



VOLUME LXXIV, ISSUE 10 PART 2, OCTOBER 2021

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Wiadomości Lekarskie is abstracted and indexed in: PUBMED/MEDLINE, SCOPUS, EMBASE, INDEX COPERNICUS, POLISH MINISTRY OF EDUCATION AND SCIENCE, POLISH MEDICAL BIBLIOGRAPHY

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Graphic design / production.

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Publisher:

ALUNA Publishing House ul. Przesmyckiego 29, 05-510 Konstancin – Jeziorna www.wydawnictwo-aluna.pl www.wiadomoscilekarskie.pl www.wiadlek.pl



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REVIEW ARTICLE



LEGAL REGULATION OF HUMAN ORGANS AND TISSUE TRANSPLANTATION: INTERNATIONAL AND FOREIGN EXPERIENCE

DOI: 10.36740/WLek202110224

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ABSTRACT

The aim: To highlight and analyze the international aspect of the legal regulation of human organs and tissues transplantation, as well as foreign experience of regulation in this area within the relevant national legal systems (for example, US, Germany, Israel, Switzerland, Spain, Argentina, China and India).

Materials and methods: Methodologically, this work is based on the system of methods, scientific approaches, techniques and principles with the help of which the realization of the research aim is carried out. There have been applied universal, general scientific and special legal methods.

Conclusions: Thus, the efforts of the international community and the countries under study in the field of transplantation are focused on a wide range of important issues that need to be regulated. The international legal regulation of transplantation covers the results of the activities of such international organizations as the World Health Organization, the Council of Europe, and the World Medical Assembly. The acts adopted by them are mainly of a recommendatory nature (with the exception of some Council of Europe acts on trafficking in human organs) and are addressed primarily to States, offering guidelines and standards for the legal regulation of transplantation within national legal orders. Therefore, the issues of donation and transplantation of human organs and tissues in the respective states are determined by special legislative acts, which comprehensively regulate the procedure for their transplantation.



Wiad Lek. 2021;74(10 p.II):2651-2658

INTRODUCTION

Decades of experience in transplantation have demonstrated the importance of this institution in medicine, as well as the need for its proper regulation at the level of international and national legislation. The increasing attention of the international community and modern states to the legal regulation of transplantation of human organs and tissues is caused by several main factors: first, the acute shortage of donor organs and human tissues, in which the needs of all patients are not de facto met; secondly, the motivation to protect the rights of participants in the transplant process, compliance with ethical requirements; thirdly, a significant intensification of illegal activities in this area, the development of human organs trafficking, which indicates the need for effective measures to combat such acts.

THE AIM

The aim of the work is, therefore, to study and analyze the international aspect of the legal regulation of human organs and tissues transplantation, as well as foreign experience of regulation in this area within the relevant national legal systems (for example, US, Germany, Israel, Switzerland, Spain, Argentina, China and India).

MATERIALS AND METHODS

The study required the author to use a number of methods – both general and special. Among general scientific

methods the following ones were applied: methods of analysis, synthesis, generalization, formal-logical, structural-systemic and some others, special methods were: logical-semantic, formal-legal, historical-legal and the method of comparative analysis. In particular, logical-semantic and formal-legal methods were used in the disclosure of the concept of "transplantation" in the legislation of some foreign countries; historical-legal method was used to determine the dynamics of the historical aspect in the development of legal relations regulation in the field of transplantation; the method of comparative analysis directed the author towards a comparative analysis of legislation on the donorship and transplantation of human organs and tissues within different national legal systems.

REVIEW AND DISCUSSION

First of all, we will provide some explanations of the concept "transplantation". For example, the Oxford Dictionary considers transplantation as the process of transplanting to the recipient organs or tissues taken from a donor [1]. The World Health Organization (WHO) defines transplantation as the transfer of human cells, tissues and organs from donor to recipient to restore body functions [2]. The Law of Ukraine "On the use of transplantation of body materials to humans" contains an interpretation of transplantation as a special method of treatment, which consists in transplant

ing human body material from a donor to a recipient, and aims to restore human health [3]. Researchers attribute the eligibility to use transplantation (from both a living and a deceased donor) and its further consequences for health to an individual who needs a donor or to an individual who is a donor, as donation can lead to adverse consequences for both participants in these relations [4]. It is generally accepted to divide transplantation into several types: 1) autotransplantation – transplantation of organs and tissues within one organism; 2) allo- (homo) transplantation – transplantation of organs and tissues from one person to another; 3) xeno- (hetero) transplantation – transplantation of organs and tissues from one species to another (for example, from animal to human) [5].

