

# **Analysis of informed consent in cancer patients: a proposal for a decisional algorithm**

## **Análisis del consentimiento informado en pacientes con cáncer: una propuesta de algoritmo decisional**

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### **Abstract**

One of the hindrances in the care of cancer patients is the possibility of them not collaborating in their treatment. Based on conceptual analysis and study of two cases, we propose an improvement on the quality of this procedure in the IMSS outpatient Oncology Clinic 180 of the IMSS.<sup>1</sup> The clinical literature reveals several limitations of patients when consenting to treatments, stress being frequently mentioned. Moreover, in the cases analyzed, in addition to the aforementioned elements, appears previous wrong information about the treatment and the severity of the disease. From the data found, a decisional algorithm was designed indicating moments that can facilitate and allow informed consent. It is conclu-

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ded that consent must be given throughout the entire process, with the decision-making algorithm being a proposal for its improvement.

*Keywords:* stress, accompaniment, grief.

## **Introduction**

One of the difficulties in the care of cancer patients is the possibility that they will not cooperate with their treatment. Intuitively, it is clear that the person has the right not to treat himself, if he considers it in accordance with the principle of autonomy. The question raised in this article is: How to ensure, in these cases, that effective informed consent has been given? Two examples of clinical cases are discussed in which the reasons for refusal of treatment are not completely clear, but which give clues or keys to how these situations should be handled. Guiding the patient in the treatment options and the consequences of being treated or not, implies adequately delimiting what should be expected from informed consent. Thus, based on the cases and the review of the clinical literature in this regard, an improvement of the care<sup>2</sup> in the IMSS 180 ambulatory care oncology office is proposed.

## **Development**

One of the factors that limit the ability to accept or not accept treatments –or sometimes, just to glimpse possibilities– is the stress to which patients are subjected. In fact: *...approximately four out of ten cancer patients show levels of clinical distress at some point in the disease process. This emotional response seems to be modulated by several factors, including those related to the disease (1).*

In palliative home care related to cancer patients, «90% of family members and primary caregivers stressed the importance of stress reduction, given the preparation prior to hospital admission by the multidisciplinary team of palliative care» (2). Again, the emotional aspects affect the perception of information and collaboration. According to the cognitive-behavioral therapy, anxious feelings hide or are associated to automatic thoughts that usually generate security behaviors.

An already classic approach in the field of clinical bioethics is the use of the four principles: beneficence, non-maleficence, autonomy and justice (3). Within these, autonomy is recognized as the guiding principle in the case we are dealing with here, because this principle conflicts with the principle of beneficence. If patients decide not to take care of themselves and there do not seem to be any proportionate clinical reasons, then what should or can we do so that at a given moment they reconsider without infringing on their autonomous decision?

Probably one of the keys is the concept of communication. Providing clear and concise information about cancer, allowing the expression of thoughts and feelings about the current state of the disorder, expectations and associated emotions, and confronting the above with reality by valuing the role of possible support or rejection from family and friends, are crucial to the possibility of coping with the disease (4, 5). In other words, it is a matter of providing authentic counseling and not just information (4). Another essential concept is trust. If a communication strategy is not sought in trust (A), it becomes almost impossible to evaluate the patient's situation in terms of his or her ability to reason and measure the risks and benefits of his or her own decision (4). In other words, adequate informed consent implies the certainty on the part of the patient that his or her decisions will be respected, and, on the other hand, that the information provided can be questioned and discussed in the same process, without moral or social sanctions for the patient. These sanctions range from the expression of the

