Presidenza del Consiglio dei Ministri

KIDNEY DONATION FROM A LIVING DONOR TO A STRANGER (SO-CALLED SAMARITAN DONATION)

23rd of April 2010

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PRESENTATION

The news circulated by the newspapers of three people prepared to donate their kidney to medical establishments and for the benefit of strangers (so-called *Samaritan donors*), and the consequent discussion started in the newspapers, attracted the attention of the Presidency of the Council of Ministers, which asked our Committee to express an opinion with regards to the criticality of this new situation, eventually updating a previous opinion by the NBC, *The bioethical problem of the kidney transplant from a non-blood related living donor* (1997), where kidney donation from a living donor was subordinated to premises of consanguinity or emotional relations between donor and recipient.

The specificity of the problem is in the fact that in this case donor and recipient do not have any family or emotional bond, they do not know each other and the gratuitous organ donation is carried out, as by law, through Organ Transplant Centres, University Institutes, Hospitals believed to be suitable also for scientific research.

In giving their answer, the large majority of the NBC felt that Samaritan donation is legitimate, as it is a supererogatory act, and as such ethically significant for the solidarity motivations inspiring it and it does not involve higher risks, from a medical point of view, for the living donor, than those that can be found in other forms of *ex vivo* kidney removal (donation between blood relatives or “emotionally related”).

The NBC however recalled that the supererogatory act cannot be demanded morally, and even less legally, and it felt that towards this kind of transplant we must have the same precautions recommended and discussed in the previously mentioned ’97 opinion.

Given the specificity of the Samaritan donation, the NBC has however highlighted how this must not substitute (unless there are biological priorities of compatibility) transplants from blood related or emotionally related living donors or transplants from cadavers.

It also recommended that this form of donation is exercised respecting the mutual anonymity of the donor and the recipient and that the information given to the donor by the medical establishment to inform his/her consent is complete and exhaustive with regards to the physical or psychological risks involved in this act.

The Committee also requests that the assessment of the donor’s clinical condition and of the reasons for his/her act is carried out by a “third party”, different from the medical organisation that will carry out the removal and then the transplant, and that a register, confidential and respectful of privacy, with the names of the potential as well as the effective donors, is created.

Finally, it was suggested that, with a similar treatment also for the other kidney donations from a living donor, this act of generosity is taken into consideration, in order to translate it into a criteria of preference in the waiting lists, should the donor him/herself need a kidney.

This text was drawn up by the Committee’s vice-president, Prof. Lorenzo d’Avack, with the written contribution of some Committee members (and in particular by Prof. Salvatore Amato, Prof. Adriano Bompiani, Prof. Roberto Colombo, Prof. Antonio Da Re, Prof. Marianna Gensabella, Prof. Assunta Morresi,

Prof. Demetrio Neri, Prof. Andrea Nicolussi, Prof. Laura Palazzani, Prof. Alberto Piazza, Prof. Giancarlo Umani Ronchi and by Doctor Riccardo Di Segni).

In the plenary meeting of the 23rd of April 2010, the document obtained the consent of Prof. Salvatore Amato, Prof. Luisella Battaglia, Prof. Adriano Bompiani, Prof. Stefano Canestrari, Prof. Antonio Da Re, Prof. Lorenzo d'Avack, Prof. Emma Fattorini, Prof. Silvio Garattini, Prof. Marianna Gensabella, Prof. Claudia Mancina, Prof. Assunta Morresi, Prof. Demetrio Neri, Prof. Laura Palazzani, Prof. Vittorio Possenti, Prof. Rodolfo Proietti, Prof. Monica Toraldo di Francia, Prof. Giancarlo Umani Ronchi, Prof. Grazia Zuffa and of Doctor Riccardo Di Segni.

A vote against was expressed by Prof. Francesco D'Agostino, Prof. Maria Luisa Di Pietro and Prof. Lucetta Scaraffia.

Prof. Isidori, Prof. Luca Marini and Doctor Laura Guidoni abstained.

Prof. Bruno Dallapiccola, Prof. Carlo Flamigni, Prof. Romano Forleo, Prof. Andrea Nicolussi and Prof. Alberto Piazza, absent at the time of voting or at the meeting, have communicated their agreement to the document.

Prof.Adriano Bompiani clarified his position in a personal remark. To better clarify the reasons of their vote against, Prof. Roberto Colombo, Prof. Francesco D'Agostino and Prof. Maria Luisa Di Pietro have already sent their personal remarks. Prof. Lucetta Scaraffia agreed with Prof. D'Agostino's personal remark.The personal remarks are published with the opinion.

