

Presidenza del Consiglio dei Ministri



**OPINION ON THE PRESERVATION OF
ANONYMITY OF DONOR AND RECIPIENT IN THE
TRANSPLANTATION OF ORGANS**

27 September 2018

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Presentation

The National Transplant Centre (NTC) put the following query to the Italian Committee for Bioethics (ICB) regarding: "Whether the anonymity requirement to which the administrative healthcare personnel is legally bound under art. 18, paragraph 2, Law April 1, 1999, n. 91, may be waived by agreement of the parties upon signature by both of informed consent".

The document moves from a procedural description of how the healthcare professionals and administrative personnel of the transplant network in our country adhere to maintaining anonymity, within the context of the various types of donations: the information provided by the national transplant network and the type of communication allowed between the National Transplant Centre and the donor and the donor's family members. Modalities can be diversified without prejudice to traceability which for medical reasons remains an indispensable requirement.

The Committee makes a distinction, within this context, between the time "preceding" transplantation and that "subsequent" to it, which directly involve the donor (or the donor's family) and the recipient. The Committee sets out the different currents of thought in favour of anonymity and those in favour of identification, outlining and reflecting on the topics in a dialectical way, and delineating an intermediate path in the context of possible agreements between the parties.

Within the context of organ donation the ICB deems it to be ethically indispensable to maintain the requirement of equity guaranteed by strictly objective considerations, based on clinical criteria and priority on the waiting list. It considers the current procedure which privileges anonymity to be not only preferable but also an indispensable requirement in the initial phase of organ donation as well as that subsequent to, it if there is no agreement between the parties to have contact.

However, it believes that it is not contrary to the ethical principles that characterise organ donation to allow the possibility for donor and recipient to give their free and informed consent after the transplant to have contact and meet, mediated by health centres or third parties indicated by legislation.

The committee urges for the guarantee of a press blackout in order to avoid exploitation by the media.

The working group was coordinated by President Prof. Lorenzo d'Avack, who drew up the draft opinion, including the contributions of Proff: Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Antonio Da Re, Marianna Gensabella, Assunta Morresi, Laura Palazzani, Carlo Petrini, Lucio Romano, Lucetta Scaraffia.

A major contribution came from the consultations of both Prof. Alessandro Nanni Costa, Director of the National Transplant Centre, and Prof. Morelli who practices at the Liver and Multivisceral Transplant Centre of Sant'Orsola Malpighi Hospital in Bologna.

The opinion was voted unanimously by those present entitled to vote, Proff: Salvatore Amato, Stefano Canestrari, Carlo Casonato, Antonio Da Re, Lorenzo d'Avack, Riccardo Di Segni, Gian Paolo Donzelli, Silvio Garattini, Mariapia Garavaglia, Maurizio Mori, Assunta Morresi, Laura Palazzani, Tamar Pitch, Lucio Romano and Grazia Zuffa.

Proff: Luisella Battaglia, Carlo Caltagirone, Cinzia Caporale, Francesco D'Agostino, Bruno Dallapiccola, Mario De Curtis, Marianna Gensabella, Massimo

Sargiacomo, Luca Savarino, Lucetta Scaraffia and Monica Toraldo di Francia, absent from the session, subsequently assented.

Despite their not having the right to vote assent was given by: Prof. Carlo Petrini, the delegate for the President of the National Institute of Health; Dr. Maurizio Benato the delegate for the President of the National Federation of MDs and Dentists Colleges and Dr. Amadeo Cesta the delegate for the President of the National Research Council.

The President
Prof Lorenzo d'Avack

1. Introduction

The National Transplant Centre (NTC) put the following query to the Italian Committee for Bioethics (ICB) regarding: "Whether the anonymity requirement to which the administrative healthcare personnel is legally bound under art. 18, paragraph 2, Law April 1, 1999, n. 91, may be waived by agreement of the parties upon signature by both of informed consent".