INTERNATIONAL ASPECT OF THE LEGAL REGULATION IN HUMAN ORGANS AND TISSUES TRANSPLANTATION

The need and importance of the transplant procedure, including its purpose, as well as the progressive development of modern medical technologies and the factor of dynamic activity in the field of illegal organs and tissues transplantation, cause feedback from international governmental and non-governmental organizations, after which documents are given a new legacy which determines principles and framework of transplantation activities and counteract their illegal conduct. Therefore, the international legal support for transplantation covers the functioning of the Council of Europe, WHO, the World Medical Assembly and other international organizations.

Therefore, at the level of the Council of Europe, first of all, it is worth paying attention to the Convention on Human Rights and Biomedicine of 1997, which, among other things, establishes fundamentally important conditions for transplantation, including the consent of the recipient (Articles 19-20), and also prohibits the use of the human body and its parts for financial gain (Article 21), as well as determines the rules forb the use of the removed part of the human body (Article 22) [6]. In 2002, the Additional Protocol to the Convention on Transplantation of Human Organs and Tissues was adopted. This act establishes the basic rules and standards of transplantation, informing issues, participants protection in this procedure, confidentiality issues, the prohibition of financial benefits from organ and tissue transplantation and other aspects [7].

In addition to the above-mentioned Convention, it is necessary to mention such important documents of the Committee of Ministers of the Council of Europe as: The 1978 Resolution on the Harmonization of the Legislation among Member States on the removal, transferring and transplantation of body materials is an impulse to the Coucil of Europe member states to bring their national legislation in accordance with rules of this Resolution(the rules on the removal, transferring and transplantation of body materials extracted or collected for therapeutic or diagnostic purposes [8]; The Xenotransplantation Recommendation of 2003, which presents the principles and

issues aimed at protecting patients and medical staff during the xenotransplantation procedure, as well as the animals used in it [9]; Recommendation "On Donor Registers" of 2003 - defines the main issues of the donors national register, which should provide ample opportunities to the person to formulate their will (decision) regarding transplantation [10]; The Recommendation «On Organ Trafficking» (2004) contains a list of measures to be taken to combat trafficking of human organs [11]; Recommendation "On Quality Improvement Programs regarding organs donorship" (2006) contains the measures to be taken to improve the quality of organ and tissue donorship at hospitals conducting transplant procedures [12]; The 2006 Recommendation "On the Preconditions, Functions and Responsibilities of the National Transplant Organization" provides issues of the legal status of the national transplant organization, which must be established at the each state level [13].

Among the important documents of the Council of Europe protecting the principles of transplantation and responsibility for trafficking of human organs and tissues, the following ones should be mentioned – the Convention against Human Trafficking (2005) [14] and the Convention against Human Organs Trafficking (2015) [15]. They contain regulations on measures preventing and combating trafficking of human beings (body organs), criminalization and penalization of human trafficking (human organs), protection of the victim rights, ensuring effective investigation, and international cooperation in this area.

In addition, the leading role in the international legal regulation of transplantation, of course, belongs to the WHO. Its most important document is the Guidelines for the Transplantation of Human Cells, Tissues and Organs, adopted at its 63rd session in May 2010. This document contains a Preamble and 11 guidelines, the role of which is to define an orderly, appropriate basis for procedures for the obtaining and transplantation of human cells, tissues and organs for therapeutic purposes in compliance with ethical principles. These regulations do not apply to the transplantation of germ cells, ovarian tissues or embryos for reproductive purposes, as well as to blood and its components transfusion [16]. Among the WHO resolutions on human organs and tissue transplantation are the following ones: Resolution WHA57.18 (2003), which appeals to countries to: effectively supervise the procurement, processing and direct transplantation of human organs and tissues; take measures to harmonize the world transplantation practices; take measures to protect the poorest and most vulnerable strata of the population against the so-called "transplant tourism" and the sale of human organs and tissues; to support international cooperation and coordination in xenotransplantation performance [17]; Resolution WHA63.22 (2010), which provides recommendations to states on: promoting the development of altruistic voluntary and unpaid organ and tissue donation, raising public awareness of these issues; promoting a system of transparent and equitable organs and tissues distribution, as well as equal access to transplantation services; maximizing donations

from deceased donors, protecting the health and well-being of living donors, etc. [18].

