once that period has finished the communicative process will take place normally. Thus, the professional has to inform the patient and his family about the illness. They have to know which pathology he has (symptoms, cause...) so that they can understand the situation and the way it can affect everyday life.

A major effort has to be done to expose which are the effective treatments and with what purpose. In first place, the clinic has to explain which are the different therapeutical procedures. As a first option the antipsychotics are shown, but there are also effective psychological methods that aim to a holistic treatment and the psychosocial rehabilitation<sup>10-13</sup> psycho-educative interventions of the family, training in social abilities, cognitive-behavioural therapies for psychotic symptomatology and integrated multimodal packages that address the cognitive deficiencies as well as the social ones. It is also available the electroconvulsive therapy, although it usually is a second option and indicated in catatonia cases, acute episodes of psychomotor and cognitive-behavioural disorder, when there is not a good response to the pharmacologic treatment or the patient does not tolerate it, if the patient is pregnant, etc<sup>14</sup>.

Nowadays, the first option treatment are antipsychotics, which can be classified in *typical*, of 1<sup>st</sup> generation, such as chlorpromazine, haloperidol, etc., and *atypical*, of 2<sup>nd</sup> generation, clozapine, quetiapine, olanzapine, among others. In general, they are efficient because they quickly eliminate the psychotic symptomatology (hallucinations, deliriums, etc.). Mainly, atypical are used because they have a larger response to negative symptoms, less affectation to the cognitive worsening, prevent from relapses, improve life quality, have a minor grade of extrapyramidal effects, among others<sup>15</sup>.

This kind of drugs, meanwhile, implies a series of unfavourable reactions that the patient and the family have to know: weight gain, anxiety, Parkinson's disease, akathisia (worry sensation and tension), sedation, sleepiness, extrapyramidal effects, late dyskinesia, etc. Late dyskinesias are characterized by a series of abnormal involuntary movements that can be produced in the head, limbs or trunk. This aspect is important because if they are produced they can be irreversible, for life, and be-

sides this there is no anticholinergic medication that can treat those symptoms<sup>16</sup>. Empirical studies show that despite communicating the patient properly about the late dyskinesias, there is not a decrease; in general, of the acceptance of the treatment<sup>17-19</sup>, therefore there are no reasons to not inform about it.

To the correct fulfilment of the process of informed consent we must communicate about: a) *risks of the treatment*: adherence, interactions (food, drinks, drugs...), doses, unfavourable reactions, stop of the medication, etc.; b) *benefits of the treatment*: good approach and fast elimination of positive and negative symptomatology and; c) information about the monitoring: how long the medication has to be taken, monitoring of the visits, when the medication starts having therapeutical effects, instructions of medicine administration, other possible unfavourable reactions, etc.<sup>20</sup>.

This has to be the information related to the pharmacologic treatment, which is the one frequently used; however, there are also effective psychotherapies that should be communicated. In this sense, it should be informed which the effective ones are and for what clinical situations. So, although pharmacologic treatment is the first choice for schizophrenia, in the explanation of the different treatments the existence of psychotherapy must be also mentioned. Jesús Sánchez and Javier Sánchez<sup>21</sup> affirm that it is convenient to communicate, and in particular when it is a long-duration psychotherapy, about: a) diagnosis used and recommendation for the treatment; b) its possible risks and potential benefits; c) alternative treatments, d) necessity of the psychotherapy; e) economic availability and; f) evaluation of the patient response to that treatment. The patient has to have the right to discuss the alternatives to the professional proposal.

Finally, it has to be informed that if it is precise and necessary the possibility of electroconvulsive treatment is possible. In that case, the clinic has to notify the unfavourable reactions, highlighting the most frequent ones: affectation to the memory, confusion and hypertension<sup>22</sup>.

Professionals, when they inform they patients, focus on the different treatments and their unfavourable reactions, but it is also necessary to wonder what kind of information the patients *wish to receive*. In the El-Wakeel study, Taylor and Tate<sup>23</sup> reveal that patients were interested, among other aspects, in which the risks and difficulties of the treatment were, the therapeutical alternatives, the change in their life quality due to the treatment, which the con-

sequences of not following the prescription would be and the information about the procedure during the staying in the hospital.