The query raised by the NTC implies that the ICB should take into consideration different types of transplantation (heart, lung, liver, pancreas, intestine, kidney, marrow, tissues), from cadavers or from donors not connected to the recipients by any emotional relationship or kinship, so-called "Samaritan donor" or as a result of "crossing", always under cover of anonymity, referred to as "crossover"¹. The specificity of the problem today consists in the fact that the donor, the family of the deceased and the recipient in these cases do not know each other; before or after the transplant, this "totally unknown" aspect characterises the donation of organs or tissues carried out at a transplant centre or a medical facility.

The query, on the other hand, does not raise the question of whether or not transplantation presupposes the "principle of gratuity", a principle currently guaranteed by our legislation, and recognised by various opinions already formulated on the subject in other circumstances by the ICB. The bioethical consideration is confined only to anonymity, which can be considered to a greater or lesser extent an instrument of protection of the principle of gratuity or assessed in relation to acceptance of the transplant itself both for the donor, or family members (in the case of cadaveric transplant), as well as for the recipient, or finally in relation to the promotion of donation. Furthermore, the ICB restricts itself to responding to the query regarding anonymity, without addressing other aspects, although relevant from the standpoint of philosophical anthropology and ethics, such as the status of the human body or the meaning of the gift.

2. Insight into the current procedure

Currently, the healthcare professionals and administrative personnel of the transplantation network in our country are committed to maintaining anonymity in accordance with art. 18, paragraph 2, of Law n. 91/1999 containing *Provisions on the collection and transplantation of organs and tissues*, which stipulates that "the healthcare professionals and administrative personnel, involved in the activity of collection and transplantation, is required to ensure the anonymity of the data concerning the donor and recipient".

In the case of cadaver donors, the resuscitating physicians check whether the deceased person has a document certifying his or her statement of intent or if it has been registered in the Transplant Information System (SIT). Therefore, it

¹ In this case, faced with the impossibility of a transplant for reasons of biological incompatibility between blood relatives or between *emotionally related persons*, we proceed to search for other couples in similar situations, willing to participate in crossover organ donation. Crossover transplantation has in time, acquired an increasingly significant factual prominence due to the chronic lack of organs, and the frequency of incompatibility within the family circle and emotionally related persons as well as the fact that it yields better outcomes compared with cadaveric organs for transplantation, with the possibility of accessing transplantation more quickly resulting in positive effects on both the psychophysical health of patients and on the economic-social burden of pre-transplant treatment.

is customary for the centres to engage with family members, since in the absence of a statement they can provide information about the relative's expressed will when still alive. For minors, the parents are always the ones to decide, with the authorisation of both parents being required. It should be noted that citizens can change their statement of intent at any time and that the last statement in order of time in accordance with the procedures laid down is considered valid.

From a procedural point of view a letter of thanks is sent to the donor and to the donor's family who has consented to organ donation or tissue donation from cadavers. The national transplant network is also able to provide a substantial amount of information, even ten years after the surgery, regarding: how many and which organs or tissues were transplanted, the number of people they were transplanted into as well as the conditions of the recipients. However, the names of donors and recipients are never communicated. Sometimes, in cases, carefully evaluated by the experts of the NTC, messages can be exchanged between the parties, but no direct contact is promoted or allowed.

The NTC can provide information to health professionals who were in charge of the donor by sending a letter, usually bearing the signature of the director, containing information on transplants, always in compliance with anonymity.

Finally, we cannot forget that, as in other forms of organ donation or parts of organs, cells, tissues of the human body, destined to permanently form part of the recipient and become physiologically and permanently integrated in the body, this can lead to the onset of disease in the transplanted organ or in the surrounding tissues. In these cases for diagnostic, etiological and therapeutic requirements, it may be necessary to know the clinical data of the donor: for the benefit of the recipient or the donor, the rights and duties of the persons involved impose forsaking absolute anonymity while preserving the anonymity of the identity of the donor and recipient in their interpersonal relationships, it is legitimate and necessary to transfer personal and clinical data from the transplant surgeon to the treating physician and vice versa (both bound by professional secrecy). It should be noted, however, that according to clinical and social experience, the greater the number of subjects involved and the flow of confidential information, the greater the risk of (intentional or unintentional) disclosures to third parties

The donation of organs and tissues remains, therefore, a free, anonymous and supportive act to restore a better life to those waiting to receive a transplant, a consolidated treatment.