The President
Prof. Francesco Paolo Casavola

KIDNEY DONATION FROM A LIVING DONOR TO A STRANGER (SO-CALLED *SAMARITAN DONATION*)

1. The news circulated in the newspapers of three people prepared to donate their kidney to medical establishments and for the benefit of strangers (so-called *Samaritan donors*[1]), and the consequent discussion started in the newspapers, attracted the attention of the Presidency of the Council of Ministers, which asked our Committee to express an opinion with regards to criticality of this new situation[2], eventually updating a previous opinion by the NBC, *The bioethical problem of the kidney transplant from a non-blood related living donor* (1997), where kidney donation from a living donor was subordinated to the clause that donor and recipient are emotionally related.

The specificity of the problem is in the fact that in this case donor and recipient are not blood related or "emotionally related", they do not know each other and the gratuitous organ donation is carried out through Organ Transplant Centres, University Institutes, Hospitals believed to be suitable according to the conditions set by law. Donors and recipients in this case are "total strangers", not only physically (genetically or with regards to consanguinity), but also psychologically (in the absence of an emotional relation or of an acquaintance) without any form of "return" or "compensation" (even indirect).

From this stems the difference with other forms of donation from a living donor and the reason why the issue raised interest in bioethical reflection, given the needs and the interests worthy of protection that are involved in it. On the one hand, finding organs is a crucial element of the transplant process, especially because the number of organs available is much smaller than the number of patients on the waiting list; on the other hand, as well as the medical problems of the surgery, the main bioethical problems involve the issue of the living donor's physical integrity, of informed consent, of the spontaneity and gratuity of the act and of the proportion risks/benefits in the relationship with the recipient.

2. The legislation about kidney transplants from a living donor (Law number 458, 26th of June 1967) was created as an explicit exemption to article 5 of the Italian Civil Code currently in force, which forbids any act disposing of our own body, if from it can derive a permanent biological damage. And in fact Article 1 of the Law in question states this: "Notwithstanding the prohibition in article 5 of the Civil Code, it is acceptable, without compensation, to offer a kidney for transplant purposes between living individuals. The exemption is allowed to parents, sons/daughters, adult twin or non-twin brothers/sisters of the patient, provided that the current law is respected. Only in the case the patient does not have the blood relatives mentioned in the previous paragraph or none of them is suitable or available, the exemption may be allowed also for other relatives or unrelated donors".

[1] Definition generally used also in international documents; alternatively we find expression like *non-directive donation* and *donation by altruistic strangers.*
This form of donation is legitimate in many countries, amongst which: Great Britain, Switzerland, The Netherlands, Norway, Sweden, Israel, North America, Canada, Japan and Korea.
[2] The request of an opinion by the Presidency of the Council of Ministers is reported in Appendix.

A law that poses a number of objective and subjective premises (indication of the possible donors, control and authorization given by the Tribunal), only in the presence of which removal and transplant become possible. Overall, the entire procedure is surrounded by a series of precautions in order to guarantee the free and conscious participation of the potential donors and the concrete realisation of the interests of solidarity with the exclusion of any financial gain. A law created most of all for the donation between people connected by a close blood relation, which however does not exclude the hypothesis that there can be cases of kidney donation also between non-blood relatives and between people who are not motivated by an emotional bond.

Similar positions can be found in the *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine* (Oviedo 1997) and the *Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin* (2002). Specifically, Article 19 of the *Convention* clarifies that the removal of organs from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ available from a deceased person or no other alternative therapeutic method of comparable effectiveness[3].

Therefore, with regards to the *Samaritan donor* hypothesis, European Union legislation does not constitute an impediment to the transplant.

3. It was the NBC that, in the opinion *The bioethical problem of the kidney transplant from a non-blood related living donor* (1997), generated because of a request by Prof. Girolamo Sirchia, focused on the legitimacy "of the removal from living donors, even those who are non-blood related but only *emotionally related*", listing in this category the spouse, the stable partner or a friend "whose emotional bond, such to justify an altruistic act like the donation of an organ, can be effectively proven, but this should be limited to particular cases". The NBC also recommended that "the documentation relative to this emotional bond" is collected together with a psychological/psychiatric assessment aimed at proving the true spontaneity of the donation[4].

The NBC's preoccupation at the time was due to the following reasons:

[3] The *Convention* does not give particular importance to blood relation. On the other hand, this can be substituted by the relationship between husband and wife, widened to include the relationship between stable partners, also because consanguinity cannot be absolute guarantee of spontaneous donation. A thesis that is closer to the guidelines which prevailed in the Council of Europe and where the principle of the autonomy of the "competent donor" is considered essential to the procedure.