Therefore, a number of documents regulating the transplant procedure have been adopted at the level of the World Medical Assembly as an international non-governmental organization. In particular, they include: Declaration on Human Organ Transplantation (1987) which contains recommendations for physicians involved in transplantation, their behavior and interaction with all its participants [19]; Regulations on fetal tissue transplantation (1989) defines the list of conditions under which the use of fetal tissues (aborted fetal tissues) for transplantation is possible [20]; The 1985 Regulation on Trafficking of Live Organs is directed against the sale of human organs for transplantation, as well as the adoption of the necessary measures to prevent the commercial use of human organs [21]; The 1994 resolution on the attitude of doctors to the problem of human organ transplantation adheres to national medical associations to follow the principles set out in the 1987 Declaration on Human Organ Transplantation and to bring to justice doctors who have committed violations.

In our opinion, it is relevant to focus on another international document, namely: the Istanbul Declaration on Transplant Tourism and Organ Trade, adopted by experts from the Association of Transplantologists and the International Association of Nephrologists in 2008. It contains a Preamble, some terminology new to international law, key positions on transplantation, as well as suggestions to increase the effectiveness of post-mortem donation, the fight against transplant tourism, human organ trafficking, and the protection and safety of living donors. The significance of this document lies in professional attitude of the international expert community towards combating transplant tourism and organ trade, which can be used by governments around the world as a guide for the development of national legislation [23].

We now turn to the analysis of the legal regulation experience concerning transplantation of human organs and tissues in such foreign countries as the United States, Germany, Israel, Switzerland, Spain, Argentina, China and India.

USA

In October 1984, the United States adopted the National Transplant Act, the result of which was a creation of a task force for organ transplantation, aimed to study the main directions of organ donorship development. In the same year, the United Network for Organ Sharing was formed to oversee the national registration of donors and the procedure for receiving organs from recipients. In 2006, the United States approved the Unified Act on Anatomical Gift. An anatomical gift is a gift of all human body or its part after the donor's death for transplantation or scientific purposes. The testamentary form of this gift implementation was provided. However, in 2007 the testamentary form of gift was replaced by a simple mark in the driver's license. The reason for this simplification was a significant shortage

of donor organs and tissues in the country [24]. Lifetime donors in the United States are divided into three types: genetically related; independent (friend, husband (wife), other person emotionally connected to the recipient); altruistic (persons who donate their organs and tissues to an anonymous candidate on a waiting list) [25]. The Transplant Act prohibits trafficking of human organs by imposing a fine of up to \$50,000 or imprisonment for up to five years for the crime.

GERMANY

In Germany, the Law on Organ Donation, Collection and Transplantation of 1997 is in force at the federal level. This act broadly regulates the procedure of organ and tissue collection from dead and living donors, the status and activities of donor tissue banks, research laboratories, transplant centers, coordination centers and other institutions involved in transplantation. There is a strict ban on the threat of criminal liability for trafficking in human organs or tissues [27]. In general, transplantation is possible under German law only with the consent of the donor. In this case, in the absence of such consent or with a written objection, the doctor may apply to the immediate family of the deceased, following two stages. In the first stage, the doctor finds out if the donor has applied for a donation in his lifetime. In the second one, the doctor asks the relatives of the deceased if they agree to transplant his organs. When making a decision, it is assumed that the relatives of the deceased must respect and be able to predict his will. In practice, a potential donor is maintained in a stable state after the establishment of brain death with the help of appropriate drugs. During this time, the doctor conducts a conversation with the relatives of the deceased, involving the presence of the transplant coordinator. It is believed that due to the professionalism of the transplant coordinator, the chances of obtaining consent for transplantation are significantly increased [28].

