COMMUNICATION AND INFORMED CONSENT IN HEALTHCARE

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Abstract

The human being represents the basis of the society's existence and all the associated issues represent the fundament for the ethical-medical, administrative, legal or political norms.The exercise of the rights of personal protection of life and health are not and cannot be susceptible to restrictive interpretations by modulation or by various normative changes. Based on the natural and constitutional right and on legal norms, in modern society there is a fully confirmed respect for private and family life, freedom of thought, conscience and religion, the right to expression, meeting and association, prohibition of discrimination based on genetic heritage and the human genome, appropriate use of medically assisted procreation techniques or consent for the conduct of scientific research on human subjects.In this context, the informed consent represents the decision of every competent person in order to benefit from or to refuse a certain therapy, to take part or not to take part in a test which might affect his or her health condition after having received, understood and analysed the necessary information and having made his or her choice without being subjected to coercion, influence, induction or intimidation.

Keywords: *informed consent, ethics, medical communication, abuse typology, beneficence.*

1. HISTORICAL LANDMARKS

Through its dynamic, science may belong to "light" or, to "the dark." In the hands of some people who are only interested in power, science may become an untamed beast, possessive, dominant, frequently destructive in its relationship with individual freedom or the good of the society. Science applied beyond reason invades all fields and becomes supracultural, kills all imaginary beliefs and may statue itself in the ascendent of ethics, placing doubt and even completely changing the moral fundaments and principles.

Research in the area of the sciences of life is necessary in order to ensure the progress of humanity which represents and will continue to represent a fundamental motor vector of social dynamics. At first, illness research on human subjects took place based on traditional empiric procedures or based on certain scientific principles, but this area of preoccupations benefited from normative regulations starting from the 20th century, laws initiated as a matter of priority by the US. The first norms conditioned the development of experiments on the prior use of medicine on animals, human subjects could only use a certain procedure after they offered their informed consent, being supervised by a doctor/medical team throughout the reference period.

During the interwar period, the Nazi Germany adopts "The regulations on the new therapies and experiments on human subjects" (SASS, 1983), which stated the following:

- research had to be based on ethical, moral and medical practice criteria;
- the life, health and dignity of the research subjects had to be protected in an express manner;
- the risk had to be minimal and thoroughly calculated based on the analysis of the added benefit;
- research had to be preceded by conclusive experiments on animals;
- it was compulsory to publish the results of the research which become a public good;
- the systemic protection of underage and of people with disabilities was instated.

Although regulations imposed correctly grounded ethical and moral norms, in reality these were completely violated, mankind recording some hard to imagine and accept horrors in the name of science, regardless of the justice of the proposed purposes. In the Nazi extermination camps there were all kinds of experiments, frequently justified through the

logic of the war, the protection of the fighters, the treatment of wounds, the increase if the ability to withstand physical exertion, cold, hunger or thirst. All Nazi experiments during 1939-1945 did not respect the existent legal norms, taking advantage of the fact that the winner cannot be judged, regardless of the character or nature of the actions produced.

The American Civil Liberties Union (1973) issued a "guide" for the ethical and legal protection of the prisoners who wished to take part in medical research, carefully managing the issue of conditional release from prison, reduction of penalties, the granting of financial and material advantages, all obligations assumed and due rights to sponsors in all categories financing the experiments.

At the end of the 1970s, the American National Health Institute introduced the so-called "consent conferences," activities whose main purpose was to adopt the best ethical solutions and, at the same time, to expend the principles of good practice in a larger reference space. Many countries set up their own ethical bodies which started to make their presence and authority visible and therefore in 1987, the French "Consultative committee for Ethics" sanctioned the influence of the financial investments in medical research as a possible vector for changing the results, including the reducibility of the person to a simple consumer good through which his or her dignity can be diminished or even annulled. Moreover, the increasing technical and economic power leads to a lack of balance in nature, whose management becomes chaotic, hides death or cultivates health through excessive medicine and related techniques. The individual risks to build hell on earth and then to perfect it and to take it to incredible parameters, knowledge making him more human, wiser or better but much more lonesome … "it can make him more insensitive to his own nothingness (BEAUCHAMP & CHILDRESS, 2001"

2. CONSENT CONFERENCES AND LEGAL NORMS

These techniques aim to substitute personal beliefs, the judgments of a professionally interested community based on arguments regarding the need to introduce those new medical procedures in relation to the confirmed therapy. Since there are no certain, arithmetical rules to follow in medicine in order to determine the standards for efficiency, physical security or acceptable therapies for the patients and the feasibility of the practitioners on the rather uncertain area of the opposable or contradictory states offered by modern medicine, compared to the classical one, in their completeness, the consensus conferences can become true arguments of ethics.