In conclusion, in Spain, the recognition of the patient's right to be informed is nothing more than the legislative monitoring in matters of health: the Law 41/2002, in its 10<sup>o</sup> article, exposes which basic information the professionals have to give in any medical intervention: a) the relevant consequences the intervention may cause for sure; b) the risks related to the patient's personal or professional circumstances; c) the probable risks that appear in normal circumstances, according to the experience or science state, or those related to the intervention in question and, d) the counter-indications<sup>24</sup>.

- **How to give it?**

Informed consent must not be understood as an isolated fact but as a process which is an integral and continued part of the care relationship. With it, a more active participation in the decision making is given to the patient.

Which criteria do we follow when it is time to inform the patients and their families? It is usual to use the "criteria of a reasonable person", that is to say, that information which satisfies the necessities of a reasonable person who was in the same circumstances. Nevertheless, this stance does not have into account the concrete characteristics of the patient and/or the family, that after all are the ones who have to understand the information. For this reason, it has more sense using "the subjective standard", which establishes that informative necessities have to be evaluated regarding *real* necessities of the concrete patient who has to send out the consent.

Therefore, the particular characteristics of the person are the ones which must determine *the quantity, the rhythm, the limits and the shape of the informative process*<sup>25</sup>, so that the patient can assimilate the information, elaborate it and put it in relation with his desires and preferences. For this reason, information has to be understandable, avoiding the use of technical terms that may make comprehension difficult. Besides this, information has to be sufficient and presented in a way which prevents the patient and/or his family from feeling "flooded" of information.

That informative process has to be done in a dialogue context in which it should be tried to *find other values which enable to increase comprehension, make it easy the process of deliberation and help us to correct the misunderstanding, if it exist-*

ed<sup>26</sup>. In order to do that, the professional has to make those “hidden values” appear in the care relationship, because in that way it can be appreciated which the patient’s and his family’s values are, their fears, worries... And it is also possible that the patients want to be informed not in order to be part of the decision making but to prepare themselves psychologically to face the treatment or the effects in everyday life of the clinical characteristics of the illness<sup>27</sup>. In patients suffering from schizophrenia there is usually fear about how to manage daily life, how to face a relapse, etc.

### Can information improve the capacity of making decisions?

As we will see when we talk about the competition issue, patients suffering from schizophrenia can have cognitive problems; however, it has been empirically shown that they are not less capable of making decisions than the rest of people. For this reason, if we want to focus the informative process to the concrete characteristics of the patient, we will have to take into account those difficulties. To do that, different empirical studies<sup>28-30</sup> analyse how the presentation of information can be done with the objective of improving the patient’s understanding.

The conclusions to which these studies arrive are that psychiatric patients probably need more time to process key concepts, not being enough only one presentation of relevant information, in such a way in some occasions it is needed to repeat key information to a better comprehension, being possible to do it in an interview or in a telephonic discussion. Remembering the patients they can ask about any aspect they do not understand is positive to establish a feedback between professionals and patients. These studies indicate that patients comprehend information in a better way if it is presented in a *powerpoint*, with graphics (before, during and after), which at the same time has to be read aloud to revise those aspects which are important. Explanatory videotaping of the process have also positive results in the comprehension of the information.

In those studies it is confirmed that the way in which the information is presented, in comparison to the classic oral or written procedure almost without interaction between the professional and the patient, improves comprehension, so that a greater number of patients can be catalogued as *competent* for the decision making.

### In which contexts does IC have to be given in writing?

There are certain criteria related to the therapeutic diagnosis or treatment that indicate it is better to give an IC in writing: 1) those procedures which are invasive; 2) those diagnostic or treatment procedures which imply risks or notorious and predictable problems that affect daily life and; 3) the more doubtful the effectiveness of a diagnostic or treatment procedure is, a more careful informative process will be required, which implies a writing support<sup>31</sup>.

In the psychiatric field it should be given in writing in pharmacologic treatments and electroconvulsive therapy, since they have a series of risks and problems that may significantly affect life quality and even have irreversible repercussions for the person.

- **To whom?**

At the beginning, the professional has to inform only the patient, considering that he is the main affected, about his psychopathology and treatments, although it is frequent for the patient to go to the sanitary center, above all in the entrance, accompanied by his relatives, so if the patient authorizes it, we have to inform the family as well. The big majority of the patients usually live with his family, so they also have to know the illness, how it affects, how to act in case of recurrence, etc. Family, besides this, can also act as a support to make a better therapeutic observance, a reduction of ambient stress, reinforcing cognitive and social abilities, etc.