3. The reasons for anonymity

As already indicated in the query, Law n. 91/1999 lays down *Provisions for the collection and transplantation of organs and tissues* stating that "the healthcare and administrative personnel, engaged in the activity of collection and transplantation, is required to ensure the anonymity of the data related to the donor and recipient".

In fact, the whole regulatory framework regarding any kind of donation and transplantation in our country provides for anonymity between donor and recipient² and the principle of explicit consent or dissent applies for the

² Legislative decree n. 196/2003 to the art. 90, paragraph 3, provides that "the bone marrow donor, pursuant to Law 6 March 2001 n. 52, has the right and the duty to maintain anonymity both

manifestation of the will to donate (see art. 23 "*Transitional provisions*" of Law No. 91/1999). Tacit consent introduced by articles 4 and 5 of Law 91/1999 has never been implemented³. Every adult citizen has therefore been offered the possibility (not the obligation) to declare their will (consent or refusal) regarding the donation of organs and tissues after death.

The ICB took the occasion in the opinion on living organ donation to strangers to emphasise that in general in these matters the introduction of forms of selection or discrimination are ethically to be avoided whereas the criteria of equity given by immunological compatibility, urgency and priority on the waiting list are to be retained. "It is essential for the donor to know that the donated organ will not be sold or snatched up by intermediaries who could derive economic benefits, but that it will be destined to the person in most need. In this procedure the ICB particularly appreciates the principle of anonymity, which above all must be carried out avoiding that the two people involved in the transplantation (donor/recipient) have mutual relations both before and after the operation"⁴.

Even the Superior Health Council, in the opinion of 4.05.2010 concerning living organ donation to strangers, expressed a positive opinion on the application of the rule of anonymity for the donor and recipient.

Furthermore, in the specific case of donation in "crossover" modality, the National Transplant Centre, lamenting that in the phase held before the magistrate the couples involved in the living-donor kidney transplantation process were summoned and heard at the same time, reiterated that anonymity is a value to be maintained and which makes it possible to:

= avoid negative feelings among the different couples that could result in the cancellation of the crossover transplantation;

= avoid comparisons between the transplant outcomes, which could be different for the recipients and generate negative feelings in the couples who have suffered the unfavourable outcome.⁵

towards the recipient and towards third parties. The legislation on the subject of cells and tissues n. 191/2007 having regard to *Implementation of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*, article 14 provides that "all data including genetic information ... are rendered anonymous in such a way that neither the donor nor the recipient is identifiable (...) the identity of the recipient(s) is not disclosed to the donor or his family or vice versa". To the regulatory framework there must be added the regulations for the protection of privacy pursuant to Legislative Decree 30 June 2003, n.196.

³ Law n. 91/99 lays down *Provisions for the collection and transplantation of organs and tissues* provides for the "tacit consent" clause, even if this clause has not actually been applied in our country. "Tacit consent", in fact, was justified only as a result of adequate information to citizens by the state, necessary to form their consent. In the absence of full and complete information, "tacit consent" cannot be asserted, and where there is "no response" registered regarding possible donation from the deceased person, the law entrusts the family with the faculty of deciding thus attributing a social value to the donation, safeguarding the right to health of other individuals.

⁴ Italian Committee for Bioethics (ICB), *Kidney donation from a living donor to a stranger (so-called Samaritan donation)*, 2010. From the ICB see also: *The bioethical problem of the Kidney transplant from a non-blood related living donor*, 1997; *Organ donation for transplantation purposes*, 1991; *Motion on the trade of organs for transplant*, 2004; *Body donation for scientific research*, 2013.

