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Ethical challenges in transplant practice in Latin America: the Aguascalientes Document

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ABSTRACT

Organ transplants are currently an alternative treatment for a growing number of diseases, which were previously considered terminal. Bioethics has played an important role since the advent of this surgical technique, mainly in defining death criteria and the optimum transplantation conditions. This issue continues being a universal focal point, mainly concerning the equity of access to transplantation, criteria for assigning deceased-donor organs, living-donor safety, risk of commercial trade, fair access to high-quality immunosuppressant drugs and organ transplant legislation. These problems are characteristic of Latin America and the Caribbean, and were the driving force behind the First Latin American Bioethics and Transplant Forum, sponsored by the Latin American and Caribbean Transplant Society (STALYC), and all the transplant societies from subsidiary countries. The "Document of Aguascalientes" is a collection of all the ideas and opinions that were proposed during round tables and analyses. The document is divided into four sections: 1) living donor; 2) organ trading and transplant tourism; 3) the state role in legislation, transplant distribution and coverage; and 4) access to and quality of immunosuppression. The Bioethics and Transplant Forum was created to analyse and find solutions for this complex issue. The "Document of Aguascalientes" aims to serve as an instrument of expression and a vehicle for the ideas put forward during the Forum, so that they can act as transplant practice guidelines in Latin America.

Keywords: Transplantation. Bioethics. Latin America. Organ trafficking.

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Desafíos éticos en la práctica de trasplantes en América Latina: Documento de Aguascalientes

RESUMEN

Los trasplantes de órganos son actualmente alternativas de tratamiento para un creciente número de enfermedades,

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otrora consideradas terminales. Los aspectos de orden bioético han tenido una relevancia particular desde los inicios, principalmente en la definición de criterios de muerte y en las condiciones óptimas para la realización de los trasplantes. Esta problemática sigue siendo un foco de atención universal, principalmente en lo referente a equidad en el acceso a trasplante, criterios de asignación de órganos de donante fallecido, seguridad en el donante vivo, riesgo de prácticas de comercialización, acceso equitativo a fármacos inmunosupresores de alta calidad y legislación sobre trasplantes de órganos. Esta problemática tiene rasgos particulares en la región de América Latina y el Caribe; ello motivó la realización del Primer Foro Latinoamericano de Bioética en Trasplante, con el auspicio de la Sociedad de Trasplantes de América Latina y el Caribe (STALYC), así como de todas las Sociedades de trasplantes de los países subsidiarios. El «Documento de Aguascalientes» es una recopilación de las ideas y opiniones vertidas durante las mesas de discusión y análisis. Se presentan en cuatro apartados: 1) donante vivo; 2) turismo y comercio de trasplante; 3) papel del Estado en legislación, distribución y cobertura para trasplante, y 4) acceso y calidad de la inmunosupresión. El Foro de Bioética en Trasplante se debe a la irrenunciable necesidad de analizar y buscar soluciones a una compleja problemática; el «Documento de Aguascalientes» pretende servir como instrumento de expresión y difusión de las ideas vertidas en el Foro para que sirvan como guías en la práctica de trasplantes en América Latina.

Palabras clave: *Trasplante. Bioética. América Latina. Tráfico de órganos.*

PREAMBLE

The important technical and scientific advances over the past six decades have allowed organ transplant to become an optimum alternative for an ever-increasing number of patients with irreversible organ failure. Offering these procedures to patients has required great generosity and altruism from donors and their families.

Since the 1950s, when the first human transplants were performed,[1-3] the bioethical complexity involved in transplantation has become apparent.[4-6] It was initially due to the need to establish death criteria, and of course, because transplant practice incorporated an unprecedented and extremely complex variable: the organ donor.

Many organ transplant-related bioethical issues arose during the second half of the 20th century, encouraging intense debate and constituting a real challenge for scientific, legal, moral and religious dimensions throughout these years.[4-11]

International standardisation of transplant practice has been the gradual fruition of these debates. Brain-death criteria have been clearly defined,[12-18] and have been accepted almost universally for more than 4 decades.[19-22] Likewise, transplant regulations and optimal conditions have also been defined.