[4] *The bioethical problem of the kidney transplant from a non-blood related living donor* (1997). The points of view expressed by the NBC about the donation and transplant of organs and embryonic cells can be found in the following documents: *Definition and detection of human death* (February 1991); *Organ donation for transplantation purposes* (October 1991); *Organ transplants in childhood* (January 1994); *The anencephalic infant and organ donation* (June 1996); *Animal testing and health of living beings* (April 1997); *NBC opinion on the proposal for a moratorium on human Xenotransplantation clinical trials* (November 1999); *Motion on the trade of organs for transplant purposes* (June 2004); *Opinion on "the cellular therapy of Huntington's disease through the implantation of foetal neurons"* (March 2005).

1) the motivation to donate a kidney could be altered or invalidated by psychological disorders or pressure/coercion external to the donor's will;

2) at the basis of a kidney donation from a non-blood related individual there could be a financial incentive.

In effect the NBC on the one hand highlighted how the act, which can be qualified as supererogatory, should be given very high ethical standing, considering the aim of solidarity it intends to achieve; on the other hand, it insisted on the objective dangers linked to this practice, so much so that it recommended for this procedure to be always carried out in exceptional circumstances, for an absolutely free donation to be guaranteed and, in principle and in effect, for any hypothesis of commercialisation to be resisted.

4. The case of kidney donation from a living donor who does not have any connection with the recipient, is certainly different from other kidney donations, it is similar to them in some aspects but it has different characteristics.

The intention, in fact, is not to benefit one person with whom we may or may not have a blood or emotional relation (where, in weighing up risks and benefits, the psychological "return" can also be calculated, due to the gratification of the act of donation in itself, destined to a known and close person) nor it translates in an exchange agreement between an unknown couple (the so-called *cross-over* transplant with a sort of "return" and "compensation" of the sacrifice due to the exchange in the donation, which directly benefits a loved one). Samaritan donation is done on the basis of an altruistic act through hospitals, for the benefit of an anonymous beneficiary or, in general, of society as a whole. The donation finds justification in the act of donating itself and it cannot be subjected to any possible psychological or moral pressure, even unknowingly, from those who (blood or emotionally related) need a transplant.

It must be remembered that international literature takes into consideration the eventuality that the donation from an unrelated living donor could also be "conditioned". It is the situation that arises when the donor gives the medical centre a binding indication of the hypothetical future recipient, explicitly including or excluding some categories. And this on the basis of area of residence, race, culture, religion, sex, age, social class or fame, lifestyle, moral behaviour, responsibility with regards to pathologies (e.g. alcoholic, drug addict, smoker).

The NBC believes that in organ donation it is ethically unacceptable to introduce forms of social discrimination and asks that the impartial criteria objectively guaranteed by immunological compatibility, urgency and priority in the waiting lists are preserved.

Therefore, in the case of the particular procedure of unconditioned Samaritan donation, it must be verified if this act of donation respects the ethical principles recommended in all other hypothesis of kidney transplant. The fact that legally it is not forbidden and it is not explicitly excluded, does not exempts us from an ethical consideration relative to its justifiability (even if they are infrequent cases).

For an answer, first of all it must be verified if this decision and the consequent authorised procedure present more risk factors than those always denounced in other forms of abovementioned kidney removal from a living donor, so that they negatively affect the ability to respect the most important principles that characterise the ethico-legal regulations on transplants. These can still be

briefly summarised in the expectation that consent is free, informed about immediate and future risks due to the donation and that it can be withdrawn up to the moment of removal; that Samaritan donation is considered as residual compared to the donation from a blood-related donor.

5. With regards to the ethical problems inherent to Samaritan donation, the NBC observes what follows.

5.1. International charters and legislations described the offer of organs for therapeutic use with the term “gift” and this indicates freedom of choice, no financial gain and the refusal of any approach, even veiled or indirect, to forms of commercialisation.

With this premise, the fact of freely donating to an unrelated person, outside of family networks or interpersonal relationships, similarly to what happens in other circumstances (the donation of blood, bone marrow, part of the liver) is to be highly appreciated. The donation to an unrelated individual finds justification in the recognition of a link of “inter-independence” that connects all human beings and that can push towards an asymmetric and non-mutual responsibility towards others.

5.2. In the Italian legislation *ex vivo* organ donation is considered a residual act compared to *ex mortuo* organ donation, if there is an actual biological-clinical impossibility to transplant a particular organ removed from a cadaver or if there is a lack of availability of organs from cadavers.

The residual nature of the removal of an organ *ex vivo* finds its reasons in a variety of considerations. Mostly, that the physical (biological) integrity of a human subject is an individual and social good of such high order that it can be sacrificed not only consciously and voluntarily, but because of a proportionate or superior benefit, which cannot be realised without violating someone’s personal integrity.

This residual character of the donation must also be at the basis of Samaritan donation, so that *ex mortuo* transplants must remain the preferred method, to be disseminated and supported.