ISRAEL

The Law on Anatomy and Pathology has been in force in Israel since 1953. Among other things, it regulates the body use of the deceased for research for medical purposes, as well as patient treatment and his life rescue. The Law also determines the cases of consent or refusal for organs removal, the procedure for notifying the relatives of the deceased donor, the procedure for the doctors conduct in these circumstances. Interestingly, this piece of legislation presupposes three levels of priority in the organs and tissues distribution: first of all, the advantage is given to people whose relatives have already donated their donor organs after death; then come people registered as donors for at least three years; and at last people whose relatives are registered as donors for at least three years [29].

In its turn, in 2008 the Law on Organ Transplantation was adopted, which broadly regulates the legal, organizational and ethical aspects of organ donation, transplantation and

distribution in the country. Organ trafficking is a criminal offense leading to three years of imprisonment and a large fine. As an incentive for altruistic organ donation, the Law on Transplantation provides for various types of compensation, namely: compensation for losses during forty days based on the average income of the donor for the last three months (for the unemployed ones the minimum wage is taken into account); transport costs (all trips of the donor and his relatives to and from the hospital); for medical care, in case of disability and life insurance (if insurance policies and relevant receipts are provided); the cost of five psychological consultations and treatment (with receipts) [30].

SWITZERLAND

The peculiarity of the legal relations regulation in the field of transplantation in Switzerland first of all lies in the fact that the fundamental regulations of such relations are appointed to the Federal Constitution of the Swiss Confederation. It contains Article 119 "Medical Transplantation", which highlights the need to protect human dignity, privacy and health in transplantation procedures, establishing a fair organs distribution; free donation of human organs, tissues and cells and prohibition of human organs trafficking [31]. Therefore, at a special normative level, in 2001 the Union Law on Organs, Tissues and Cells Transplantation was adopted, the norms of which provide for: the powers division between federal and cantonal bodies in the field of transplantation; licensing procedure; various legal regimes of human organs, animal organs and stem cells transplantation; mechanism of legal protection in this area; special legal regimes for Swiss citizens (both donors and recipients); issues of criminal and administrative liability [32].

SPAIN

First of all, it should be noted that the Spanish model for organ donation is nowadays recognized by the WHO as the best in the world. Its main principles are systemic and organizational approaches to the donation process at both the institutional and regulatory levels.

The key legal acts on transplantation in Spain today are: the 1979 Law "On Organ Collection and Transplantation" and the 2012 Decree of the Ministry of Health and Social Services "On the activities of obtaining, clinical use and territorial coordination of human organs intended for transplantation and setting quality and safety requirements". Thus, the first of these acts (small in size) is aimed at determining the basic principles of activities in the field of transplantation, in particular: its altruism, ie the absence of a commercial element; carrying out this procedure exclusively for therapeutic or scientific purposes; identification of requirements for a living donor (reaching the age of majority, free and conscious consent, warning of the consequences of transplantation); the possibility of removing organs from a deceased donor only after the statement of his death, etc. [33]. The decree of the Ministry of Health and Social Services, first of all, contains the understanding of transplantation as a process aimed at restoring certain

functions of the human body by replacing a diseased organ or its function with another from a living or dead donor. It regulates the protection of donor and recipient rights; the procedure for obtaining, transporting and exchanging organs; activity of transplantation centers; issues of quality and safety of organs; coordination of activities in this area by authorized authorities, etc. [34].

In 1989, the National Transplant Organization was established in Spain to coordinate all donation and transplantation issues. There is a network of organizations that deal with this procedure at the national, regional (seventeen focal points) and hospital (hospitals where transplantation is possible) levels. The main link in the Spanish system is the transplant coordinator, an intensive care physician who is appointed by each hospital (its management and reports to it) and is designed to facilitate the early detection and referral of potential donors [35]. Spain is characterized by the number of organ and tissue transplant operations – more than one hundred and four per one million population. There is also a government Quality Assurance Program, aimed at conducting ongoing audit of mortality, donor audit and donor capacity of hospitals [36].

It also should be added that since 1991, more than fifteen thousand specialists have been trained in organ donation. These are not only doctors who are directly involved in transplant procedures, but also specialists whose activity is related to organ donation: resuscitation, emergency care, stroke department, etc. [37].