Various arguments explain why the bioethical debate on transplantation is still open. Some of the most important (listed below) inspired the First Latin American Bioethics and Transplant Forum:

1. Organ transplantation has become an ever-increasingly important part of the therapeutic armament for a large number of diseases, which were previously considered terminal. This creates the need to ensure that patients have correct and fair access to medical assistance and to medical treatments which entail highly elevated costs.

2. Until now, deceased-donor transplants have always been a scarce resource. Given the growing number of patients that require a transplant, it is absolutely essential to ensure equity in access to this resource.

3. Living donors are not an exception. Given the growing demand for transplant services, there is always the possibility that transplant programmes become more permissive in accepting potential living donors, even when the donor's safety may be put at risk. Furthermore, the pressure that this demand represents may promote organ trading.

4. Countries need legislative systems that ensure optimum conditions for donation and human organ transplantation.

Transplant medicine is practiced with great dignity and professionalism throughout the world. It is an exemplary field of contemporary science and its scientific contribution has been vast and generous, with thousands of human beings having benefited from it. Nevertheless, it is important to recognise that there are key issues concerning transplant practice.

Recently, the sixty-third World Health Assembly unanimously endorsed the WHO's Guiding Principles on Human Cell, Tissue and Organ Transplantation, and approved various measures for optimising transplant safety and efficacy. The document states: "to oppose […] organ trafficking and transplant tourism and encourage healthcare professionals to notify relevant authorities when they become aware of such practices […] and to improve the safety and efficacy of donation and transplantation by promoting international best practices."[23]

However, there is global disparity between the growing demand and limited supply of transplant organs, meaning that undesirable practices have been revealed, such as: "…trafficking in human beings who are used as sources

of organs and of patient-tourists from rich countries who travel abroad to purchase organs from poor people…," as was recently expressed in the Declaration of Istanbul.[24] The meeting that brought about this Declaration was based on the principles of the Universal Declaration of Human Rights.[25] This document presents the pressing need for international collaboration to seek a global consensus for optimising donation and transplantation practices. It was the fruit of the meeting between more than 150 representatives of international medical and scientific organisations, government members, social scientists and ethics specialists. The meeting emphasised the fact that "the legacy of transplantation must not be the impoverished victim of organ trafficking and transplant tourism but rather a celebration of the gift of health by one individual to another."[24] Furthermore, debate on the matter has a long history and tradition, and the central objective has always been to protect the donor and to perform the transplantation under the best conditions, with certified programmes and duly educated and qualified staff.[26-32]

The efforts made by healthcare authorities and other organisations involved in transplantation throughout the world to promote the Declaration of Istanbul has been commendable. Its aim is an unprecedented attempt to organise and standardise the best possible donation and transplantation practices. Many countries have endorsed the guidelines stated in the Declaration, and they have even positively influenced the adoption of its regulations.

Latin America and the Caribbean is a multicultural region with great diversity and contrasts. It also possess common grounds concerning transplants, since, despite its uneven education and health development, studies from the past decade reveal that transplants are increasingly being used in all countries in this region. The results from the Latin American Transplant Registry, a feature of the Latin American and Caribbean Transplant Society (STALYC),[33] show that deceased donations increased by 3.8 per million population (pmp) in 6 years, with a perspective to reach an average of 20pmp in 10 years, with a growth rate of 1-1.5pmp per year.

The same trend is observed for different types of organ transplants during the same analysis period (10 years). The annual growth rate for kidney transplant was 7%, (15.7pmp). Liver transplant was somewhat higher, 11% (3.4pmp), and the increase in heart transplant was 5.8%.[33]

The region's potential places it in a particularly interesting positioning, which allows us to further the progress already achieved, improving the system's weaknesses, which is especially caused by the socioeconomic reality and health policies present in each country.

Progress must be made in creating plans that guarantee accessibility, transparency, and quality in transplantation in Latin America and the Caribbean.

The idea behind the first Bioethics and Transplant Forum was conceived at the core of the Latin American and Caribbean Transplant Society. The Forum originated because a platform for analysing the region's situation was lacking. We saw that reflection was needed and that solutions would be necessary in some cases and consensus in others. However, we would only be able to make proposals for solutions in some instances. The Latin American transplant community decided that it could in no way continue being indifferent to such problems.