⁵ Letter of 23.10.2012 to the Vice-President of the ICB, Lorenzo d'Avack, requesting an opinion on the need to ensure anonymity at all stages of the transplant kidney transplantation process in crossover modality.

It is precisely because of these protection requirements that, the NTC, in the Protocol for the realisation of living-donor kidney transplantation in crossover modality of 20.11.2006, established that transplantation according to this modality must be carried out in such a way as to ensure the highest possible degree of anonymity and confidentiality and that the couples involved in the procedure have no right to know one another.

The Directive 2010/53/EU of 7 July 2010 of the European Parliament and of the Council of the European Union⁶, in the "recital" on the quality and safety standards of human organs intended for transplantation applicable to the donation of organs by living donors and deceased donors provides for "In principle, the identity of the recipient or recipients should not be disclosed to the donor or his family or vice versa". Article 16 of the same Directive also requires Member States to take all necessary measures to ensure that donors and recipients whose data are processed within the scope of this Directive are not identifiable. The NTC deems it necessary to respect the principle of anonymity for living-donor kidney transplantation in crossover modality in collaboration with other European countries, as is frequently the case today.

Finally, the Italian Association for the donation of organs, tissues and cells (A.I.D.O.) in the informative material specifies that "The donation of organs and tissues is an anonymous and gratuitous act of solidarity. No type of economic remuneration is allowed and it is not possible to know the identity of the donor and the recipient".⁷

The obligation and the reasons of anonymity between donor and recipient relevant in the case of living donor transplants can also be found in cadaveric organ donation. Even in these cases the rationale is to be sought in avoiding possible unwanted consequences both for the donor's family and for the recipient and his family, such as feeling obliged to do something in exchange for the received organ or even emotional distress arising from disappointment when the expectations of both sides are not met. There may be the fear that one party will make unreasonable emotional and economic demands on the other or that there may be negative effects on the donor's family or the actual donor should the donation fail, or the recipient be an undesirable person for the most diverse reasons. There may also be "idealisation" of the donor by the recipient: and possible "disappointment" on knowing the donor which could cause "psychological rejection" of the organ. Moreover, living with a transplanted organ also means "welcoming the other": an acceptance that may be different depending on the transplanted organ and its symbolic meaning. It is understandable that the recipient may experience psychological difficulties in acquiring a new organ and knowing that he or she is alive because another person is dead.

The problem of the length and complexity of the process of organ acceptance, even in the post-transplant phase, was underlined by Prof. Cristina

⁶ The Directive was transposed, with over three years delay, with the decree dated November 19, 2015 ("Implementation of Directive 2010/53/EU of the European Parliament and of the Council, of 7 July 2010, concerning the quality and safety standards of the human organs intended for transplantation, pursuant to Article 1, paragraph 340, Law 24 December 2012, No. 228, as well as application of the Commission Implementing Directive 2012/25/EU of October 9, 2012, which establishes the informative procedures for the exchange between Member States of human organs intended for transplantation", published in the Official Journal of December 1, 2015).

⁷ <https://www.aido.it/faq>.

Morelli⁸, in the hearing held at the ICB: "Even the most successful transplants require a psychological pathway for the recovery of the patient's role in the family and in society. The recipient often expresses the desire to have information about the age of the donor, but rarely asks to know the family. This type of patient has to be protected, as the patient is overwhelmed by new conditions; chronic pharmacological treatment, protection from infections, changes in family structure. The message that has to be made clear to the family of the donor is that they have done so much for society rather than for the individual, whose transplant experience could also fail. Personalisation of the donor/recipient relationship is to be considered very risky" (hearing of 18 May 2018).