displeasure of the treating physician or his impatience with the patient's «naive» questions or even threats of withdrawal of treatment. These elements that we have highlighted must be included in the same decisional process (B). In the different moments of contact with patients (See Figure 1). There are other factors to be considered in the consent process such as: cultural level, age, type of tumor, prognosis, aggressiveness of treatment, need for aggressive and potentially curative surgery, attitude of the physician, health education of the physician, cultural background, previous experience, psychology, environment, expectations and prejudices, among others (C) (5). All of these factors must be considered as part of the truly individualized consent process, even though the written sheet that is usually used for this purpose is the same for all patients. We are therefore faced with the problem of the truth that is tolerable for the patient (D). Its «calculation» is prudent, in the sense that it must be measured here and now how much information the patient can handle and assimilate in order to make decisions about his or her life. This prudential calculation must be seen from two angles: that of the health care personnel and that of the patient. Health care providers must fairly measure their ability to deliver or evaluate a medical intervention in its proper cost-benefit balance. That balance is not only given by the medical talent: it implies a judgment where that talent finds a fair means dictated by the reason in the concrete case. Thus, a doctor with a tendency to generosity may well be lost in his judgment of his patient, giving him unfounded hope of improvement due to his optimistic tendency. Optimism must be regulated by prudence in order to hit the target of the virtue of gentleness/optimism which is a midway point between the dryness of pessimism and immoderate optimism.

The above balance also applies to the patient: one with too much optimism may accept, for example, experimental treatments that have no clinical proportion whatsoever. For example, a patient with metastatic stage IV gastric cancer with ECOG (a functional sta-

te where he stays in bed more than half the day, having had three lines of palliative treatment to which the disease progresses) could receive and accept the offer of some treatment such as temozolomide. However, in that case, it is most likely that such therapy will cause physical harm to the patient without providing any relevant benefit.

Prudence somehow guarantees the achievement of virtue, but in a circular way, virtue, in turn, allows for the correct orientation to prudence. In other words, if we do not regulate our tendencies to pleasure and aversions to pain, prudence is skewed. But what do we do then? What do we regulate first? Prudence as an intellectual virtue allows us to «measure», if here and now, the norm is applicable. For the physician, questions such as is the protocol appropriate to the patient's circumstances, are indispensable in almost any clinical decision. At the same time, the patient, by analogy, questions whether he or she has the physical strength and disposition to face the treatment. Prudence, then, is not «cunning» insofar as it seeks the means that are appropriate to my interests, but rather the search for the means that are appropriate to virtue (6). But is this not, perhaps, a circular argument? It turns out that one has to learn to be virtuous in order to be prudent, but one has to be prudent in order to find virtue. The answer is that one learns virtue along with judgment. So, when we want to be temperamental, we do it by evaluating our tendencies and making a judgment about them. We do not learn by pure conditioning, but by a rational evaluation of the situation (even if the judgment is wrong). As Vigo summarizes: *we cannot identify in the abstract the content of prudence without indicating how the prudent one acts in front of everything. And, vice versa, the virtuous cannot be identified as such without making reference to prudence, that is, the brave is the prudent in the face of fear. There is a back and forth between moral virtue and prudence* (6).

The oncology patient does not become brave by reasoning, but by facing the situation by evaluating risks, benefits and suitability

for personal development. This evaluation is done with the support of the health personnel and not outside of them. The proposal to improve the care in the informed consent is not only an intellectualist attitude: the health personnel not only informs and provides data of the procedures, but helps the patient to confront them by evaluating from the perspective of the virtues. This, of course, takes more time than just filling out a form or asking for a signature. It implies dedication and an adjustment to care times that are, unfortunately, usually very short in time in the public health sector (E).

Well, these elements should be considered in the process of informed consent: to seek virtue with the judgment provided when offering health alternatives and when receiving it, so:

It is not recommended that in the first moments the intention is to tie up all the ends and end the work of information and relationship with the patient. In the first interview there is a risk that any information given will be too much. In addition, the doctor does not yet have references to know what the patient understands or what he or she extracts from the flood of data provided. It is not necessary to pretend to provide all the information in a single conversation: the time factor is necessary for the patient and the family to mature the data provided.

The physician in turn suffers from a duality: on the one hand his knowledge is technical (*poiesis*) he must seek the clearest means to eliminate/decline a cancerous tumor; his technical rationality does not seem to imply perfection of himself. But because cancer is not a separate entity from the personal reality of the patient, his action must also be focused on himself. For example, when a patient is treated, it is also done for the virtuous good of the doctor or health personnel in general and the patient is cared for by the virtue of generosity. Thus, clinical process activities are dual: an extrinsic or other intrinsic purpose is sought. In other words: one must not only be a good doctor/nurse/social worker, but a good person, doctor, nurse, etc. This duality must be considered in the processes

of patient care: balancing care without neglecting oneself (F). This implies the consent process.