The Forum has not only focused on issues concerning transplant bioethics (although a priority), it has also proposed to evaluate the fundamentals with regard to which transplant and deceased-donor organ distribution legislation applies to these countries, acknowledging its qualities and proposing solutions for its shortcomings, which are very much associated with the correct application of fundamental ethical principles. It is also essential to analyse the way in which health authorities from these countries attend to the permanent and universal care coverage required by transplant recipients, including immunosuppressive therapy and its quality, as well as the commitment implied in the short- and long-term monitoring of living donors.

With the aim of producing a sufficiently detailed and useful document, transplant doctors and bioethics specialists in Latin America and the Caribbean were convened to participate in developing the Forum and were assigned different tasks. They examined in depth the practices that currently prevail in our countries, detecting the weaknesses and proposing solutions which were later assessed and discussed in work groups throughout the first Bioethics and Transplant Forum held in Aguascalientes, Mexico, from 2-4 September 2010. During the event, the coordinators analysed opinions and agreed upon proposals at each of the four round tables. Once each group had concluded their discussions, all of the Forum participants attended a plenary session in which the results and proposals for each matter were presented and consensus reached. A draft document, including points of reflection, analysis criteria and action guidelines, was then produced and was sent to all of the participants so that they could evaluate it and provide their final comments.

Four topics were chosen for discussion during the First Bioethics and Transplant Forum:

1. Living donor.

2. Organ trading and transplant tourism.

3. The state role in legislation, transplant distribution and coverage.

4. Access to and quality of immunosuppression.

GENERAL PRINCIPLES RECOMMENDED

The main bioethics fundamentals that must be considered are dignity and beneficence, integrity and nonmaleficence, precaution and/or vulnerability, autonomy and responsibility, distributive and local justice.

Bioethics, as a science and an art, is continuously evolving. Therefore, new principles have been formulated to clarify the conflicts that imply progress in life sciences, as well as reintroducing others. These first principles of good will, nonmaleficence, autonomy and justice were formulated in an English-speaking context, but new contributions in the field of human know-how are therefore necessary in our environment, given that bioethics have globalised.

The term *Human Dignity* means that the person has worth but not a price, i.e. he or she is not on object of gain *Principle of beneficence*: in this context it is understood as acting on the best interest of the donor and recipient.

We understand *integrity and nonmaleficence* as being the patient's right to preserving his or her functional unit, and *precaution and/or vulnerability* represent the threat to the fragility of a given person due to biological, psychological and cultural risk.

Autonomy

The word autonomy comes from the Greek *autos* (self) and *nomos* (law). Being autonomous involves taking on the right to have one's own opinions, making choices and performing actions based on values and personal beliefs. We must always respect people's points of view and rights, provided that their ideas and actions are not detrimental to other or to themselves.[34,35]

The principle *responsibility* is defined as the obligation that everyone who has access to science and technology is aware of one's own actions, which should respect human life and preservation.[36]

Distributive and local justice

The expression distributive justice refers to the suitable distribution of the goods and/or burdens belonging to a given society so as to compensate for the inequalities that are experienced. As such, resources, taxes, and opportunities are shared fairly.

The justice principle in bioethics refers to access to health resources and health promotion, offering a response to the community's needs and protecting the State.

The terms equity, worth and ownership, or the expression "to which one has right" have been used in health services to explain distributive justice. A situation is considered fair when a person receives the care to which he or she has right. Injustice emerges when an individual is deprived of the care that he or she should receive due to his or her need or social conditioning.

Distributive justice seeks to supervise the methods employed to successfully assign a replacement therapy, such as transplantation, with the aim of avoiding discriminatory effects.[37-39]

The Aguascalientes Document also considers important the definitions of *solidarity* and *subsidiary*:

Solidarity

If every human being has the right to find what was needed for his/her growth and development, solidarity means that we take on the needs of other people who do not have these resources, so that they are able to obtain the means of survival and the instruments of personal progression.

Subsidiary

In a social reality where there is inequality of opportunities, this principle's aims is that those who know more, are more capable and have more may see and attend to those who are lacking. This does not limit the initiative or the responsibility of people and social groups, but makes them be more valued, promoting and encouraging them.