In some occasions, it is also necessary to inform the family if the patient cannot make decisions in case of legal incapacity, because of being under age or having lack of competence. In that case, a legal representative, tutor or family is needed to be in charge of the communicative process and giving the consent.

In the case of decision making by representation, the following criteria must be used: 1) The *subjective criteria* has the aim to apply the previous instructions that the person has expressed and it can be in an oral or written way, although the most usual way is a document of advanced will; 2) The *substitute opinion criteria* is the one in which a competent person makes decisions in the name of another person who is incompetent and has to have as a reference the wishes, preferences, etc. of the incapable person not those of the substitute one and; 3) The *major benefit or the best interest criteria* is always used when the person has never

been declared competent, or if he has not given serious arguments regarding that, if he does not have any family or relatives who can supply information, choosing only in order to look for the major benefit evaluated from the person's life quality<sup>32</sup>.

### Competence for the decision making

For an action to be substantially autonomous it has to show capacity or competence for a specific aim. In decision making it is talked about "capacity of behaving", that is to say, the internal conditions that allow the person fulfilling his rights and obligations. Even so, it has to be distinguished between "legal capacity or capacity of right" from "fact capacity". The first one refers to the requirements that the legislation asks for, by means of which the subject aptitude to exercise his rights and make valid acts is recognised. The second one is related to the subject's aptitudes, here and now, to do that act and not other<sup>33</sup>.

This last term is related to the one of "competence", which is in certain way its specification in the health field; we use it *to describe the state of a patient who can, legitimately, participate in decision making regarding his diagnosis and his illness' treatment, because he has the aptitudes and the psychological abilities needed to warranty that his decision expresses a sufficient grade of personal autonomy*<sup>34</sup>. Now then, it has to be reflected in a determined context; show the relevant capacities: a person can be capable of doing an action but incapable of another or even vary through time. Therefore, for an action to be substantially autonomous it has to reflect competence or "fact capacity" to fulfil a concrete task in a precise moment.

Empirical studies that evaluate competence usually focus on the analysis of 4 criteria: *comprehension, reasoning, assessment and expression of a choice*<sup>35-37</sup>. Comprehension refers to the ability of a person to understand the diagnosis and treatment of his illness. This means that the patient has to have enough ability to be able to remember and understand the information that the professional is giving him. The best way to see it is asking him to *paraphrase* it, that is to say, to explain with his own words which clinic diagnosis he has and which treatment is the most appropriate.

The second criterion is the one of assessment and it consists of the capacity of relating the information with his own situation. In the end what is expected is to analyse if he knows which the nature

of his diagnosis is and if he is conscious that the proposed treatment can benefit him. The reasoning is centered in the analysis of the ability to process and analyse the information, weighing the different therapeutic alternatives related to the unfavourable reactions and its possible impact on their everyday lives. Finally, the expression of a choice refers to the ability to communicate what decision he has taken regarding proposed the medical treatment.

Now then, the evaluation of the competence has to be focused on the reasons why he chooses one option and not on the option itself. The fact that a person rejects a treatment that *is recommended does not mean it is an incompetent decision. The right to autonomy also* includes the option of being able to reject a medical treatment, according to Law 41/2002 of November 14<sup>th</sup>, articles 2.3 and 2.4. Besides this, we do not have to forget that there is a possibility for a psychiatric patient of having made a document of anticipated will in which he declares a preference or rejection of a treatment. So, the thing the competence has to value is *why* and *how* it is chosen and not *what*. This supposes that we have to start from thinking that psychiatric patients can also make competent decisions, therefor their decisions have to be valued like any other people's, that is to say, regarding assessment, comprehension, reasoning and the expression of a choice.

It is usually accepted that the grade of competence required for a decision is proportional to the kind of decision, that is to say, to major seriousness of the decision, higher will be the level of demand required. Now then, we have to take into account some factors that are associated with the decision and even to the person who chooses it: 1) probability of a certain kind of damage; 2) value given to that damage; 3) probability of fulfilling the task taking into account there is a probability of damage; 4) value given to the aim; and 5) possibility of risking taking into account the alternatives that may fulfil the same task<sup>38</sup>.

In people suffering from schizophrenia there are factors that can condition the competence or incompetence for decision making: the intensity of the psychopathology, the cognitive worsening (attention problems particularly), a low intellectual performance, problems with information storage, etc<sup>39-42</sup>. However, although in these patients the competence for the decision making may be affected, empirical studies<sup>26,39,43</sup> show that it is not mainly due to the positive symptomatology (hallucinations, deliriums), but it is associated with the negative symptoms and concretely to the cognitive functions.

