Transfusion and Apheresis Science xxx (xxxx) xxxx

Contents lists available at ScienceDirect

Transfusion and Apheresis Science

journal homepage: www.elsevier.com/locate/transci

Review

Is the Italian consent to transfusion really informed? A medico-legal analysis between old ghosts and new evidence

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ARTICLE INFO

Keywords:
informed consent
transfusion risk
patient blood management
medico legal evaluation

ABSTRACT

In healthcare systems of developed countries, obtaining informed consent is a necessary and fundamental requirement for the administration of any medical treatment. In Italy, for the administration of the recipient's informed consent for a blood transfusion, a pre-printed form is used in line with the Decree of the Ministry of Health dated 2 November 2015. This paper aims to analyse this form in light of the European legal provisions and following the enactment of Italian Law No. 219 of 2017 on informed consent and advance treatment directives.

Our review shows that the structure of the form can be improved in light of the new direction provided by Italian law, the scientific advancement on transfusion risks, and the potential to reduce the use of blood components. Revising this form could be the opportune time to include written information on Patient Blood Management strategies. Though not exhaustive, this proposal may stimulate debate on the point and produce further contributions.

1. Background

In nearly all healthcare systems in Western countries, obtaining informed consent is a necessary and fundamental requirement in medical activities and for the proper recognition of patients. [1]

Although there are numerous applicable ways of expressing and obtaining informed consent, the underlying principle remains the respect of a person's autonomy and right to define his or her objectives and make decisions so as to achieve those objectives [2–6].

One effective legal definition of the concept of consent relating to medical-surgical activities is that it is a 'permit' by means of which the power to act is conferred upon the recipient. As authoritative as it may be, this definition, of a legal nature, is not entirely adequate for the complexity of the doctor-patient relationship and, therefore, this albeit unobjectionable definition must be enhanced and developed in order to grasp the true meaning of the term consent. The noun derives from the verb to consent, the meaning of which, given its Latin etymology, is to "feel together". The term therefore expresses a conformity of intents, the premise for the final act, represented by a patient's expression of a permit to a healthcare professional as regards appropriate or necessary activities. Consent is therefore to be understood as follows: a process of preliminary participation, an act of acceptance or non-acceptance of any proposed medical action.

Therefore, consent must necessarily involve: 1) recognition of the relationship, intended as direct and not mediated, between a healthcare professional and a patient, and 2) respect for a patient's self-determination (freedom of choice) in accordance with the information and decision-making process in relation to his or her health.

The relatively recent importance given to the theme of consent and the doctor's obligation to obtain such from the patient, as well as the considerable emphasis given to emblematic legal cases on the topic, has resulted in the creation of a widespread collective medical ethos which is often acritical and characterised by common misconceptions such as the need for oral expression of consent always to be confirmed in writing by the person concerned. Other commonalities include excessively formal attitudes such as the obsession with producing pre-printed forms in numerous diagnostic and treatment healthcare facilities or even inappropriate practices such as requesting forms to be signed even though the procedures described have not been performed, or that the form be signed after the procedure has been carried out but dated earlier. In addition, doctors authorise other healthcare professionals to ask an admitted patient, without having been previously

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https://doi.org/10.1016/j.transci.2020.102823
Received 20 April 2020; Received in revised form 8 May 2020; Accepted 18 May 2020

informed by the doctor themselves, to sign at the bottom of a consent form for a specific treatment or request one of the family members to give consent when the patient is not able to self-determine.

This behaviour is common in many medical activities, including in the field of transfusion medicine. As shown by the examples provided thus far, there are common practices recommended by doctors or other healthcare professionals, or even made policy by hospital management, based heavily on the age-old emotional impact rather than on solid legal and scientific basis. Therefore, it would appear necessary and beneficial to attempt to clarify some fundamental points as regards: 1) the most recent legal sources on the topic of informed consent and their effect on current transfusion practices, and 2) the most recent evidence as regards the real and common risks associated with transfusions, and the methods of introducing elements of consent for the implementation of Patient Blood Management (PBM) in hospitals.