Furthermore, we believe that it is of utmost importance that a joint-responsibility is established between the medical team and the donor-recipient pair and their social environment. This joint-responsibility does not exempt state responsibility. It is therefore necessary to highlight the following:

Informed consent

In the Aguascalientes Document we reiterated that the informed consent must be used with regard all components in order to safeguard the donor's and the patient's autonomy throughout the transplant procedure. We can summarise these components as:

Voluntary action

It must be guaranteed that donors have freely chosen to subject themselves to a procedure, medical treatment or clinical study without having being coerced, persuaded or manipulated.

Right to information

Information must be easily understandable and must explain the object of the study, treatment or medical procedure. It must clearly explain the benefits, short-, medium-, and long-term risks of the procedure or the medical treatment, as well as the alternative therapies.

Understanding

The patient's level of understanding should be assessed by different people, as well as the informing doctor. This information may be provided by a psychologist, social worker or a nurse who fully understands the procedure that is being offered to the patient or the organ donor. The patient must be given the information in their mother tongue or the regional dialect, providing the patient with translation or interpreting services if necessary. The written document granting authorisation shall be signed by the potential donor, and if it is not provided in his or her mother tongue, it shall be signed by the translator and at least two civil servants from the institution, testifying that information that has been consented to in writing is the same as that which appears in the document. It is necessary to take into consideration the person's education and social background with the aim of understanding whether he or she has completely understood the information given both verbally and in writing.

The Societies and law-makers in each country should use strategies that produce national laws based on international law models, so as to achieve and maintain optimum results and protect recipients' and donors' rights.

LIVING DONOR

The evaluation of a potential donor should only be limited to certain bio-psychological aspects. However, it is difficult to be able to ensure that the individual is not part of other underlying environmental circumstances, which may be capable of influencing his or her final decision.

The kidney donor may be subject to risks, both during and after the surgical procedure, given that he or she will have to live with a single kidney. In fact, many people considered as good candidates for kidney donation are found to be at the limit of current criteria, concerning age, weight, blood pressure, and could be at risk in the short- or long-term. Similar situations can arise for living donors of other organs (e.g. liver).

It is therefore considered to be the responsibility of each transplant programme to establish a system ensuring that the donor undergoes detailed assessment to guarantee minimal additional risks. This task would ideally be performed by an independent group of transplant experts who assess the donor at every stage of the procedure: pre-surgical assessment, surgery; immediate post-operative care; and long-term treatment to monitor this person's overall health. It is essential for there to be an interdisciplinary transplant committee which helps in decision making.

Nonmaleficence should be a priority over other bioethical principles, so as to protect donors with additional risks, even when the donor wishes to practice his or her autonomy, insisting on donating.

DEFINITIONS

1. **Blood-related living donor.** Genetically-related donor with first, second, third or fourth degree of consanguinity with the recipient (father, mother, grandparents, aunties and uncles, and cousins).

2. **Non-blood related living donor.**

A. *Emotionally-related living donor.* Donors that are not blood- or genetically-related, but which have a *strong emotional link* which is perceived and evident, and can be determined and evidenced. *Spouses*, *common-law partners*, *step-parents*, and, *step-children* are included in this category.

B. *Non-related living donor.* Donors which are neither blood- or emotionally-related, such as:

- *Altruistic donor.* Any person that offers an organ to any other person that is ill, even if a stranger, for the good and benefit of someone else and for purely humanitarian reasons.

- *Crossover donation*. Crossing over donor and recipient pairs, whether genetically- or emotionally-related, with ABO incompatibility, sensitisation, hereditary kidney disease or because no other donor is available.

- *Paid donors*. The person is subject to "regulated" or illegal sale of organs.

RECOMMENDATIONS FOR ACCEPTING A LIVING DONOR

Blood-related living donor. Donors with first, second, third and fourth degree of consanguinity are accepted.

Emotionally-related living donor. Spouses, common-law partners, step-parents and step-children which have been legally checked and approved by the relevant judicial department are accepted.

Crossover donation. Only blood- and emotionally-related pairs are accepted. All pairs must be assessed by specialised committees in the hospital and obtain authorisation from the relevant health and legal authorities.