Poor health personnel produce or may produce poor technical results by deviating from the objective of doing good and doing good to others from an ethical point of view. The physician can prescribe a therapy according to the protocol because he knows it works, but he does so with the wrong patient, the one who, for example, could not comply with the therapy. In that case, the technique has been undermined. Vigo sums it up very well: *...the technique is morally neutral, but in the sense that by purely technical means it is not possible to determine for what purposes to use the instruments that the technique makes available. The purposes for which the technical instruments are ultimately applied seem desirable for considerations that are not technical, but moral* (6).

Below, based on the proposed categories, a decisional algorithm is presented for patients with a diagnosis of cancer that considers experience in clinical practice, which helps to reduce reticence and to guarantee, within the possible, authentic consent on the part of the patient, seeking the intrinsic good of both health personnel and patients. In this way, it points out areas that imply this duality of virtue/prudence of health personnel and the physician and which are highlighted in this text.

To exemplify the need for this algorithm, below we review two true cases of patients that we have verified in our clinical practice, and then move on to the proposal.

#### **Case 1**

Female, 52 years old. Hypertensive woman being treated with enalapril. Auto detected mass of more than 2 cm in left breast. Mammography with data of probable malignancy. Cutting needle biopsy with data of malignancy. Left ductal breast cancer Clinical Stage IIIA. Estrogen receptors over 100fmol, Progesterone receptors 90%, HER2NEU negative. Sent to surgical oncology for mastectomy but patient did not accept. In her case the surgery could have left her tumor free and she would have a chance to be cancer free for life.

She refused to have a mastectomy because «she has seen people who operate on them and return to the same thing». The patient believes that the intervention is not effective.

Here we find the case of a patient who has refused the treatment, because of a probable incorrect cost-benefit assessment and probably also because of a lack of detailed and, we could say, visualized information about the process she must undergo. One of the patients' fears is having to endure unknown processes. In this sense it is not only useful, but also necessary to illustrate the procedures, as for example the palliative care service of the National Institute of Cancerology does (3). Another strategy is that the patient can visit and see other patients in their same treatment circumstances to diminish the fear of that same process (G). Naturally, this implies a follow-up process that absorbs a good part of the time available and that is sometimes practically impossible (4); however, we think that this is one of the strategies that, without manipulating the patient, allows him/her to make a truly informed decision. This process of familiarization with the environment can and, in our opinion, should be carried out by the nursing personnel who often accompany the patient at many times during the treatments.

A second strategy suggested by this case is to assess whether or not the consent is really based on the patient's own experience and expectations (H). On occasion, patients make the decision influenced by their family environment or, on the contrary, it is feared that by accepting the treatment, it will not be possible to retract their decision afterwards, sometimes because of pressure from the family (2, 5). One of the possible strategies is to use the test minimal<sup>3</sup> as a criterion for the patient's decision-making capacity. With this we would have several criteria to perfect the patient's informed consent. Let us now look at the second case.

#### **Case 2**

59-year-old female. It refers to allergy to penicillin and cortisone. Hypertension in homeopathic treatment. A mass was felt in the left breast in



2015. She did not go to the doctor initially, out of fear. In February 2018 ulceration was added, it was when she went to see a private physician. April 25, 2018: biopsy of left breast lump with Histopathological Report on April 30, 2018: infiltrating ductal carcinoma without specific pattern Grade III histological classification Scarff Bloom Richardson, with lymphatic permeation and extensive areas of necrosis. Evaluated by oncological-surgery on May 14, 2018, not being a candidate for surgical treatment due to advanced stage. Medical Oncology in Texcoco evaluated her with body surface 1.83 and indicated a cycle of epirubicin 160mg trisemanal and cyclophosphamide 1100mg trisemanal, but the patient did not accept chemotherapy. Chemotherapy in her case would have helped shrink the tumor and make it operable.

However, she does not accept chemotherapy: «for everything they say happens; for everything you have to go through», so she prefers a quality of life in which she can fend for herself.

In this other case, fear is manifested as an obstacle to the decision (7). The fact of presenting oneself «late», due to the mere fact of the possibility of late diagnosis. Once again, the problem of the lack of *in vivo* knowledge of the care process arises.