ARGENTINA

At the federal level, the legal regulation of transplantation activities in Argentina has long been ensured by the 1993 Law on Transplantation of Human Organs and Tissues. It provided for the possibility of transplantation only if other methods and possible means have already been used or are insufficient or inappropriate, or if it is a therapeutic alternative for the patient's health. It was necessary to adhere to the following principles: respect for human dignity; autonomy of the will of the person; justice in the organs distribution of and donors tissues; equal access to transplantation; adherence to ethical principles in research activities; voluntariness and altruism. Donors and recipients or their legal representatives had to give voluntary informed consent for the transplant. In addition, it was assumed that the donor - an able-bodied adult - could confirm or deny his will for transplantation, limit it to the provision of only certain organs or tissues, and express the purpose of donation - for specific people, for educational or research purposes [38].

It should be noted that a few years ago there was a situation in Argentina that led to significant legislative changes in the field of transplantation, as a result of which the 1993 Law expired. This is the case of Khustina Lo Cane, who needed a transplant at the age of twelve due to heart disease. When she was included in the waiting list in 2017, she decided to fight not only for her own life, but also for the development of the donation system in the country. At her request, her

parents organized a campaign "Multiply yourself by 7" on the social network, the main content of which was that each person can save seven more after their death. In the end, the girl did not wait for a transplant, because her heart stopped. However, her example inspired not only society but also legislators. If previously the consent of the donor or the consent of his relatives was required to obtain an organ for transplantation, then under the new law called by the girl's name ("Law of Khustina" of July 26, 2018), anyone who did not record refusal in life (i.e. all adult citizens of Argentina). In addition to novelties at the legislative level aimed at radically simplifying transplant procedures, the number of people wishing to become donors has increased significantly since the death of Khustina Lo Cane [39].

CHINA

Starting from the 1970s, China developed the practice of removing organs from prisoners who had been sentenced to death without their consent or the consent of their families. Under the 1984 Provisional Regulations on the Use of Dead Bodies or Organs from Convicted Criminals, organs were confiscated from executed prisoners provided that their bodies were not required, or the prisoner voluntarily agreed to the donation or his family agreed. In this case, the removal of organs had to be strictly confidential. Under these circumstances, in many cases, families of prisoners received only the results of cremation without reporting what had happened to their relatives. Later, after several decades of human rights violations and after the adoption in 2007 of the Regulation on Human Organ Transplantation, China's national transplant system has been reformed. It is currently assumed that human organ transplantation requires the donor's written consent. In 2013, within the framework of the National Congress on Transplantation, a unanimous decision was made by experts on the inadmissibility of trafficking in the organs of prisoners sentenced to death. Prior to that (in 2010), the Chinese government recognized organ trafficking as a crime, while launching a voluntary donation program.

With regard to the established order of donor organs distribution, the following principles apply in China: 1) compliance with medical needs; 2) the hospital has the right on the basis of a medical opinion to refuse to accept organs unsuitable for transplantation; 3) avoiding "waste" of organs in order to maximize the chances of patients for transplantation and increase the efficiency of distribution; 4) optimization of compliance with the quality of organs, as well as improving the postoperative health and recipients life standards; 5) fair distribution of organs and reduction of the impact on this process of physical, pathological and geographical differences; 6) regular review of organ allocation policy [42].

INDIA

The law on transplantation in India was adopted in 1994. It regulates the following main aspects of the relevant legal

relationship: the procedure for removing organs from deceased people, from living donors, the status of hospitals and health workers, as well as the issue of liability for illegal transplantation. According to this Law, transplantation is defined as the transplantation of any human organ from a living or dead person to another living person for medical purposes. It has been established that any person may consent to the removal of his or her body after death in the presence of two or more witnesses. Such a permit can be specified in the driver's license. If the person did not provide it during his lifetime, another person who legally disposes of the deceased body may consent to the removal of organs, provided that none of the close relatives of the deceased objects to this. An important aspect of organ donation after death is the certification of brain death by a board of medical experts [43].