Non-blood or emotionally-related living donor. They are not accepted, except in the following cases:

1. **Altruistic donor.** Only accepted if not directed donation. We recommend that all cases are assessed carefully by expert committees authorised by the relevant health and legal authorities.

2. **Paid donors.** They should not be accepted under any circumstance whatsoever.

ORGAN TRADING AND TRANSPLANT TOURISM

Recent events concerning organ transplantation, the laxity in the resource of non-related living donors and using prisoners condemned to death in China has aroused international criticism. The Latin American and Caribbean Transplant Society, concerned with this situation, considers it necessary to emphatically declare its opinion with regard to organ trading and transplant tourism. Unethical transplant practices have been recognised which promote inequality and human explotation.[40] These unethical practices are based upon false premises such as "profit" and "opportunity" that a person can obtain to "improve" his or her financial situation. In the same manner, "autonomy" is used to justify the right that these people have to sell their organs. However, this is nothing more than a way of hiding an "illegal trade" in which poor people in need of money are not those that benefit from organ trading: it is the intermediates that make the profit. It is clear that the poor people are those who are at risk from participating in this type of procedure, given their vulnerability. Latin America has had to take necessary measures to protect the vulnerable population from new forms of human exploitation, such organ trading and trafficking, given the social gap between rich and poor in our region, the high poverty rates, and low level of education.

The Aguascalientes Document endorses the following definitions from the Declaration of Istanbul[24]:

- ***Organ trafficking*** *is the recruitment, transport, transfer, harboring or receipt of living or deceased persons or their organs by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor for the purpose of exploitation by the removal of organs for transplantation.*

- ***Transplant commercialism*** *is a policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain.*

- ***Travel for transplantation*** *is the movement of organs, donors, recipients or transplant professionals across jurisdictional borders for transplantation purposes. Travel for transplantation becomes* ***transplant tourism*** *if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals and transplant centers) devoted to providing transplants to patients from outside a country undermine the country's ability to provide transplants for its own population.*

The Aguascalientes Document categorically refuses any idea or mechanism which tends towards organ and tissue trading by individuals or by States. It opposes any mechanism that disguises organ trading and the functioning of any type of organisation that ascertains that organs are tradable articles. For example, this includes the regulated market, free sale of organs, or payment to donors beyond the costs for assessments, surgical procedure, follow-up and complications after donating.

THE STATE ROLE IN LEGISLATION, TRANSPLANT DISTRIBUTION AND COVERAGE

On the understanding that our States are responsible for the welfare of the citizens and aim to promote common good, their role must be mentioned with regard to authority, funding, safeguarding, availability, control and surveillance of any activity carried out in their own country associated with human organ, tissue and cell transplantation.

The growing demand for donated human biological materials to tackle the situation of thousands of our citizens, requires organised development of donation and transplant systems, and specific policies set within an ethical and legal context which considers the common good and universal access.

To a lesser or greater extent, there is a strong and growing unbalance between supply and demand of organs for transplantation in each of our countries. Furthermore, there is a fragmentation in health care and partial or restricted access to transplantation as an alternative therapy in wide groups of the Latin American and the Caribbean population.

Even though the rate of deceased donors in many of our countries has grown extensively, at present other internationally-used alternatives are analysed which need strict ethical, legal, and citizen control if they are to be considered appropriate.

The only way to face this situation is for the different components of our society to take responsibility and a committed attitude, especially those that hold greater political, ethical-legal, health and economic power.

In this context, the public society holds a very special role, having a more active and organised attitude towards defending its rights.

The political decision giving impetus to these systems has clear objectives, such as guaranteeing the right to transplantation, increasing the number of transplants, reducing waiting lists and improving transplant results. This should be developed by means of donation and transplant policies, considering the problems associated with access and equity, coverage, and the integrity in health care.[41,42] For these measures to be applied correctly, the States must guarantee universal coverage of health services to all individuals in need of transplantation. Each State's organisational characteristics must meet "correct" ethical guidelines.

In those countries in which donation or transplantation do not exist, the authorities should make every effort to develop systems that attend to the needs of the population with the objective of achieving self-sufficiency.