5.3. In this procedure the NBC believes that *the principle of anonymity* is indispensable, that most of all must be realised avoiding that the people involved in the transplant (donor/recipient) have a relationship either before or after the operation. A principle that – also guaranteed by the healthcare worker – on the one hand ensures that the donation is not bound by obligations or conditions between the parties involved and on the other hand avoids the problem, frequent in the removal from a living donor, of comparisons between donor and recipient, which can cause in each of them negative psychological attitudes. Anonymity would also avoid these cases becoming the object of “exploitation” by the media, depriving them of their authenticity[5].

In the informed consent, undersigned by donor and recipient, which will have to be given a lot of attention and we hope will be set up uniformly over all the

[5] A failure in the commitment to guarantee the anonymity, both of the donor and the recipient, by healthcare personnel – in particular if it leads to the illicit exchange of money and/or material advantages – should be considered as “illegal organ trafficking”, and as such it can undergo (in iure condendo) the current reflections of the European Council aimed at carrying out an adequate prevention and repression.

national territory, the two subjects will be informed of the confidentiality of their personal identities and clinical data and their assent to not get to know each other will be clarified. Nevertheless, the traceability of all clinical data will be preserved in line with current regulations, but ensuring anonymity.

The recipient must be informed that the kidney comes from a Samaritan donor.

5.4. The Italian transplant network gives ample guarantees that the kidney has not been sold or procured by intermediaries, who could obtain financial gain from it, but that it will be destined to those who have most urgent need of it.

The problem, similar to all organ donations to non-related persons, is the reliability or not, of the way the healthcare network is organised. The role of the doctor and/or of the healthcare organization in these situations is not simply that of intermediary, because receiving the organ gives them obligations towards both the donor (obtaining a clear consent, giving exhaustive information about the risks and the aims of the surgeries, about the possibility of withdrawing consent for the removal at any moment, the commitment to anonymity, etc.) and the eventual beneficiary (state of real and urgent need, suitability of the organs, etc.).

It is necessary that whilst ascertaining the donor's motivations, healthcare Centres always take into consideration that kidney donation from a living donor is in contrast, as already mentioned, with the general prohibition to self-mutilate accepted in our legislation and that the consent to removal is recognized as a derogatory hypothesis and as such must be applied restrictively. It follows the need to clarify to the subject offering to donate, that this availability is his/her choice, but that it does not give rise to any expectation or right (the so-called right to donate), being subordinated to the eventual availability from a cadaver and a parent and to the necessary medical assessment of the donor's clinical condition. After all, if the kidney offered can benefit another patient, it is also true that the person donating it can encounter risks and in time a reduced functional reserve (potential vulnerability) that can determine the need for medical care or even a kidney transplant. From a social perspective, therefore, as in any organ donation from a living donor, it may not be possible to describe the result obtained as "net benefit": the solution of the problem relative to the patient could in fact cause an illness in the donor. It would be appropriate to take this into account by contemplating in the donor's favour a preferential criteria in the waiting lists, should the need of a kidney arise.

Then, to avoid any form of veiled trade[6] the Committee recommends "guidelines" that, although different from region to region or between interregional groups, recall common principles, shared and scientifically sound, transparent and documented for any interested party requesting it.

The guidelines, accepted in the Agreement between the Healthcare Ministry, the Regions and the autonomous Provinces of Trento and Bolzano, for kidney

[6] We can foresee follow ups also in countries where the trade is forbidden because of organisations or centres which, in competition, propose "better offers" to this category of donors. A competition that, once started, can lead to dangerous practices from an ethical point of view, like the use of less rigorous criteria to select donors, or a reduced focus on anonymity, or a financial compensation masked as "reimbursement of expenses" (healthcare, insurance, travel or being absent from work, etc.).

transplants from living donors and cadavers[7] should therefore be modified to be adapted also to Samaritan donors.

5.5. Also in the case of *Samaritan donors,* there is a fear that the motivation for the act can be altered by questionable reasons: pathological attitudes, states of depression, the hope of gaining benefits from society (a sort of indirect return for your own kindness), the desire for a possible, future, moral or financial involvement with the recipient.

In relation to this, as it already happens for other donations from a living donor, the NBC believes that it is appropriate for the donor to undergo medical assessments aimed at identifying any physical-psychological contraindication. The assessment of a subject's suitability to be a donor must be carried out by a commission, made up by various professions and independent from the medical establishment executing the removal and transplant.

However, against these and other preoccupations we can put forward the same reassuring arguments generally expressed towards other forms of kidney transplant, which can be summarised in the idea that any argument aimed at limiting, if not excluding, organ donation from a living donor is a prudential argument, being, as mentioned above, the donation in itself not only a morally legitimate act, but in fact a highly commendable one, which is even more so, and with a smaller risk of commercialisation, in the case of Samaritan donors.