The president of the National Transplant Centre, Dr. Alessandro Nanni Costa, pointed out that contact between donor and recipient could present various problems. "The first is that very often the recipient wants to remain anonymous and, in fact, has the right not to have links with the donor, just as he/she has the right to treatment. Moreover, the donor often has to deal with the process of 'mourning' and the risk of projecting the life of the relative, lost in dramatic and sudden circumstances, to the recipient. These basic movements are then filtered through the cultural and social status and the different individual conditions. The legislator does not prohibit contact, but stipulates that health personnel are not required to provide information. Relationships are normal in some cases, other times death, which is an unfavourable event, can be a problem for the family that has donated" (hearing of 18 May 2018).

The basic idea is that we must protect families and patients from other pain and that respect for the cardinal principles of transplants is to be guaranteed: in addition to the principle of medical ethics of appropriateness (safety, efficacy, quality) also the ethical principles of gratuity, solidarity, transparency, equity. And this leads back to the problem, similar in all organ donations to strangers, which is the reliability of the healthcare network that manages the transplant.

It is difficult to evaluate statistically how real these risks are in clinical practice in our Country, given that the interested parties generally know that they are covered by anonymity. It is therefore essential that any exceptions to the anonymity criterion do not tarnish citizens' trust in the transplantation system: such damage would be serious.

4. New requests

In view of the current regulatory framework on the matter, the NTC has shown that there is a heated public debate on whether or not there is the need to preserve the anonymity of donor and recipient in all phases of donation and transplantation. Above all, the question of whether the obligation of anonymity can be waived, when there is a specific informed agreement between the parties, is discussed⁹.

⁸ Who practices at *The Liver and Multivisceral Transplant Centre* of Sant'Orsola Malpighi Hospital in Bologna.

⁹ Particularly active in this campaign in favour of an end to anonymity is the journalist Reg. Green, father of Nicholas Green, the 7-year-old Californian boy accidentally killed during an attempted robbery on the Salerno-Reggio Calabria motorway in 1994 and whose organs and corneas were donated for transplantation purposes.

The issue of preserving anonymity appears to be more complex with the spread of new ICT technologies in the era of "big data" and "social networks".¹⁰ Despite the NTC's limited willingness to provide information regarding donor and recipient (e.g. age and sex), it is possible to identify them with greater ease and rapidity than in the past, with the increase and acceleration of collection, storing and processing of information.

When addressing the issue of anonymity within the sphere of transplantation, it can be discussed distinguishing between two different phases: the time "preceding" transplantation and that "subsequent" to it.

It should be remembered that there is no lack of currents of thought that believe that cadaveric organ or living organ donation to strangers in its initial phase can also be "nominative" or "conditioned". The donor could give the medical centre a binding indication of the hypothetical future recipient or simply include or explicitly exclude certain categories of people, based on their residence, ethnicity, culture, religion, gender, age, social position or fame, lifestyle, moral behaviour, personal responsibility for diseases (e.g. alcoholism, drug addiction, smoking).¹¹

We can also consider those cases in which the transplant is obtained by means of a "public appeal"¹² by the person who needs it urgently despite the person being on a waiting list for a cadaveric transplant, their own family or friends being unsuitable or unwilling. In this type of organ or tissue donation one party, the donor, remains anonymous, while the other, the recipient is well known by the donor, from the very beginning of the procedure.

Foreseeing the bringing to an end of anonymity right from the initial phase of the transplantation procedure is certainly a different supposition to its being realised at a later stage after transplantation has taken place with the consent of the parties involved. In the first case we have in theory a far more marked separation from the "donation" ethos in the bioethical context and a procedure that more easily leads to a negotiating relationship. In both cases, however, those who advocate these possibilities are part of that current of thought which places strong emphasis on respect for the private choices of each individual as well as on autonomy which should be affected as little as possible by the restrictive intervention of the state. What is deemed to be important is the sharing, even if it remains a supererogatory act, of the important bioethical principle of "consent".

Surveys conducted in various countries show that living donors, but above all family members in the case of cadaveric organ donation, who want to "know" about the recipient and the work performed by transplant centres, lay claim to personal values and the right or at least the possibility of having complete

¹⁰ See the ICB opinion, *Information and Communication Technologies and Big Data: bioethical issues*, 2016.