2. Legal Sources

The right to self-determination in treatment choices is supported by international principles. Out of all of them it is most definitely worth remembering the first three articles of the European Charter of Fundamental Rights, in particular art. 3, which states: “Right to the integrity of the person. Everyone has the right to respect for his or her physical and mental integrity. In the fields of medicine and biology, the following must be respected in particular: a) the free and informed consent of the person concerned, according to the procedures laid down by law. (…)”.

The Convention on Human Rights and Biomedicine (or the Oviedo Convention) adopted on 3 April 1997 follows the same tenor, which, at the behest of the European Council, drafted said charter for the purposes of dictating ethical principles before legal on medical issues and on the patient-doctor relationship. In particular, article 5 states: 1) An intervention in the health field may only be carried out after the person concerned has given free and informed consent. 2) This person shall first be given appropriate information as to the purpose and nature of the intervention as well as regarding the associated consequences and risks. 3) The person concerned may freely withdraw consent at any time. (…)

The Convention was ratified in Italy by Law No. 145, 28 March 2001, but only after Law No. 219 of 2017 in the Official Gazette dated 16 January 2018 entitled “Provisions for informed consent and advance treatment directives” came into force has there been a real, organic and systematic discipline of activities pertaining to the information to be provided to the patient and to the means by which consent can be expressed [7–9].

Art. 1 states: “This Law (…) protects the person’s right to life, health, dignity and self-determination and stipulates that no healthcare treatment may be initiated or pursued without the free and informed consent of the person concerned, with the exception of the cases expressly provided for by law. (…)

3. Everyone has the right to know his or her health condition and to be informed in a complete, up-to-date way that he or she understands regarding any diagnosis, prognosis, benefits and risks of diagnostic tests and recommended healthcare treatments, in addition to the possible alternatives and consequences of any refusal of or withdrawal from healthcare treatment or diagnostic test. He or she may refuse in whole or in part to receive information or indicate the family members or a trusted person appointed to receive that information and express consent in his or her stead, should the patient so desire. Refusal or waiving of information and designation of an appointee is to be recorded in the medical records and the electronic medical file.

4. Informed consent, obtained using the methods and tools most appropriate for the patient’s condition, is to be documented in writing or by means of video recording or, for a disabled person, by means of devices that allow him or her to communicate. Informed consent, in whichever form expressed, is to be included in the medical records and in the electronic medical file”.

The law even delineates the methods in which a person may determine his or her treatment choices in advance by drafting an advance directive or a shared care plan. However, we want to focus on some important aspects emphasised by the laws in effect regarding consent.

A patient’s right to be informed regarding: 1) his or her health condition, and 2) any diagnosis, prognosis, benefits and risks of diagnostic tests and healthcare treatments recommended, in addition to the possible alternatives and consequences of any refusal of the recommended healthcare treatment.

The law explicitly states the characteristics that the information must include. More specifically, it must be complete, up-to-date and understandable to the patient. Therefore, standard practices inherent in the doctor-patient relationship should include a method of communication appropriate for the patient’s condition and ability, thus focused on his or her needs and characteristics, without compromising its complete and up-to-date nature in relation both to the pathological condition from which the patient suffers and the recommended treatment along with the associated risks and possible alternatives.

These indications are given in order to guarantee the patient the most complete and articulate decision-making freedom possible. They are such fundamental attributes that the law itself emphasises the doctor’s communicative obligation towards the patient, as it states: “Art. 1 (8): The communication time between doctor and patient constitutes care time. (9): Every public or private healthcare facility must guarantee the full and accurate implementation of the principles of this law by means of organisational initiatives, ensuring that patients receive the necessary information and that personnel receive adequate training. (10): The initial and continued training of doctors and others in the healthcare profession includes training in matters of relating to and communicating with the patient, of pain therapy and palliative care. (11) With the exception of the application of special regulations that govern obtaining informed consent for certain medical actions or treatments”.

Healthcare professionals are therefore required to perform the important task of providing complete information in order to obtain consent. Providing information to a patient calls for an active process of communication between the healthcare professional, who provides knowledge, and the patient, who asks for explanations and clarification regarding any recommendations. The information should therefore be put in such a way as to encourage the receiver to participate in the discussion critically and potentially, but not necessarily, to make a decision on the basis of such. This cannot always be completed in one conversation but should be developed throughout the care process.