Conclusions and recommendations

= The NBC, in answer to the Presidency of the Council of Ministers with regards to the problems raised by so-called Samaritan donors, believes that this practice is bioethically acceptable. In fact, we can apply to it the same qualification that, in the previous opinion, *The bioethical problem of the kidney transplant from a non-blood related living donor* (1997), was attributed to the donation from an *emotionally related* subject, that is, that this is a supererogatory act, and as such ethically commendable for the motivation of solidarity that inspires it.

The supererogatory act cannot be expected either from a moral perspective, and even less from a legal perspective and it must be exercised respecting the mutual anonymity of the donor and the recipient.

= Also in consideration of the fact that this procedure does not involve higher risks, from a medical point of view, for the Samaritan donor, than those present in any kind of *ex vivo* kidney removal, the NBC believes that the same precautions recommended and contemplated in the abovementioned opinion must be employed towards this type of transplant.

= Kidney donation must not be a substitution (unless there are biological priorities of compatibility) to the transplant from a blood related or an emotionally related living donor or to the transplant from a cadaver.

= It is necessary – as in any other donation from a living donor – to ascertain that the donor fully understands the surgery's potential risks, its irreversibility and the psychological consequences.

[7] *Linee guida per il trapianto renale da donatore vivente e da cadavere*, Gazzetta Ufficiale n. 144 of the 21st of June 2002.

= It is necessary to set up confidential registers guaranteeing the privacy of the names of the potential and effective donors.

= We recommend that an assessment of the donor's clinical and psychological condition with regards to the motivations of the act is carried out by a "third party", different from the medical establishment that will execute the kidney removal and transplant, and that the procedure, as already happens in *ex mortuo* transplants, guarantees the correct collection of the organ and of its allocation, so that the respect of the key principles of transplantation is ensured: no financial gain, anonymity, transparency, fairness, safety and quality.

= We propose that, with a similar treatment also for other kidney donations from a living donor, this act of generosity is taken into account, in order to translate it in a preferential criteria in the waiting lists, should the donor himself need a kidney.

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PERSONAL REMARKS

Personal remark signed by Prof. Adriano Bompiani

As the question presented to the NBC was discussed to establish whether kidney donation from a living donor to a stranger – giving this as an unrenounceable requisite together with that of the absolute lack of financial compensation – has the ethical value of "benefit" for the recipient affected by a serious renal failure, the answer could only be "positive".

This does not hinder an evaluation on the appropriateness for the healthcare authorities to accept or not this kind of kidney donation, evidently supererogatory, from a living donor to a stranger.

Personally, I take the liberty of highlighting that the NBC did not explicitly examine the strictly "legal" aspects of a particular method of finding kidneys, urged by the strong imbalance between donation from cadavers and "waiting lists", which is being debated in many European countries. These aspects come under the jurisdiction first of all of the political power and should be coordinated at the European level.

Personal remark signed by Prof. Roberto Colombo

The *Opinion* on "Kidney donation from a living donor to a stranger" intends to tackle, from a bioethical and bio-legal perspective, a particular consensual method of *ex vivo* organ transplant, which has also emerged in Italy because of three persons' availability to having a kidney removed in favour of a nephropathic patient unknown to them. The "exceptional" nature of this form of organ donation compared to *ex mortuo* donation and, secondarily, *ex vivo* donation from relatives and people connected by a bond of affection or friendship, was expressed in the *Opinion* by using the operative category "residual" in contrast to the other two (cf. paragraphs 4 and 5.2) and the justification of the "exception" was found in the high ethical and social standing of acts of "gratuity/altruism" of a non-futile nature (cf. paragraphs 4; 5.1; *Conclusions and recommendations*) and in the consideration of the unavailability of a sufficient number of organs from cadavers (cf. paragraph 5.2). The guarantee of the "honesty" of such an ethical organ donation has been entrusted to the "mutual anonymity of the donor and the recipient" (*Conclusions and recommendations*) and to assessments aimed at excluding "that the motivation for the act can be altered by questionable reasons" (paragraph 5.5).

As well as the "impossibility of legally verifying the ultimate reason for Samaritan donation (compared instead with the possibility of legally verifying the consanguinity or the emotional bonds that can exists between donor and recipient)" and the consideration that the "exceptionality" of *ex vivo* organ donation, in contrast with the "fundamental legal principle of the non-disposability of the body", can only be justified "by the very high ethico-legal value of being blood related" or by "emotional bonds that can be fully compared to those existing in a family context" (F. D'Agostino, *Personal remark, see further*), I believe that other arguments make the ethical conditions and the legal guarantees suggested in the

Opinion too weak to resist possible and unacceptable deviations from the normal procedure in the proposed regulations.