¹¹ A possibility excluded in our organ donation legislation.

¹² The methods used to solicit the public can include any means of communication: newsletter, billboards, appeals through community groups (religious groups or congregations), workplaces, websites and media platforms (Facebook and Twitter). For the Canadian Medical Association, which has addressed the problem, the acquisition of organs or tissues via public notice should always be discouraged, as it "raises justice problems" and considerable risks for the person making the request in view of the public solicitation both before and after the transplant. See the Canadian Medical Association, *Organ and Tissue Donation and Transplantation*, 2014. See also Comité Consultatif De Bioéthique De Belgique, *Avis n. 72 du 8 mai 2017 relatif à la sollicitation publique de dons d'organes par un donneur vivant*; AA.VV., *Public Solicitation of Anonymous Organ Donors: A Position Paper by the Canadian Society of Transplantation*, in "Transplantation Journal", 2017, vol. 101, pp. 17-20.

autonomy in making such decisions and disposing of their organs or tissues or those of a family member. They place their moral gesture within the domestic sphere and the realm of interpersonal relationships, and have no intention of sharing their solidarity and empathy with the whole community.

Those supporting an end to anonymity highlight several reasons and advantages:

- = the family members of a donor can recover from their bereavement more easily on receiving positive news of the results obtained directly from the persons involved and gratified by the gift and who have once again become active members of society;

- = it would be possible to establish an emotionally strong and rewarding relationship between the donor and the recipient that would make that gesture of human generosity even more profound;

- = the recipients, in favour of direct contact, in turn, even in the face of certain fears (emotional consequences or inability to handle the situation), would have the opportunity of achieving a positive state of mind, such as, for example, showing gratitude or sharing the result of the transplant;

- = the concern that the two parties involved in the transplant may suffer psychological harm, when writing or meeting each other, rarely occurs;

- = another reason in favour is that the percentage of organ donations tends to increase, thanks to the potential publicity carried out.¹³

These arguments in favour of ending anonymity in the phase succeeding transplantation, despite the initial secrecy maintained in the relationship between donor and recipient, draw mainly on common practice in the USA,¹⁴ where, if there is a mutual desire to meet, the deceased donor's family can meet the recipients of the organs, in accordance with criteria of prudence and rigorously verified freely expressed mutual will.

However, although the debate on communication between the family of the organ donor and the recipient is ongoing in the field of transplantation, the number of studies dealing with this in medical literature are few and of low scientific quality, leaving the families of donors, patients, citizens, healthcare workers and ethics experts in huge uncertainty. For example, the arguments with regard to possible increases in donations as a result of ending anonymity and the existence of relationships between donors and recipients, are in fact, not verified. Other reasons, for example of an organizational nature, could explain increases in donations. In this regard, the Report on donation and transplantation activities (31 December 2017) of the National Transplant Centre showed that - while respecting anonymity - in that year there was a "record" number of donations and

¹³ Reg. Green has stressed that after the donation of his son's organs and the publicity that came about "in that period the percentage of organ donations in Italy tripled, an increase to which no other country has come close to ... the phenomenon has been defined as The 'Nicholas effect', and those front-page stories and the television interviews that showed us together with vigorous transplant patients were a crucial part of the phenomenon" (R. Green, *La privacy sulla donazione di organi causa inutile dolore alle famiglie?*, in "Giornale italiano di nefrologia", 2017). See <http://giornaleitalianodinefrologia.it/2017/07/18/la-privacy-sulla-donazione-di-organi-causa-inutile-dolore-alle-famiglie/>.