To support the effort of individual professionals, hospital institutions are required to be proactive in implementing management provisions aimed at enabling continual communication training.

The spirit of the law differs greatly from common practices, which view consent as a mere written attestation, a necessary bureaucratic act to be tolerated due to pointless legal requirements.

Art. 1 (11) of the law refers to special laws that govern obtaining informed consent for certain medical actions or treatments. These are particular conditions for which other laws expressly dictate that the patient must provide clear and documented consent (Table 1), among which only some expressly require written consent such as Medically Assisted Procreation, drug trials and the use of blood components.

This does not mean that written attestations are not useful on the matter of consent; on the contrary, documenting the attestation of patient consent is appropriate, especially in relation to diagnostic or therapeutic interventions of a complex, non-routine nature and/or affected by significant risks. Such consent should be accompanied by the appropriate notes made in medical records, citing the advance information provided and verification that the patient has understood. These notes, like others in the records, should be appropriately dated and signed and can be included with the patient’s written and signed confirmation. Some deontological codes also envisage the convenience

Table 1
Special law for written consent.

Reference in Law	Passage of Interest
Law No. 458 of 26 June 1967 "Kidney transplant between living people"	**Art. 4** A transplant of a kidney lawfully removed and assigned to a certain patient cannot take place without this person's consent or in the absence of an emergency.
Law No. 135 of 5 June 1990 "Programme of urgent interventions for the prevention of and fight against AIDS"	**Art. 5 Infection Test** 3. Nobody can be subjected, without his or her consent, to analysis to test whether infected with HIV unless on the grounds of medical necessity in his or her interests (…).
Law No. 94 of 8 April 1998 "Conversion into law, with adjustments, of Decree-Law No. 23 of 17 February 1998, containing urgent provisions in matters of clinical trials in the field of oncology and other measures in healthcare matters"	**Art. 3. Observing Authorised Therapeutic Indications** 2. In individual cases, having first informed the patient and obtained consent, a doctor may, under his or her direct responsibility, administer an industrially produced drug for a recommendation or method of administration or use different from the one authorised (…) Art. 5 – Prescription of Magistral Medicine. 3. Doctors must obtain the patient's consent to medical treatment and specify on the prescription the particular needs that justify resorting to an extemporaneous prescription.
Law No. 483 of 16 December 1999 "Regulations for permitting a partial liver transplant"	**Art. 1. Partial Liver Transplant** 2. For the purposes of that referred to in clause 1, the provisions of Law No. 458 of 26 June 1967 are to be applied where compatible.
Legislative Decree No. 211 dated 24 June 2003 "Implementation of European Community Directive No. 2001/20/CE regarding application of good clinical practices in performing clinical drug trials for clinical use"	**Article 3 – Protection of Persons on Clinical Trials** 1. Clinical trials can be only undertaken provided: (…) d) the person participating in the trial or, if the person is not able to provide informed consent, his or her legal representative, has given consent after being informed as to the nature, importance, scope and risks of the clinical trial. If the person concerned is unable to write, he or she may as an exception give oral consent in the presence of at least one witness, in respect of the regulatory provisions in effect in said matters.
Law No. 40 of 19 February 2004 "Regulations on Medically Assisted Procreation"	**Art. 6. Informed Consent** 3. The wishes of both persons to avail themselves of the techniques of medically assisted procreation are to be expressed in writing along with the head doctor of the facility in accordance with the methods defined by the Decree of the Ministers of Justice and Health, …
Law No. 167 of 19 September 2012 "Regulations for permitting a partial lung, pancreas and intestine transplant between living people"	**Art. 1. Partial Lung, Pancreas and Intestine Transplant** 2. For the purposes of that referred to in clause 1, the provisions of Law No. 458 of 26 June 1967 and of the regulation referred to in the Decree of the Minister of Health dated 16 April 2010, No. 116 are to be applied where compatible.
"Blood Ministerial Decree" Decree of the Ministry of Health 2 November 2015 Provisions relating to the requirements of quality and safety of blood and blood components (Official Gazette No. 300 of 28 December 2015 – Ordinary Supplement No. 69)	**Art. 8 Informed Consent (…) for the donation of blood and blood components.** 2. Having completed the procedures for arriving at a judgment of appropriacy, the doctor responsible for the selection shall request the donor, who has been duly informed in advance, to give consent to donation, to tests prescribed by the law being carried out on that blood sample, including for HIV or other tests for the safety of the blood donation, to the eventual use of donated blood components for studies and research aimed at protecting the donor's health, third parties and the community (…) 3. The donor must give informed consent for donation by signing the form in Attachment II, part C. **Art. 24. Recipient's Informed Consent** 1. The recipient of a transfusion of blood or blood components and/or the administration of blood derivatives is required to give consent or state his or her refusal of transfusions explicitly in writing. He or she must first be informed, including by means of the appropriate informative material, that such procedures may not be completely risk free. 2. In cases that involve repeated transfusion treatments, consent given at the beginning of the treatment is considered valid for the duration of the treatment, unless explicitly revoked by the patient. 5. The recipient must give consent to a transfusion of blood or blood components and/or the administration of blood derivatives by signing the form referred to in Attachment VII, point G.