Palmer, Dunn Appelbaum and Jeste<sup>39</sup> analyse the capacity of decision making in patients suffering from schizophrenia and in a control group showing that although those patients had worse results in the tests of the areas of *comprehension, assessment, reasoning and choice of a treatment* the incapacity of making a medical decision was associated with cognitive functions neither with the age nor the severity of the pathology. On their behalf, Capdevielle and collaborators<sup>44</sup> examine the level of *insight* (consciousness of the pathology) and capacity of consenting a medical treatment. The *insight* was analysed from different points of view: regarding the level of consciousness, both of having an illness and of its own symptoms, and related to the therapeutic necessity and its effects.

Results show a correlation between a poor level of *insight* and the low appreciation of risks and benefits of the treatment, a reduction of the probability to compare therapeutical alternatives and scarce ability to express a choice. Regarding comprehension of the given information correlations were found between difficulties for decision making and cognitive functions, following to that the fact that the negative symptoms play a more important role than the positive ones in the decision making.

Other studies corroborate these data reinforcing the relation between incompetence and negative symptomatology, level of *insight* and cognitive deficits<sup>45,46</sup>. Wong and collaborators' study<sup>47</sup> compares competence in people suffering from chronic schizophrenia, with mental retardation, dementia and ordinary people with venous pathology. Those authors observe that patients suffering from dementia or mental retarding are usually less competent than ordinary people, but it is not the same with the ones who suffer from schizophrenia. Jeste, Deep and Palmer<sup>45</sup> came to the same conclusion: schizophrenia presence not *necessarily* damage competence.

In the end, people who suffer from schizophrenia, *a priori*, are not less competent than ordinary people, although some patients may have difficulties due to cognitive deficits, but it is not *exclusively* related to schizophrenia's symptoms. In general, incompetence is more associated with affectations in the cognitive level, but this aspect can appear in many illnesses (dementias, depression...) and not only in schizophrenia. Besides this, not every person suffering from schizophrenia has the same deficits or even they can be competent for a determined decision but incompetent for another one. Therefore, the competence for a specific task has to be valued

regarding to the intensity of the deficits for a concrete task in a determined period of time.

## Exceptions to the informed consent

It is accepted that there are clinical situations in which it is lawful to make a medical intervention without the patient's IC: medical emergencies, patient's abdication to be informed, therapeutical privilege and patient's incapacity of decision making<sup>7</sup>.

### Emergency

Emergency situations in which the person's life or the public health is at risk are an exception to act medically without the patient's IC. In these situations there is not enough time to elaborate the consent because the priority is to look after the patient or avoid the damage to third party.

Different sanitary laws state this exception: in 1997 the *Oviedo Agreement*<sup>48</sup>, in chapter II, article 4, establishes that any essential intervention is justified from the ethic point of view for the person's health. The General Health Law<sup>49</sup>, article 10.6, orders that it is legal to act without the IC when the lack of intervention supposes a risk to public health and when the emergency does not admit delays because death or irreversible damages are possible. In the same way, Law 21/2000, article 7<sup>th</sup> points that in those cases where there is risk for mental sanity or physical integrity it is justified the delay to obtain the consent.

Now then, as clinical symptoms are different not every emergency situation has the same meaning nor the same connotation. It is not the same an emergency situation because of a cardiorespiratory attack than a disordered behaviour due to psychiatric causes. In a psychiatric context we can define an emergency situation as that in which some psychopathologic symptoms or a disruptive behaviour, perceived as perturbing or threatening to the patient or even to his family or other people, mark a breakup with reality, in a way that an emergency psychiatric intervention is required to avoid a damage to the person or a third party. In schizophrenia such situations are consequences of severe psychologic alterations (anxiety, depression, etc.), unusual psychomotor behaviours like those in the catatonia (catalepsy, astonishment, shaking, restless motor attitude, etc.), hallucinations, deliriums, among others. In these cases, the intervention without the informed consent is justified.