We can ask ourselves whether mutual anonymity is, on the one hand, an absolute need to guarantee the quality of "gratuity"/"gift"/"solidarity" of the organ donation to patients who are not linked to their donors by a bond of consanguinity, affection or friendship (civil life has seen supererogatory acts that show an appreciated and unquestionable individual and social solidarity, which do not contemplate the anonymity of the donor and the beneficiary of the gift); and, on the other hand, we can wonder whether anonymity is sufficient and effective in preventing the risk of illicit organ trafficking and the commercialisation of parts of the human body (considering the practical need of intermediaries between the donor and the recipient – who perform clinical, administrative and logistical tasks – and the difficulty of carrying out non-invasive assessments in all phases of the transplant and afterwards).

With regards to the first point, in kidney transplants – as in other forms of donation of biological components of the human body destined to be permanently transplanted and integrated in another subject (unlike blood or other tissue with a high cellular *turnover*) - there can be cases of pathologies in the transplanted organ or in the surrounding tissue which, to be given diagnostic, etiologic and therapeutic consideration, might need the knowledge of the donor's name and of his/her personal and clinical data. In contrast, the discovery of a pathology (of genetic or cellular origin) in the even numbered, non-donated organ, occurred after the donation, can be significant for the prevention or the monitoring of the same pathology in the recipient. In these cases, for the donor's or the recipient's benefit, the rights and duties of the parties involved could suggest or even impose an ending to the anonymity, making it, in fact, a condition that remains *ut in pluribus* and not *simper et pro simper*. It is true that revealing the donor's and/or the recipient's identity could involve only a transferral of personal and clinical data from the transplant surgeon to the GP and vice versa (both bound by professional secrecy), but it is also known that the more the subjects involved and the exchange of sensitive data multiply, the more the risk of revelations (international and non-international) to third parties.

The second point leads us to ask ourselves, as it has been done for other individual acts of donation that present some similar aspects, if it is not the transparency of the identity of the donor and of the beneficiary to guarantee, better than any other condition, that badly intentioned third parties (individuals and organisations) do not interfere with the relationship of gratuity between people and exploit the act and the circumstances to gain illegal profits or advantages.

Finally, I believe that the character of "circumstantial residuality" of the so-called "Samaritan donation" (case by case, and not in relation to the collective demand of the patients awaiting a transplant and to the overall availability of organs *ex mortuo* or from a blood relative) – the only type of "residuality" that would not betray the principle of "exceptionality" of every single donation to a stranger – can be strongly guaranteed only by a "*call for proposal*" (public appeal) of a hospital or transplant centre in case of an individual urgency due to the extremely critical conditions of a patient on the waiting list for an *ex mortuo* transplant and whose family, friends or acquaintances are not suitable or available. A situation, this, different from anticipating, instead, signing up voluntary donors,

deemed physically and psychologically suitable, in a national or regional register of potential donors (cf. *Exposition of the opinion* and *Conclusions and recommendations*), where the "exceptional" nature of the decision to deprive your body of an organ "because of a proportionate or superior benefit, which cannot be realised without violating someone's personal integrity" (paragraph 5.2) would be much less evident and unequivocal, if there is no possibility of identifying such a "proportionate or superior benefit" in a concrete and current case. Even the evaluation of the authenticity of this act of donation, highlighted in the *Opinion* as condition for its significance and acceptability, would be more objective and sensible for being closer to the donor's deliberate will (because of a clear appeal to his/her freedom by a patient's state of need) than in the remote perspective of an eventual need deriving from the unavailability of organs from a cadaver or blood relative.

Personal remark signed by Prof. Francesco D'Agostino

However ethically and emotively suggestive the hypothesis of the *Samaritan* donation of a kidney can appear, I believe that it is unjustifiable, essentially for *bio-legal* reasons.

To argue this statement, I will take for granted some extremely general bioethical principles of the donation of an organ or more in general of parts of the human body by a living donor. They can be summarised in a *prerequisite:* that of the acquisition of a *fully informed consent* both from the donor and the recipient (a prerequisite that is valid for any medical procedure) and three criteria, the first, bioethical (*absolute lack of financial gain*), the second, biomedical (the *non-futility* and *harmlessness of the removal for the donor*) and the third, *bio-legal* (the donation by a living donor must be legitimised not as an unquestionable way of disposing of your own body, but as a *rigorously justified exception* to the fundamental legal principle of the *non-disposability of the body*). These three criteria, naturally, can be easily distinguished theoretically, but interlink with each other.

The criterion of *no financial gain* is absolute and it is down to the wisdom of the individual legislator to identify adequate procedures in order to avoid organ donation becoming a form of monetary (payment) or non-monetary (we can hypothesise various forms of organ *exchange*) commercialisation. Unfortunately there's often a lack of effort about this on the legislator's part. The paradoxical use of the expression *donor for a fee* is proof, according to some, of the unacceptable spreading of *bad faith* in well known biological contexts (think about the ambiguity of the expression "reimbursement of expenses" in reference to the donation of gametes for procreative or research purposes).