of consent in written form in certain situations.

3. Transfusion Consent

Having stated the general, legal, national and international principles that regulate informed consent, of particular interest for this discussion is informed consent given by the recipient of a blood transfusion. This type of consent is one of the very few cases in which, by law, informed consent must be obtained in standard written form. This type of attestation was recommended in the Decree of the Ministry of Health, 2 November 2015 - Provisions regarding the requirements of quality and safety of blood and blood components.

The Decree recommends the following formula: "I, [name, surname] born in [city] on [date of birth] have been informed by Dr. [name, surname] that, for my clinical condition, I may need to undergo transfusions of blood and blood components and/or the administration [infusion] of blood derivatives [products], and that this therapeutic practice is not completely free of risks (including the transmission of viruses responsible for transmissible infectious diseases, such as AIDS, Hepatitis B, Hepatitis C etc.). I have understood what was explained to me by Dr. (…) regarding my clinical condition, the risks associated with transfusions and the potential consequences of refusing a transfusion. [] I consent or [] I do not consent to undergo blood transfusions or the administration of blood products that might become necessary for the duration of the treatment. Date, Signature, Signature of the physician who obtains consent".

This form is utilised in many hospitals throughout Italy but must be considered outdated given the contents of Law No. 219 of 2017.

In fact, there are numerous problems with the formula:

a) it does not clearly explain the pathological condition for which

the patient needs a transfusion, nor the desired result of the treatment; rather, it refers to a generic and hypothetical need for a transfusion.

b) there is no differentiation between the administration of blood components and blood derivatives. The difference is substantial and the risks involved with blood derivatives are notably different and much more contained.

c) the formula refers to poorly defined "risks". There is only one sentence given as an example which only mentions the infection of AIDS and Hepatitis B and C.

Although the tragedy of viral transmission, particularly of HIV, by means of blood transfusions in past decades has focused medical and media attention on the infectious risks of transfusions, today, at least in Western countries, the risk of contracting an infection from these three pathogens as a result of a transfusion of blood components is statistically very low, so much so that these events can be considered ghosts of the past. However, there are more frequent and similarly frightening risks that exist today, not only of an infectious nature. The principal causes of death and serious damage due to transfusions today are represented by transfusion-associated circulatory overload (T.A.C.O.) (1 case per 100 transfusions), transfusion-related acute lung injury (T.R.A.L.I.) (1 case per 10,000 transfusions), transfusion error wherein a patient is administered the wrong blood component, and bacterial contamination of the component [10–13]. However, the formula above makes only brief mention of transfusion-related risks, citing only the most remote and more easily controlled of today. No mention is made of the negative consequences that arise from transfusion treatment, above all immunomodulation.

d) the formula gives no importance to the clinical strategies involved in PBM; rather it offers a dichotomous choice between accepting or refusing transfusion support without even taking into account the options for avoiding it.

The suggested formula evidently needs to be reformulated in order to guarantee that when transfusion consent is obtained, the information the patient receives can be defined as complete and up-to-date in accordance with current scientific and epidemiological evidence. Similarly, adequate information must also be included regarding the PBM program that is to be implemented in order to avoid or at least reduce recourse to blood components.

