

THE JEHOVAH'S WITNESSES' REFUSAL FOR BLOOD TRANSFUSIONS: NEW ITALIAN LEGISLATION AND TRANSPLANT MEDICINE BETWEEN ETHICS AND RIGHTS

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ABSTRACT

In the Italian national context the promulgation, on December 22nd 2017, of Law n. 219, states the overcoming of Hippocratic ethical-deontological tradition; the patient's conscious and freely expressed will concern its health condition becomes the nodal point of the lawfulness of the medical-surgical treatment.

Transpose this innovative forensic matter in the field of transplant medicine is an essential operation. Authors conduct a critical analysis according to traditional criteria of the "triptych" legal medicine/ethics/law of a case evaluated by the Apulian Regional Transplantation Centre, developing general considerations valid for others health systems too.

The case refers to siblings. The receiver, a 53 man, suffers from chronic renal failure under dialysis for three years; and the potential donor, his sister of 51, is affected by thalassemia trait and, as Jehovah's Witness, rejects blood transfusions.

This case represents a paradigmatic example of the latent conflict between the right of the individual and the community interest: the patient/receiver versus the donor/bearer rights. Seems important to consider also the general frame in which the case has developed: the Italian public health national service, with its needs, its workers' rights and duties and its economic limits.

The questions are: Who comes first between patient, donor and health system? Which criterion and scientific method should be used to harmonize the whole system?

The transplant community will have to reformulate the method, criteria, organization and routine procedure through a deep meditation about ethical-deontological assumptions and "new" legislation.

Keywords: Law, Medical law, Transplant Medicine, Blood Transfusions, Jehovah's Witnesses'

INTRODUCTION

As has already happened in many Western Countries, with the Italian Law n. 219, a systematic regulation of informed consent concerning the diagnostic-therapeutic practices that introduce the new institute of Italian Advance Healthcare Directive (AHD/DAT), also known as living will with the prevision of the appointment of a Health Care Proxy (HCP), has been defined.

The law, which was approved in 2017 and entered in to force in 2018, is the final point of a year-long process and the subject of heated debate throughout Italian society (Paolo et al., 2019). More detailly, it identifies three distinct but converging paths towards the affirmation of a

care relationship based on reciprocal trust and respect: the possibility to consent or refuse treatment, the shared care planning, and advance directives. From the legal perspective L. 219/2017 is a constitutive law.

The “revolutionary aspects” result in the possible ethics rather than legal conflicts between the need to respect the patient’s health self-determination and the role of the National Transplantation Commission that must guarantee the national health security.

The Law promotes and enhances the relationship of care and trust between doctor and patient, which includes the competence, professional autonomy and responsibility of the medic and the decisional autonomy and right to self-determination, to make an informed and voluntary choice about the possible treatment, of the patient (Delbon, 2018).

Spirituality and religiosity are often underestimated, but they are influential factors in Western medicine, as demonstrated by Jehovah's Witnesses’ (JW) experiences and their “religious restrictions” in the approach to the care system.

The informed consensus is certainly an essential connotation of the treatment relationship as well as the advance directives are tools for self-determination and the manifestation of the beliefs and preferences of people (not yet patients) for the future and not just as patients for the present (consenting to or refusing current treatment).

There are studies in literature moving beyond “dyadic relationships” and caregiving contexts and also contribute to a deeper understanding of care and relational conceptualizations of JW’s patients' autonomy globally.

Since there is still no assessment of the effects of the new law on transplants between living beings, the case received by the Apulian Regional Transplantation Centre became a leading case of the management of decision-making powers by the doctor. The analysis of this rare case offers a hint for an ethical and legal-medical evaluation of the consequences of the new laws in all countries with patients of different religions.

The analysis also demonstrates that the resolution of complex cases, such as the one object of our study, can be represented by the possibilities of treatment and care without the use of blood components or their strong reduction through a proactive approach called Patient Blood Management (PBM). This approach is implemented in many countries of the world with significant reductions in the use of blood products, it appears to be particularly performing in cases of programmed surgical interventions like the one described. The World Health Organization has adopted a resolution (WHA63.12) for the implementation of patient blood management PBM programs. Patients treated according to the PBM pillars have their own blood optimized prior to surgery and minimized blood loss during surgery. The donation of an organ is certainly an invasive surgery that exposes the person to become patient and to risks even if blood transfusions is accepted. It therefore becomes necessary to make a real balance of risks, as would be the case in all cases of transplantation with patients suffering from comorbidity (Althoff, 2019).