### Abdication of the patient to be informed

We have already commented that one of the professionals' duties is to inform, in enough quantity and quality, about the caring process. The patient has also the right of not being informed. It is established in this way in *Oviedo Agreement* in its article 10.2: *the will of a person of not being informed will have to be respected*<sup>48</sup>. This, in the end, is nothing but respecting the patient's autonomous decisions. However, it is a professional duty to be assured that the patient is conscious of the consequences of not being informed and that he has reasons for not wanting to. To do that, the professional could follow the steps below<sup>50</sup>:

- 1) the patient has to be advised that he has the legal right to IC;
- 2) he has to document his reasons for rejection;
- 3) the professional has to start a discussion about the abdication;
- 4) the patient's capacity has to be evaluated.

In this way what is desired is to assure it is about a reasoned and reasonable decision and not a fruit of psychiatric symptoms. In patients suffering from schizophrenia it could happen that the rejection was motivated by some kind of chase or stealing of the thought delirium, being able to think that the information can be "stolen", that the informative process can be a strategy to "catch" him, etc. It is also possible for him to think he is not ill and, therefore, that he does not need medication, reason why he would reject any information considering it unnecessary. In both cases it denotes incompetence for decision making because they show some kind of delirium or lack of insight.

### Therapeutic privilege

We talk about therapeutic privilege when professionals hide, in a deliberated way, certain information to his patient because they are convinced that revealing it may suppose a psychological damage or physical repercussions. In patients suffering from schizophrenia this procedure is usually used for unfavourable reactions to antipsychotics. However, concealment of that information is a mistake, because it is empirically proved<sup>17-19</sup> that information does not decrease the treatment acceptance, but on the contrary, patients have a better adhesion to the treatment and a better comprehension of the pathology and the psychotropics' reactions too. Therefore, it is not legal to refer to therapeutic privilege and hide information about counter-indications to the patient, because it is not proved that there

is a therapeutic rejection neither it is ethic not to inform him, because everybody has the right to true and quality information to be able to choose among different therapeutic lines and even to be able to refuse the proposals.

### Incapacity

As it is established by law, when a person shows incapacity for decision making he will not be able to give his consent. Therefore, the Civil Code, article 200, establishes that: *illnesses or persistent physical or psychic deficiencies that prohibit the person to govern himself are causes of incapacity*<sup>51</sup>. This incapacity can be only declared by judicial sentence, being need the intervention of the Public Ministry<sup>52</sup>. That sentence will have to determine the extension and the limits of the incapacity, as well as the guardianship regime of the incapable person<sup>53</sup>.

In those cases, a legal tutor or a representative will be needed. Now then, the fact that somebody cannot give his consent does not mean that he cannot participate, to the best of his ability, in the decision making process. It is more, it is necessary and positive for him to participate in the deliberative process because he is giving information about how he wants to be treated, although other people is deciding for him. In any case, the one who promotes the incapacity of a person, according to the article 757 of Law 1/2000, *of civil lawsuit*<sup>54</sup>, must be the spouse or somebody in an assimilable fact situation, as to know, descendants, ascendants or brothers of the presumed incapable person. It will be competence of the Public Ministry to promote the incapacitation if the responsible people (spouse, tutor, etc.) do not exist or have not asked for that.

In the majority of the patients, the incapacity is something that must be proved *a posteriori*, although unfortunately reality shows that in psychiatric patients it is usually the opposite, capacity is something that must be proved. Besides this, in this psychopathology patients usually present a symptomatologic variability, as positive as negative, motivated by adhesion or rejection to drugs. So, there should be a periodic revision to evaluate if the person shows incompetence in a specific situation.

### Final considerations

The IC must not be conceived as an isolated process in a caring relationship, but as an appropriate space to make shared decisions between the professional and the patient. In this sense, it must



be understood as a revisable and changeable process related to the pharmacologic adhesion, to the unfavourable reactions of the treatment and to a possible therapeutic change in the doses or even in the kind of treatment. It is necessary that the person and his family receive good information about how the therapeutic process has to be. The way of transmitting the information has to be in agreement with the cognitive and sociocultural characteristics of the patient and his family. The misunderstanding of the information may suppose incompetence for decision making, and on the contrary, good information can increase the capacity of comprehension, reason why an additional effort has to be done.

The IC must not be understood as the obtaining of a signature, but it is about a *communicative process* in which a series of necessary elements have to be valued to be able to talk properly about "informed consent". Among them, we must pay great attention to the sufficient competence to be able to consent a medical process. By its part, the therapeutic privilege does not have to be an excuse to not informing the patient about the unfavourable reactions of the pharmacologic treatment, because it has been proved that information about counter-indications does not lead to a worse therapeutic adhesion, moreover the opposite occurs.

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