¹⁴ Some US studies have shown that a percentage oscillating between 52% and 77% of recipients would be favourable to direct contact. See. <http://trapianti.net/news-letteratura/anonimato-del-donatore-opinioni-a-confronto/>. The work done and the experience gained in this field by the 58 Organ Procurement Organizations (OPOs) in the United States, accountable to the Government for the supervision of organ donation in their States or areas of competence recommend contact between the parties, this should be taken into consideration.

transplants.¹⁵ "The growth is not only in the numbers of donations and transplants of organs, tissues and cells, but in an entire health network, which proves to be among the most efficient in our country; to benefit from this positive trend are the patients on the waiting list, with a reduction recorded for the second consecutive year". "These excellent results - says Alessandro Nanni Costa - are the result of our desire to create a system". And he adds: "In these years we have supported everyone, we have taken care of critical realities as well as excellences. Nobody has ever been left alone. We are convinced that growth is possible only if we all work together, from regions to local coordination level. These numbers comfort us because they prove that our strategy pays"¹⁶.

5. An intermediate solution

The Committee did not intend to go into detail here on the controversial issues related to the legal status of the human body and the philosophical and social significance of the gift. It has only taken them into account to the extent that they may have an impact on the specific question of anonymity raised by the NTC.

Law n. 91/1999 limits itself to prohibiting healthcare personnel from disclosing personal information about the donor and the recipient. It is well known that anonymity is in itself already called into question through the varied and contextual information that comes from the media or from the Internet, so that donors and recipients can frequently meet. An encounter that, left to the absolute autonomy of the parties, may not always be spontaneously desired by both and which could give rise to unintended consequences.

The legitimate question arises as to whether the condition of anonymity is an indispensable requirement for ensuring the spontaneity of the gift of organs between strangers, characterised by disinterestedness and solidarity. Above all, as in other instances of donations to strangers (e.g. welfare activities, transfer of assets to charities, economic aid in cases of social and personal need, etc.) it is not necessarily the mutual knowledge of donor and recipient to cast doubt on the ethicality of the gesture. The actual term "gift" is used in this context more to underline the absolute freedom and spontaneity of the action, the value of solidarity, the non-marketability of the act rather than to classify a necessarily anonymous provision. The gift of organs and tissues has characteristics that distinguish it from other gifts: it is at the same time a very personal gift, since it makes available a part of one's body; it is a gift that takes place in an impersonal context through centres and hospitals; it is a gift that cannot be returned; it is a gift whose purpose is particularly significant: the prolongation of life. All this characterises the gifting of organs and tissues in a unique and singular way. So much so that the question was raised as to whether the gifting of organs was truly a gift and what kind of gift it was.

¹⁵ In 2017, 3,921 transplants were performed in Italy, thanks to the generosity of 1,741 donors; a figure that must continue to grow to respond to the requests of approximately 8,743 patients registered on waiting lists (as of 31.12.2017). Compared to European countries with a population comparable to ours, Italy is in third place after Spain and France for the number of cadaveric organ donations. (www.Issalute.it/index.php/donazione-organi).

¹⁶ [www.trapianti.salute.gov.it/cnt/cntPrimoPianoDet.jsp?area=cnt-general & menu = menuPrincipalemenuid = 400](http://www.trapianti.salute.gov.it/cnt/cntPrimoPianoDet.jsp?area=cnt-general&menu=menuPrincipalemenuid=400).

Therefore, anonymity is a precautionary element in order to avoid the marketability of acts of disposal of the body, but it is not deemed to be indispensable. In this sense, transplantation can be considered a gift, even without the need for anonymity: what is important is that it takes place outside a purely instrumental, productivistic logic, which is a logic devoid of humanity.

These reflections can converge to identify a third path, that is to say that, if the principle of anonymity is an indispensable requirement in the initial phase of organ or tissue donation in order to guarantee and honour the true meaning of the gift, namely, the desire to give without receiving anything in return, even if it limits the right of the donor to dispose of his/her body; anonymity could, however, at a subsequent stage, be relinquished and left to the free and conscious will of the parties involved. It is in the initial process that it is rationally necessary to keep those precautions for the purpose of maintaining the free and conscious participation of potential donors and favour the concrete realization of a solidarity of interests with exclusion of any profit, discrimination or other additional determinations of will. In this sense, anonymity seems to be an indispensable prudent principle of guarantee, which also ensures the correct application of the criteria for the allocation of organs obtained in our country by the NTC.