In all cases, all information related to access to current transplant programmes, patient and graft survival rates, availability, coverage levels and allocation criteria, should be made available.

Access to information by the different actors, including patients, ensures transparency in allocation and forces results to be accounted for.

ACCESS TO AND QUALITY OF IMMUNOSUPPRESSION

The objective is to guarantee the health of the patients by using drugs that have proven quality and efficacy by means of a process defined and approved by a scientific and academic institution.[43] This process does not however approve or disapprove the use of generic drugs, but does require that they meet the conditions established.

Transplant coverage should be understood as the need to implement health care strategies to ensure access, quality, transparency, equity and efficacy in patient care, ensuring that patients are quickly registered onto waiting lists, being on them for as short as possible, and the possibility of receiving a transplant with the aim of the patient being fully reincorporated into society.

Health care professionals must be ethically committed to the transplantation, not only with the patient, but also with the community enabling donation to be a common, yet scarce good, further implying their responsibility for the patient that continues on the waiting list.

The State must ensure that the doctor-patient relationship remains within the ethical framework which assumes the dignity and autonomy of the individual. Any change or regulation that may modify this balance may affect the patient's psycho-physical welfare.

Problems associated with incorporating generic immunosuppressive drugs on the market are a current issue. It is a universal debate, and to date, there is not enough information in the literature concerning the therapeutic safety of generic immunosuppressive drugs, and there is even less on the results of their interchangeability.

The transplant doctor must supervise the quality of the immunosuppressive drug that the patient receives, being an ethical obligation. As a result, adherence to the prescription should also be achieved, and the patient must be provided with all information to ensure that he or she is able to exercise his or her autonomy and freely make a decision. Any change in immunosuppressive treatment should be authorised by the patient by means of signing a legally accepted informed consent. Furthermore, the person who shall be legally responsible for the consequences due to the change in medication must also be acknowledged.

Immunosuppressive drugs constitute a special category of drugs which have special characteristics, making them different from other therapeutic groups.[44] These drugs are associated with a high health risk, given that they have a narrow therapeutic window and a high inter-population and intra-individual variability. As such, dosage errors, no matter how small, may cause the following results: *1*) lack of efficacy and transplant loss; *2*) an excessive immunosuppression accompanied by infections; or *3)* severe undesired effects due to the drug's toxicity. As

such, it is believed that the variability in bioavailability of immunosuppressive drugs in transplanted patients is significantly greater than in healthy volunteers. As a result, the results from pharmacokinetic bioequivalence studies performed on health volunteers can not be directly extrapolated to the highly heterogeneous population of patients subjected to transplantation. It is therefore necessary to carry out studies on the efficacy and safety of the generic immunosuppressive drugs to provide evidence of equivalence, or at least non-inferiority, compared with patented immunosuppressants.[45]

We believe that health authorities, by means of specialist drug control entities, must test generic immunosuppressive drugs to monitor serum, plasma or blood concentration in transplant patients, assessing the intra-individual and inter-individual variability of the different formulas available. Intensive drug monitoring studies should also be conducted to recognise the variables that may interfere in the availability of new formulas.[45]

A data capture tool must also be made available, so that all doctors can provide information on adverse effects and so that it can be made available on scientific Societies' public websites in conjunction with the regulating documentation, to ensure drug monitoring. It is recommended that each countries' scientific Societies generate an information flow about drug monitoring which is circulated in transplant hospitals and in health centres which follow-up patients with low immunological risk.

Interchangeability between innovative and generic immunosuppressive drugs is not recommended if the clinical verification process has not been completed. Children, elderly patients and those at high immunological risk are vulnerable groups and should not be incorporated in any interchangeability programme.[45]

Purchasing generic immunosuppressants at a lower cost is not a valid argument within the bioethical principles framework, which must ensure that the principles of beneficence and nonmaleficence are met. Pharmacoeconomics does not just consider the purchasing cost of the drugs, but also includes those costs associated with lack of effectiveness and safety of a drug. If using generic immunosuppressants results in a greater graft rejection rate, savings generated from the drug price shall be exceeded by therapeutic failure costs. Therefore, using a poor quality generic immunosuppressant results in additional costs. In contrast, a generic immunosuppressant that is as effective and safe as a low-cost innovative immunosuppressant provides significant savings. This type of generic immunosuppressive drug should therefore be promoted by the regulatory authorities.[45]