By focusing on ethical and legal-medical aspects, today the doctor-patient relationship can be understood as the meeting of two autonomies. The therapeutic doctor-patient relationship is one of the fundamental aspects of the treatment process and of medical activity in general. It can be considered as a “specific characteristic of medicine” as it would constitute its essence. In this perspective, a problem has a “medical” dignity only if it emerges in the context of the complex doctor/patient interaction (Uhlmann et al., 1984).

Traditionally, researchers have treated doctor/patient interaction as a situation in which doctors exercise power over patients. The drive towards patient-centred medicine rests partly on a conceptualization of medicine as some kind of personal service or product, accessed as a result of an individual decision about purchase or usage (Pilnick & Dingwall, 2011).

Already Kravitz in 1996 had underlined how literature on patients expectations for medical care suffer from definitional confusion and lack of a conceptual model and then no changes seem to have occurred (Kravitz, 1996).

In assessing the patient's expectation, it would be necessary to include the concepts of practical outlooks (what individuals expect can happen), perceived duty (what people expect should happen) and ideal expectations (what an individual most would prefer to be).

The ethical/bioethical reflection has undoubtedly contributed to the elaboration of the doctor-patient relationship model which, abandoning the paternalistic approach, was able to foresee the duty of the doctor to inform the patient about his clinical condition, in such a way as to promote the autonomy within the therapeutic relationship (Williams et al., 1998).

The disclosure of this model has therefore contributed to promoting and enhancing a historically pivotal principle in the care relationship: the principle of informed consent.

If an historical judgment in Minnesota recognized, in 1905, the right to self-determination in the health contexts, such as to prohibit to the physician to violate the physical integrity of the patient without his explicit consent, in Italy a sentence of the Constitutional Court, in 2008, defined informed consent as an expression of an adhesion aware and voluntary to the medical treatment proposed by the doctor. Informed consent, which nowadays is progressively but almost universally recognized, is a fundamental principle in the field of health protection, representing one of the essential elements on which the modern conception of therapeutic relationship is based.

The doctor that allows the patient to consciously choose whether or not to undergo a health treatment mainly bases the legal category of informed consent and its validity on the existence of an informative activity (Janzen et al., 2006).

Law n. 219 has definitively exceeded the ethical-deontological tradition of the Hippocratic type, going towards an even more personalistic approach, as has been happening for some time in the Anglo-Saxon countries.

This Italian norm has, moreover, incorporated a progressively established jurisprudential orientation, which identifies in the patient's conscious and freely expressed will the main point of the lawfulness of the medical-surgical act. Law n. 219 has, in fact, redistributive effects in the relationship between doctor and patient, introducing the shared planning of care that is the process that promotes the sharing of values, existential objectives and people's preferences with reference to their future therapeutic choices. It is a path that doesn't involve the person only in the moment of the manifestation of the illness (as a patient) but which concerns him at all ages and in relation to each state of health (as a person), with the aim of ensuring that the individual can receive the most consistent care with his own values and with what previously indicated in the DAT. Traditionally it is based both on the expression of consent/dissent and on the therapeutic necessity.

The relationship between these two elements of the path may vary, but their simultaneous presence was the cornerstone on which the doctor-patient relationship was shaped. It is therefore obvious that the introduction of different matrix principles produces cascading effects and poses new questions in terms of "limits of lawfulness" as previously understood.

THE CASE STUDY

In 2019 a couple of siblings came to the attention of the Apulian Regional Transplant Centre (CRT) and of its "Third Commission" (an independent commission from the donor, the recipient and the respective surgical teams, which has the task of verify the free donation by the donor and the awareness of the related risks).

The recipient was a man of 53, on dialysis for about three years to treat chronic renal failure. The donor, his sister, was a 51 woman, who occurred to be the most compatible person and was therefore selected as a donor. She was in apparent good health but bearer of thalassemia trait, a condition that falls within the group of thalassemia syndromes. These are a group of inherited hematologic disorders caused by defects in the synthesis of one or more of the haemoglobin chains. Alpha/beta thalassemia is caused by reduced or absent synthesis of alpha/beta globulin chains. Imbalances of globulin chains cause haemolysis and impair erythropoiesis. Silent carriers of alpha thalassemia and persons with alpha or beta thalassemia trait are asymptomatic and require no treatment.