The criteria of *non-futility* and *harmlessness* are difficult to define, because they must be evaluated on the basis of the risks the donor is made to undergo, on the pathology's gravity and on the level of benefit the recipient can have from the transplant. They still have to be evaluated exclusively by doctors, with what is essentially a case by case judgement. We can't see particular difficulties in this regard, if not those that can be generally linked to the uncertainty that is structurally inherent to any form of diagnosis, prognosis and therapy.

Much more complex is the strictly *bio-legal* problem of the donation from a living donor. *If we believe that the human body and every single part of it are in principle non-disposable* (a principle that I believe is taken for granted and unquestionable), to justify the donation of an organ it will be necessary to identify a *legal* principle that is of an even higher order. This appears particularly difficult, because the non-disposability of the body is a direct consequence of a *person's dignity* who, disposing of his/her own body would degrade it (and therefore would degrade him/herself) to mere *instrument* (Kant, *Metaphysics of morals, The doctrine of virtue*, part I, book I, first chapter, paragraph 6). The supporters of Samaritan donation usually justify this form of donation as a variant of the supreme principle of *solidarity* in its noblest form (*Kindness of strangers*): a principle that is undoubtedly very suggestive, but which finds its proper place in experiences that do not have a bioethical relevance (like many forms of voluntary work, or adoption, fostering and other similar situations) and in which there is no risk of the *exploitation of self* as highlighted by Kant, who arrived to condemn even the sale or donation of a *tooth*[8].

The donation of a kidney from a *relative* can seem justified, so that it overcomes the principle of non-disposability of the human body, because of the very high ethico-legal value of family ties, thanks to which every subject, through his/her family role, states and defines his/her identity (the *value-person* would presume the *value-family,* seen as there is no human being who comes into the world outside the context of a family community). Although family contexts are not devoid of very concrete risks of *exploitation* or even *violence,* it seems reasonable to think that in extreme circumstances, like that of a patient needing the donation of a kidney for therapeutic purposes, it is justifiable to legitimise the organ donation (in the respect of the bioethical and biomedical conditions mentioned above). This justification was wisely extended by the NBC (*The bioethical problem of kidney donation from a non-related living donor,* 1997) to hypotheses where the donor and recipient are *emotionally related,* that is, united by emotional bonds that can be fully assimilated to those of a family context. These justifications have a specific *bio-legal* significance, because they can undergo a social positive verification, the only form of verification allowed in the law.

I believe that there are no sufficient arguments to go beyond these wise boundaries established by the NBC at that time. Surpassing them, in fact, seems *bio-legally risky,* because there is no *convincing* legal technique to ascertain the authenticity of a Samaritan donation. The objectively *extreme* character of this donation would lead us to think that only very few people, with an absolutely *heroic* morality, could declare their availablity to do this; but the law is not able to regulate and guarantee such noble practices (because this is what they are and this is what the law is supposed to do), practices that would project it in such a rarefied atmosphere, to appear easier to imagine than to experience (when, reasonably, will we happen to meet a Samaritan donor?). Evidently, we do not deny that these

[8] The example can make us laugh. But as well as Fantine's episode, narrated by Victor Hugo in *Miserables*, which demonstrates how Kant might have in mind concrete situations, when we accept the indiscriminate availability of the body is very difficult to then refuse more in general the indiscriminate availability of the person, in *all* its dimensions. If the sale of a tooth is considered legitimate, we don't see why the sale of a *vote* should not be.

extreme possibilities can happen. I simply observe that the duty of the law is to manage *extreme* but ordinary situations that can be repeated and standardized[9].

In reality, the impossibility to verify legally the *ultimate reasons* of the availability for a Samaritan donation (compared instead with the possibility to legally verify consanguinity or the emotional bonds that can exist between donor and recipient) effectively means accepting an act that disposes of the body and consequently the alteration, unjustifiable and probably irreversible, of a fundamental legal principle.

In agreement with this *Personal Remark:* Prof. Lucetta Scaraffia.

Personal remark signed by Prof. Maria Luisa Di Pietro

The kidney donation from a "non-emotionally related" subject raises some ethical problems, which make it completely different from the kidney donation from an "emotionally related" subject. On the other hand, in evaluating human actions we don't only take into account the object or the purpose of the action (*finis operis*), the intention of the acting subject (*finis operantis*) and the means, but also the circumstances. And, if in both cases the object or the purpose of the action and the intention of the acting subject (helping those whose life is in danger because of the unavailability of a kidney for transplant) and the means (donating a kidney) seem similar, very different is the situation in which this decision is taken.