Lastly, we consider that health authorities have the opportunity to define policies that guarantee the best universal coverage for immunosuppressant treatment and that in conjunction with regulatory authorities, commercialisation of new generic drugs may be authorised once their quality standard is assured.[46-48]

RECOMMENDATIONS AT A COUNTRY AND PROGRAMME LEVEL

Below are the conditions for developing a salutary donation and transplant system in each country of this region:

1. It must have a specific legislation, based on bioethical considerations that contemplate regulating donation, allocation, transplant and follow-up.

2. It must guarantee universal access to the health services, including transplant access, in all region countries.

3. It must establish a state national organisation responsible for donation, procurement and allocation of organs, as well as promoting and creating national transplant policies.

4. It must promote deceased-donor programmes and ensure maximum use of each countries' resources, as well as international cooperation, including the exchange of medical-clinic, educational, bioethical and scientific research resources on donation, immunology and transplantation.

5. It must create a national waiting list for each organ or tissue and allocation systems with defined criteria with regards the order, certainty, transparency, credibility, and traceability of the system.

6. It must promote the creation of necessary controls in health institutions to protect the vulnerable population.

7. It must unite the principles of distributive justice (equality, usefulness and community).

8. It must rely on systems for monitoring and accounting allocation processes.

9. It must promote the need to report when a living-donor transplant has been performed to the national donation and transplant system in each country and the relevant ministries of public health. Data related to traceability and follow-up must also be reported.

10. It must create assessment committees for non-related donors in hospitals that perform transplants.

11. It must create national donation and transplant registers which assure adequate analysis of the short- and long-term results.

12. It must establish criteria for certifying hospitals where transplant procedures are to take place.

13. It must register and authorise transplant programmes.

14. It must establish national criteria and protocols for selecting deceased donors and procurement.

15. It must define criteria for certifying staff dedicated to procurement and transplant activities.

16. It must prepare competent and qualified clinical transplant teams for different organs, with transplantation programmes which include different pre-transplant, transplant and post-transplant activities.

17. It must train staff for donation and procurement activities.

18. It must establish mechanisms that support and encourage deceased-donor and procurement programmes in all region countries.

19. Companies initiating negotiations for generic immunosuppressive drug formula approval before the relevant health ministries must fulfil the following:

    a. Present references on the origin of the drug and its use in other countries.

    b. Submit the generic formula to clinical transplant trials which guarantee therapeutic safety and efficacy, with the supervision of authorised third parties. These trials should obtain adequate statistical power.

    c. Guarantee the provision of the drug for a period of no less than one year to prevent the risk of drug interruption and interchangeability. It is likely that the generic marketer may have production and/or distribution problems that restrict adequate drug supply.

20. It must announce and circulate the Aguascalientes Document in all transplant forums and conferences that take place in Latin America and the Caribbean.

21. It must make this Document reach all State institutions that participate in health management in the region.

CONCLUSIONS

This Document contains the results from the work sessions and round tables from the First Latin American Bioethics and Transplant Forum and its publication complies with the proposal to circulate the content to all health care professionals who give every effort on a daily basis to caring for transplant patients, as well as to the medical Societies involved in transplant activities and the health authorities from all countries in the Latin American and Caribbean region.

The Aguascalientes Document does not attempt to be a dogma which censures transplant practices or defining what is correct and what is not.

The Aguascalientes Document reaffirms its identity with the highest values which define medical practice, strengthens its commitment to dignity, respect to life and duty to helping those that are suffering.

Although the Aguascalientes Document accepts that each country and each transplant centre has the prerogative to defining their own practices, it does aim to serve as an instrument of expression for transplant groups in Latin America and the Caribbean. It is therefore determined to influence the transplant activities that are carried out within the context of justice and equity.

The greatest challenge, and consequently the task which all groups involved in transplants will probably have in the coming years, will be granting the necessary control of the commendable measures suggested in this Document, in an effort to optimise (under the strictest ethical principles) the donation and transplantation results obtained from the joint effort of the region's countries.

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