The main element that made this case very rare is the presence of a thalassemia trait in a JW donor. She signed, advised by a lawyer, a document that could be considered as DAT at the time of the final evaluation by the third commission. In this document the donor expressed dissent to possible blood transfusions during the intervention necessary for the donation of the kidney to her brother.

The possibility of a blood loss during a surgery to remove a healthy kidney in a healthy person could not be excluded a priori. This was reported in the consensus document that the donor should have signed.

The Third Commission, taking into account the priority requirement of the patient (the brother) in chronic renal failure, carried out an in-depth reflection, suspending the procedure already started (before the Law 219/17) of donation/transplantation and postponing the evaluation to the National Commission. The Commission, following a detailed study of this case conducted in sight of the new law, confirmed the suspension of the procedure.

DISCUSSION OF LEADING-CASE

This case is paradigmatic of the difficulties related to the applications that follow the legislative evolution. The solution of the case, regardless of clinical measures, could only be achieved through a profound multidisciplinary and multi-professional analyses addressed to all stakeholders (in this case, primary to JW Community). In fact, transition from an individual autonomy to a “relational autonomy”, which highlights the relatedness, interdependency, and social embeddedness of patients, is required.

Conflicts between two ethical and legal conditions such as life and freedom are frequent in medical practice and it appears even more complex when criticalities linked to religious faith are added up. Their refuse transfusions of whole blood or its primary components, which is a non-negotiable religious stand, even in an emergency situation.

The JW principles affirm that the human being's soul lies in the blood and, as such, it cannot be passed on to another person. If that happens, the adept would disobey the God's commandments.

This refutation is supported in the biblical texts Genesis and Leviticus employed in the discussion of blood transfusions, there are two underlying and related themes: the belief in the sanctity of blood and the necessity of proper preparation of animals prior to consumption. It is very clear from the passages above that blood was seen as the “life substance” of the human as well as the animal.

In principle, the right to life takes precedence over the patient's autonomy because, based on professional ethics, physicians have a duty to attempt a cure. Thus, the patient's liberty is infringed, giving rise to interventions that may give rise to complaints and lawsuits.

This refusal raises complex medical, legal and ethical issues for the treating medical staff in any specialized area and in the medicine of transplants between living people. It seems more relevant in a case like this in which there is a donor who is a person but not a patient (even if it

could become so in the event of a haemorrhagic complication of the operation) and the recipient who is a “patient” suffering from pathology to which the health system should guarantee clinical improvement (transplantation). Legal responsibilities are directly involved in surgical decisions about JWs.

In Italy most of medico-legal doctrine recognizes, in the JW's blood refusal, the physician's limited position whereby, it seems, he or she must submit legally to an expressed therapeutically dissent even when the patient is in a condition of incompetence and is no longer capable of expressing his or her refusal, or else must risk an indiscriminate violation of the patient's right to religious freedom and choice.

Before Law n. 219 the respect for persons requires the physician to accept the patient's refusal of a blood transfusion regardless of balance of benefits and harms.

According to the JWs' calculus of values, the harm resulting from receiving a transfusion (denial of eternal salvation) is greater than the harm caused by refusing the transfusion (the end of mortal life on earth).

In the case in which the donor is a JW and refuses the transfusions, there is a contrast between the will freely expressed by the donor subject (person and only potentially patient) and the therapeutic possibilities that the doctor could have available to realize the chance of bleeding risk, predictable and not absolutely preventable. The freely expressed will of the person/patient must be respected, regardless of the context conditions. In this sense the content of Law 219 is unequivocal.

One wonders if the donor can and should be considered “patient” or not, given the absence of any pathological condition and indeed the pathological actuality in contrast with the status of donor (which by definition must be healthy). And again, if at the realization of the risk (in the case of haemorrhagic examination) he must turn from the condition of donor to that of patient.

In fact, if the exonerating element is the will, it does not matter whether it is provided by a subject who is in any case qualified or unqualified. The incipit of the art. 4 of Law 219 is in fact related to “every person of age and capable of understanding and willing”. What will have to take on greater importance, also in order to formally and substantially qualify the “donor”, will be the method of ascertaining the real will and capacity to understand and want. In this sense, a significant contribution can only come from psychiatry and more specifically from forensic psychiatry.