Another strategy that can be applied to this case is that of home care. The patient often presents fear of suffering outside of his environment. Considering the option of home care in case of aggravation, which would imply not moving the patient away from his comfort zone, may be a factor in reducing rejection.

This second case can be better understood and interpreted with the classic stages of grief, even when the prognosis is not death. That is, there are the stages of shock, denial, anger/anger, bargaining, depression, and resignation/acceptance. The same stages can occur in the family members and even in the health personnel themselves. It should be remembered that they are not always sequential or causal in a necessary way, that is, more depression can be generated by anger or more acceptance with negotiation without becoming necessary (8). Disorders derived from information, depression and

anxiety, are psychological indicators: *The phases of mourning are independent of the time that has passed since the diagnosis; more than phases that define a sequence of evolution of mourning, psychological responses to mourning for the loss of health are observed that coexist and are interrelated* (8).

Either way, it requires an accompaniment. In a study with breast cancer patients, no statistically significant differences were found between patients with more advanced cancers in terms of response to mourning (7). This gives us insight into how these symptoms can be presented subjectively without an objective correlate of the same proportion.

The cases show us that the underlying rationale for both cases is quality of life. There is a medically disproportionate perception of risk and action. In both cases, however, medical intervention would objectively help to improve their lives. Then, the questions that arise are: What limits does informed consent have without falling into paternalism? Does the patient really understand the implications and consequences of not accepting the treatment? Is it really understood that behind the patient's refusal of treatment lies a stress of such a degree that it prevents him from making a decision about his health? (H).

What we propose here is that an assessment of the different variables be carried out in order to improve the response of the patients in the process of informed consent. Studies have found factors that prevent or at least diminish the patient's decision-making capacity. It should not be forgotten that part of the informed consent process involves being evaluated throughout the process, even if the legal signature has been obtained:

In fact, it is important that the choices of the sick person are respected, even though we know that there are special circumstances surrounding this situation that must be discussed. Health professionals should consider whether the information transmitted was adequate and whether consent for treatment, care, or other procedures was free and informed (7).

In summary, the key concepts of improvement in the care process of the oncological patient have been pointed out:

- a) Real and effective trust/communication.
- b) Avoidance of sanctions, need for information discussed and analyzed together with the patient.
- c) Always consider the cultural and social level of the patient.
- d) Keep in mind the level of truth tolerable to the patient, without lying.
- e) Never forget to promote the virtues in the patient and the health personnel.
- f) Consider the care of the patient as a priority without neglecting the care of the health care personnel.
- g) Combat fear by familiarizing the patient with the entire process.
- h) Consider the stages of grief and distress presented in all patient decisions.

Already with these elements, the proposal of the care algorithm is presented in the first visit. The process is indicated with the indications at the different moments where the categories should be considered and in parallel with the nursing functions with the indication of Gordon's functional pattern (9) to be remembered in the collection of data for the Nursing Care Plan (NCP). See Figure 1 on the next page.

It has been pointed out at the same time that the virtuous and prudential capacity of the care process must be taken care of to the maximum. Assessing nutritional and mobility risks implies neither underestimating nor overestimating the patient's capacity for self-regulation, i.e., temperance. It should be examined not merely on recommendation or to provide guidance, but to understand the patient's difficulties and to monitor the health care provider's actions. The provider must have the right measure between commiseration and indifference and act according to the right means in respect to the situation.