In the case of kidney donation from an "emotionally related" subject, there is, on the donor's part, the choice of helping a loved one towards whom he/she feels a great sense of responsibility, to the point of being available to sacrifice a part of him/herself. In the case of a donation from a "non-emotionally related" subject, a fundamental dimension of the gift is missing: the interpersonal relationship between human beings. In fact, the donor does not know the recipient, so that it seems unsuitable to use the term "donation". Additionally, this practice – coming away from a parental and emotional context – not only distorts the meaning of the donation itself (gifts happen when there is a relationship) sanctions also a dual view of the relationship body-person. To avoid reducing the bioethical debate on this point to the mere request of consent or to a variety of procedures, we cannot – therefore – but ask the question: what is Man and what does the body represent in his/her life and for the formation of his/her individuality?

Experience itself is sufficient to highlight the fact that Man can only be his/her own body, which is the beginning of his/her individuality and identity. Reducing the

[9] It could be objected that similar preoccupations should give way to the consideration that the survival of people affected by very severe nephropathies is at risk. Unfortunately, this argument, although very suggestive, clashes with the criteria usually accepted to bioethically legitimise not only transplants from a living donor, but also from a cadaver. Those who want an argument like this to prevail should first, to be coherent, demonstrate the existence of a general *duty* to *give up* (and not simply to *donate!*) a kidney (and more in general any organ) from a cadaver, in favour of patients whose life is in danger, and without the need to have the previous consent (explicit or implicit) of the deceased or his/her family. The ethics of organ donation however moves in the opposite direction.

relationship body-person to the category of being and not being, leads – consequently – to the non-disposability of the body: man – Kant writes in *Lectures on ethics* – “cannot do with his body what he will. The body is part of the self; in its togetherness with the self it constitutes the person. A man cannot make of his person a thing”, or dispose of himself as a thing: “he/she is not allowed – we still read in the *Metaphysics of morals* – sell a tooth or another part of himself”. We can, in fact, dispose of things but not of people: “The prohibition of killing a man – Guardini writes in *The right to life before birth* – represents the greatest achievement of the prohibition of treating man as a thing”. Considering the human body as an object we can dispose of, even if only in some of its parts, means thinking about the body as the aseptic covering of an ability to choose (the Cartesian *res cogitans*) which decides the destiny of it. Can the reality “Man” be broken up and put together again only on the basis of the needs of a society that requires him to dispose of his body? And, once we can dispose of our bodies and of its parts, why should it be forbidden for it to be the object of a sale?

Certainly, to what we have said so far it could be objected that it is already possible to dispose of our own body and of its parts, as we allow the donation of blood or bone marrow and kidney by an “emotionally related” subject. Given that blood or bone marrow donation involve a “momentary” availability (these are tissues that reproduce quickly), the availability of a part of the body in the kidney donation by an “emotionally related” subject is justified in the exceptionality of the situation and in the strong emotional bond with the recipient. With a limitation: the possibility, in any case, of immediate or future damage following the donation both in the case of tissues and – even more so – a kidney. In this last case we cannot avoid mentioning the risk of short or long term damage, with the possibility of initiating a chronic kidney failure so that the donor must undergo dialysis or transplant. For this reason even the “emotionally related” subject must not – anyway – forget his responsibility towards himself and other people apart from the potential recipient, therefore we cannot condemn him for refusing the donation.

Allowing a kidney donation from a “non-emotionally related” subject, even with all the precautions possible, would start a practice that could involve – amongst other things – an increase of pathological conditions in society, in order to respond to the health requirements of others. There is, however, a big difference between pathologies that happen and pathologies that are the consequence of human choices also accepted by society, although for reasons of great moral value and in the name of solidarity.

Even if solidarity – in its social dimension (participating to the realization of a common good) and supportive dimension (intervening with more focus where there’s more need) – is fundamental in human life, we must ask ourselves – however – if it should not have limits. In other words, if in the name of solidarity there are those who are allowed to decide, in a particular situation that cannot be resolved in any other way, to risk their own life to the extreme of sacrificing themselves, society must – nevertheless – make sure that such extreme situations do not reoccur. From an objective point of view, in fact, we must take into account that every life has an incommensurable value and that we cannot allow one to be at risk in favour of another; from a subjective point of view, it is possible that an unlimited solidarity also involves less responsibility towards ourselves and our body.

These considerations precede the analysis of the criticality that kidney donation from a “non-emotionally related” subject can raise from an organisational point of view or of its effect on the balance of donation procedures, which are, anyway, relevant and could be prevented in part.

It does not resolve, however, the anthropological and ethical *vulnus* – which is not taken into consideration in the document by the National Bioethics Committee – created by kidney donation from a “non-emotionally related” subject. The avenues to be used are others, amongst which, first of all, the promotion of a culture of post-mortem donation.