The Indian Transplant Act separately regulates the procedures when the donor is a relative of the recipient and when the donor is a third party. Thus, in the first case, the patient's relative submits an application for donation to the competent authority (the director of the hospital or a special commission of the hospital). If the decision is made by the commission, a conversation is held with the donor, recipient and their relatives, on the basis of which a decision is made on permission for transplantation. Interestingly, all actions are subjected to video recording. In the second case - when the donor is a third party - a two-level inspection of the recipient, donor and their relatives is performed. Initially, it is carried out by a special commission of the hospital, and then – by the State committee that also interviews the recipient, the donor, and their relatives to ensure that there is no commercial element of the relationship between the donor and the recipient.

CONCLUSIONS

Thus, the efforts of the international community and the countries under study in the field of transplantation are focused on a wide range of important issues that need to be regulated. The international legal regulation of transplantation covers the results of the activities of such international organizations as the World Health Organization, the Council of Europe, and the World Medical Assembly. The acts adopted by them are mainly of a recommendatory nature (with the exception of some Council of Europe acts on trafficking in human organs) and are addressed primarily to States, offering guidelines and standards for the legal regulation of transplantation within national legal orders. Therefore, the issues of donation and transplantation of human organs and tissues in the respective states are determined by special legislative acts, which comprehensively regulate the procedure for their transplantation. The exception here is Switzerland, whose Constitution formulates the key principles of its implementation. The main attention in the special normative act is focused on more detailed aspects: determination of the procedure for giving consent to organ and tissue donation; the legal status of hospitals that perform

transplant activities, as well as transplant coordinators; ensuring fair distribution of donor organs; protection of the rights of donors and recipients; fixing the ban on transplantation on a commercial basis and establishing criminal liability for trafficking in human organs. The Israeli experience, among other things, demonstrates how the state can encourage altruistic donations from donor elements (to cover the costs of medical care, loss of earnings, insurance, etc.). The practice of human organ and tissue transplantation procedures in China demonstrates the importance of donor consent for organ and tissue transplantation, as well as the need to ensure fair and efficient distribution. The Indian Transplant Act sets out the specifics of pre-transplant preparations (depending on whether the recipient is a relative of the recipient or an outsider), which aim to eliminate the commercial factor in the appropriate form of medical intervention. To this we will add that among the countries analyzed by us, the experience of Spain, whose model of organ donation is recognized by the WHO as the best in the world, deserves special attention. Its main principles are systemic and organizational approaches to the donation process at both the institutional and regulatory levels. In particular, in Spain, a network of focal points has been set up to provide transplant procedures, doctors have been systematically trained, and a government program has been adopted to carry out ongoing audits in the field of transplantation.

And at the very end we state the urgent need for further scientific research on the peculiarities of the legal regulation of human organs and tissues transplantation (in in the context of international and foreign experience), which is obvious based on the Ukrainian state and legal realities. Thus, Ukraine, which has just embarked on the "transplant path", has shown itself quite successfully in this direction over the past few years. First, it should be noted the basic legal act - the Law "On the application of anatomical materials to humans" from 17.05.2018, which was amended accordingly. Secondly, the adoption of the Resolution of the Cabinet of Ministers of Ukraine of 23.12.2020 [45] was an indicator that in Ukraine from January 1, 2021 the Unified State Information System of Organ and Tissue Transplantation de facto started its activity, which stores and accumulates in electronic form information on donors and recipients, as well as on donor organs and tissues. Thirdly, every year, starting from 2019, there is a positive trend in the number of organ and tissue transplant operations performed in our country.

At the same time, in Ukraine in the context of transplantation procedures there are still problematic aspects of legal and organizational nature, among which, for example, experts note: the presence of a "presumption of disagreement" (which should be replaced by a "presumption of consent" as it's applied in a number of foreign countries); lack of transplant coordinators and specialists in the field of transplantation; the complexity of the procedure for posthumous donation, including the lack of donation consent in driver's license; lack of information campaign aimed at encouraging the population to donate.

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Conflict of interest:

The Authors declare no conflict of interest.

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Received: 22.06.2021 **Accepted:** 17.09.2021

A-Work concept and design, B-Data collection and analysis, C-Responsibility for statistical analysis,

 ${\bf D}-{\sf Writing\ the\ article}, {\bf E}-{\sf Critical\ review}, {\bf F}-{\sf Final\ approval\ of\ the\ article}$