PBM is defined as an evidence-based bundle of care to optimize medical and surgical patient outcomes by clinically managing and preserving a patient's own blood (www.ifpbm.org) or alternatively, the Italian Society of Anesthesiology, Analgesia, Resuscitation and Intensive Care - SIAARTI [14] provides the following definition: "a multidisciplinary, multimodal and personalized approach aimed at reducing or eliminating the need for allogeneic blood transfusions via the evidence-based management of anemia, the reduction of blood loss and the optimization of blood-saving strategies".

By means of a multi-discipline approach undertaken by applying different strategies that can be summarised by applying the three pillars [15–16] improvement of patient outcomes and a considerable reduction in recourse to administering blood products can be achieved. On this point, a systematic review of the PBM programs implemented worldwide has shown a significant reduction of transfusion rates by 39% [17]. The implementation of Patient Blood Management in hospital facilities is one of the first objectives to be achieved in order to guarantee national self-sufficiency in the future and above all to guarantee patients greater safety and improve outcomes.

Redefining the formula for transfusion consent might be the ideal occasion to implement the indications contained in the Guidelines for the Patient Blood Management Program published by the National Health Institute by means of the National Blood Centre of Italy [18]. On this point, the guide lines refer to Recommendation No. 9 where it recommends "that all adult patients who are candidates for more elective surgical operations for which a multi-discipline program of coordinated operations has been arranged, which requires the implementation of pharmacological and non-pharmacological techniques to optimise erythropoiesis, containing blood loss and optimising tolerance of anaemia, before giving consent to one or more of the above-mentioned treatments, should receive exhaustive information on their clinical situation and on the strategies for containing the need for homologous transfusions included in the local Patient Blood Management program. This may include material produced ad hoc by the hospital facility".

The production and use of such material structured so as to help patients understand the importance of diagnosing and treating anaemia through a proactive approach with a view to preventing blood loss and situations requiring transfusions may help when informing patients regarding their condition and blood requirements. Such an awareness may not only adequately satisfy legal obligations but also enhance patient understanding and participation in PBM strategies, especially in cases of planned operations, thus ensuring full patient compliance in association with the best clinical results [19].

Furthermore, it could standardise the procedures of transfusion consent and consent to blood conservation strategies in PBM, thus avoiding clear imbalances.

In Italy, PBM was initially implemented by applying the first pillar through treating anaemia by means of parenteral iron formulations. Many facilities have prepared complex and articulate written consent forms for administering them, some of which refer to other, quite remote, risks in view of transfusion consent that is inadequate for the reasons previously explained.

Having reiterated the fact that in Italy there is no legal obligation to make patients sign a written consent form for the intravenous administration of iron, it may however prove to be useful, especially if the patient is provided with complete information and planning as regards the complete range of PBM strategies used with a view to balancing transfusion risks and minor risks derived from strategies for avoiding blood transfusions, some of which completely risk free such as the use of microsampling, point of care methods or the implementation of meticulous surgical approaches. Even when patients are subjected to the administration of drugs to optimise erythropoiesis, such as intravenous infusions of iron, which inevitably involve some risks, it is reasonable to conclude that these risks are well-known and can be adequately controlled by means of prevention strategies [20] and that "the benefits of all medicines containing iron for intravenous administration continue to outweigh the risks" [21–22]. Therefore, there should be no medicolegal obstacles to the complete implementation of each aspect of Patient Blood Management programs [23–26].

4. Conclusions

The discipline of informed consent serves as a fundamental clinical activity which guarantees the patient's exercise of rights. In order to accept medical treatment, patients must be adequately informed as to their condition and the risks and benefits expected from the recommended treatment. As concerns transfusions, it is evident that the methods for expressing consent must be updated by means of a thorough revision of the written attestations in use to include not only the transfusion risks that are the most up-to-date and closest to the current situation but also the options made possible by the implementation of the Patient Blood Management program. In so doing, not only will it be possible to adhere to the indications provided by recent legislation but also, and most importantly, to increase patient safety and wellbeing.

Declaration of Competing Interest

The authors declare no conflict of interest.

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