The real risk is that the application of the principle of self-determination, however, to be defended in terms of freedom, can facilitate the so-called “Medicine of Desire”, debasing even more the medical act towards the mere execution of orders.

The DATs are proposed as an instrument of self-determination and guarantee of dignity of the person/patient but perhaps should not focus attention on specific treatments or outcomes, but, rather, it should supply doctors with the patient/person's scale of values so that they can use it as a border within which they are free to decide case by case what to do for the patient's best interest accordingly with evidences and their experience.

If it is true that Law 219/17 does not explicitly provide for conscientious objection, it is also true that paragraph 2 of art. 1 provides for the enhancement of the relationship of care and trust between doctor and patient “which is based on informed consent in which the patient's decision-making autonomy and the competence and responsibility of the doctor are met”. It is clear that the limit of self-determination lies in clinical judgment, based on evidence and is a function of the physician's capacity and the health system.

It is also obvious that so much is not a function of the free will of the individual doctor but must be in the informed consent. The latter must provide for the presence of procedures,

guidelines and good practices, but it cannot take place except in respect of equity, efficiency and effectiveness.

A final element of reflection concerns the essence of Modern Medicine. It is based on the concept of risk. It can be said that the health activity is based, due to biological vagueness, on the concept of “probability”. In the case of risk, this concept takes the form of the possibility of producing damage to the patient. It is also obvious that the goal of modern medicine is to reduce the risk to a minimum, creating barriers so that the potential does not materialize.

If so much is true with reference to medicine in general, it is also true in the case of organ donation.

If a medical treatment does not have direct therapeutic purposes, but is motivated by a commendable solidarity impetus, the assumption can only be the safety of the donor and therefore the certainty of having foreseen all possible precautions, both to prevent a risk from being realized, both to reduce the potential effects.

This must be considered fundamental and cannot be considered to have been superseded by the acceptance of an increased risk by the donor.

For non-life-saving transplants, the very essence of their practicability is lessened, and the keeping of the system and its solidarity presupposition would be put at risk. All this is not acceptable and in really complex issues, showing evident legal and ethical possible causes of conflict, the new law has not change the scenario. Probably the final decision of the National Committee would have been the same also before the approval of the law.

Finally, considering that deliberately in this article the economic aspects have not been analysed, the question remains whether in a health system with scarce resources it is right or not to channel resources for choices, certainly justifiable, but very personal, to the detriment of the majority of users.

CONCLUSION

The critical analysis on the effects of Law 219 in the medical field with particular reference to transplantation medicine highlights some essential points:

1. An unambiguous definition of the hierarchy of the interests of the patient and of the donor is necessary in the awareness that the system must aim at the maximum protection of the citizen/user. It seems appropriate, also for economic purposes, to identify structures that can guarantee specific standards for Jehovah's Witness patients, be they recipients and/or donors.
2. If the DATs are an instrument of relationship between doctor and patient, the will of the recipient and that of the donor constitute an unavoidable constraint. The revision and in-depth study of the criteria and methodology of ascertaining the will of the individual and his ability to understand and desire seems appropriate. In this sense we hope for interaction with Forensic Psychiatry and Psychiatry companies. In any case, in the presence of a Jehovah's Witness donor, the religious convictions must be considered by the decision-making algorithm, and be able to envisage, with the same clinical efficiency, the opportunity that other donors, if any, should be preferred.
3. The choices made must be evidence-based, transparent in their application in order to avoid misunderstandings and/or application difficulties. The scientific criteria are therefore useful to harmonize the behavioural model in the national territory in light of the risks of medicine and relational autonomy. This is also useful to prevent unjustified health tourism, but above all in respect of the principle of equality, enshrined in the Constitution of Italy and, more generally, of other Western countries.
4. The safety of the donor and of the System is non-negotiable and non-vicarious requirements. Acceptance of the increased risk on the part of the donor cannot be considered more important than the interest of the community. If the System is to be ready to safeguard the recipient/donor, the risk, minimized as much as possible, must be accepted by the donor.

On the basis of these critical elements, it appears necessary in the transplant community a review of the method, of the inspiring principles, and of the organization through a profound

meditation on the ethical-deontological hypotheses and on the “new” normative provisions so that they are translated into a useful and safe compromise for everyone.

From the clinical perspective, the resolution of complex cases such as the one object of our study can be represented by the possibilities of treatment and care without the use of blood components or their strong reduction through a proactive approach called Patient Blood Management (PBM).

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