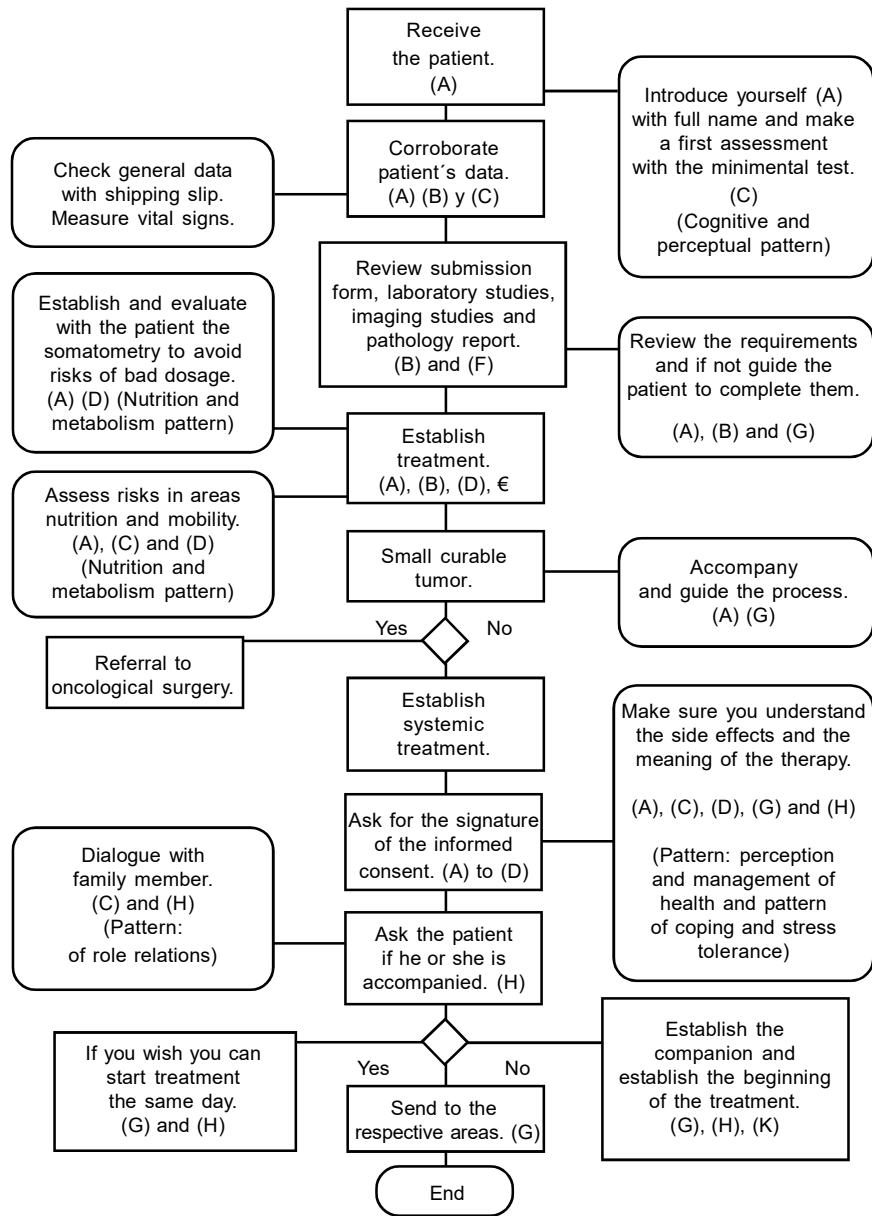


Figure 1. Decisional algorithm in the oncology patient care process.  
Source: Own elaboration.

## Conclusions

We can subscribe to the words of Allende S. *et al*: *IC is not a simple legal requirement or a self-protection of the physician or hospitals against a lawsuit, but it is the ritual and informative process that every professional exercises with responsibility for palliative care* (2). Although it refers to palliative care, this extends to the first contact of the patient that is still treatable. Both the doctor and the nurse: (a) must collect information to establish intervention guidelines with the patients, so that both carry out a synergetic work that leads to the act of obtaining authentic informed consent by collecting data that guarantees care by the doctor and the nurse that will last beyond the signing of the document throughout the care process.

## Bibliographic notes

- <sup>1</sup> Located at Av. Solidaridad s/n Col. Providencia, Valle de Chalco, Edo de Mexico.
- <sup>2</sup> The improvement is expressed by means of a decision algorithm where the concepts to be considered are pointed out. In the text are indicated with letters terms to consider and the algorithm indicates the time or times when they should be considered.
- <sup>3</sup> The minimal is a short questionnaire used mainly in geriatric patients to measure if there is presence of cognitive impairment. It consists of 30 items. It can be seen at: [https://www.farmaceticoscomunitarios.org/anexos/vol11\\_n1/ANEXO2.pdf](https://www.farmaceticoscomunitarios.org/anexos/vol11_n1/ANEXO2.pdf)

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