In the subsequent phases of transplantation, in general, as already mentioned above, the principle of anonymity is called upon to avoid comparisons and contrasts between the parties involved that can give rise, in each of them, to negative psychological attitudes (unrealized expectations, resentment, depression, feelings of guilt). However, these risks,, both from an ethical and legal standpoint, may prove insufficient to limit the autonomy and freedom of the properly informed donor/recipient, who does not wish to remain anonymous. Gratuity does not need the cover of anonymity to be sincere, even if the latter privileges and guarantees disinterested solidarity in every eventuality. On the other hand, there is no convincing legal technique capable of ascertaining the authenticity of a donation.

If, before dying, the donor has expressed the will to remain anonymous even for the successive phases of the transplant process, this will has to be respected.

According to what can be foreseen from a new discipline, this future and possible relationship between donors and recipients must in any case be managed by a third structure within the healthcare system, through the instruments deemed to be most suitable in order to ensure compliance with the cardinal principles of transplantation (privacy, gratuity, justice, solidarity, charity) on the assumption that both the family members of deceased donors, as well as the actual donor and recipient are vulnerable subjects, each to be protected. In so doing, there could be control by the centre or the healthcare facility responsible for this task so as to avoid inappropriate behaviour in these situations.

Recommendations

1. The ICB recommends that ethically in the field of organ donation the introduction of forms of arbitrary subjective selection are to be avoided, whereas, the criteria of impartiality and equity guaranteed by rigorously objective considerations, based on clinical criteria (immunological compatibility, urgency) and priority on the waiting list, are to be retained.

2. It considers, as is the case in the current procedure, the favouring of anonymity to be an indispensable requirement not only in the initial phase of organ donation but also in the next phase, once the transplantation has been carried out, if both the parties involved do not manifest any free valid and informed consent regarding the possibility to know one another.

3. It believes, in the phase following transplantation, that it is not contrary to the ethical principles which characterise organ donation if the donor, the family of the deceased donor and the recipient have the possibility to give free, valid and informed consent to contact each other and meet. It should be clear to those concerned that knowledge of the identity of the donor is not a claim, rather, it is an ethically justified possibility under certain conditions. In such an eventuality specific attention must be paid to informed consent that is understood and signed by those persons entitled to do so, in order to prevent the conditions of objective difficulty in which donors and recipients find themselves from rendering consent a purely formal act.

The bringing to an end of anonymity for persons involved in transplantation must be corroborated legislatively in order to establish the third party responsible for the donor/recipient mediation and regulate the procedure; it is advisable for the basic model to be preferably prepared by the National Institute of Health, valid throughout national territory.

Future regulation must strive as far as possible to prevent any attempt to trace donors and recipients which is extrinsic to the established path, especially if such attempts are made in a "stalker-like" fashion, either publicly or privately, or even through the internet.

Should a lack of consent by both parties be verified by the mediator, the possibility of repeating the request for access to information is to be denied to both sides for a reasonable interval of time.

With regard to third parties, the centre and healthcare facilities should always guarantee to donor and recipient the confidentiality of their personal identity and their clinical data, even in the eventuality of agreement between the parties.

An appropriate time interval is essential after transplantation before the procedure to end anonymity between donor and recipient may be initiated, in order to allow a more informed and reasoned decision by both parties.

4. Although news from the press and the mass media about the spontaneous donation of organs can provide citizens with a kind of example and solicit them to donate, there should be due respect for the privacy of the parties involved in episodes of donation (especially in the case of minors). In the context of social networks, where it is difficult to control the research and dissemination of information and where even informed consent in digital practice is much more complex, it is still necessary to ensure protection for those who wish to remain anonymous through strong reference to the rules that guarantee privacy.¹⁷

¹⁷ *EU General Data Protection Regulation*, n. 679 of 27 April 2016, entered into force on 25 May 2018.