Consonant to these realities, it is useful to notice the preoccupations of some institutions, practitioners or even patients to counterpose the research activity of some special procedures with the purpose of confirming the therapeutic results, to promote products and procedures, including the solving of some scientific, legal, economic or ecologically disputed issues. Therefore, the consent conference adds up the specific qualities of an assessment method and of the confirmation of the values generated by the actual research activity through:

- the acquisition and consolidation by the product / therapy of a certain position, validated on the health or drug market;
- the identification of the "strengths" which should be improved and of "weaknesses" which should be eliminated from the negative behaviour of the therapy/medicine;
- tracking the detection of effects on different graphs / evolutionary terms and quantifying the potential (benefit gained), compared to the limitations (dissatisfaction produced);
- the elimination of contradictory manifestations from the future practice of therapy.

There is the relatively well-sedimented suspicion that the vaccines based on messenger RNA, such as Pfizer-BioNTech, Moderna, AstraZeneca and **Johnson** & Johnson do not respond to therapeutical parameters and to the ethical and moral issues and this led to a refusal of vaccination for some parts of the population.

The informed consent cannot be fulfilled in the absence of a correct and complete information of the population in relationship to age, training

degree, profession, health status etc. Medical ethics should advance the rules and implicitly the health legislation but it does not have the competence to become a guide that offers definitive, comprehensive solutions and even less, unanimously accepted, with universal values. The behaviour of the above-mentioned vaccines travelled the route from theoretical research to laboratory research, respectively mass production in a suspicious short time generating serious uncertainty. Therefore, it is the duty of the research and production staff to guarantee the security of the patient's life, health, intimacy and human dignity in accordance with the basic principles adopted by all countries through this consent (WMA.NET, 1964).

Performant medical communication is necessary because it becomes obligatory to defend the individual from his own humanity. Three major scientific layers met, without any doubt, in this idea: medical and research knowledge in the field, legal, ethical and philosophical, interdependent in terms of issues, lucrative principles and their purpose.

The restlessness of public opinion represents a key factor which negatively combined itself with numerous violent manifestations imposing a comprehensive approach to the specific issues of ethical communication based on basic principles unanimously accepted and adopted by the national healthcare system respectively the non-injury, autonomy, benefice and justice. But, to what extent is the individual ready for this moment, without risking to go into the unknown or to open the doors of totalitarianism in medicine? At the same time, there is a question of whether, at this point, it is advisable to temper the scientific convictions and enthusiasm, to reconsider the ethical issues and to apply a consonant system of protective measures or, on the opposite, the measures should be applied only in certain cases of obvious and severe and immediate danger generated by the Covid-19 pandemic. Due to his wish of attaining perfection through biotechnology, the individual may trigger the risk of turning from human into more inhuman or even to self-destruct. That is why, we do not know if these effects can be controlled when it comes to the safety parameters required by humanity in order to corroborate this field with the other recognized aspirations.

There are some restraints reported in connection with the excessively bureaucratic legislation in the field and also to the request for some additional protective regulations, because the behaviour of the individuals is dependent more on the law, on constraint than on ethics. In the interference with the norms of law, research activities were subjected to some theoretical analysis regarding their pertinence, degree of precision and level of explanation. Could these norms operate in such a sensitive field in which they were substantially affected, both for the individual and for the collective conscience? The answer is usually affirmative, with the mention that in each approached case, the decision has to include the specificity, the uniqueness and the particular.

Communication and the authority of the judged activity cannot have an implicit, minimally accepted justification in which the jurisprudence sums up at most a role of application to concrete situations of a general rule, suitable, enacted by law. Some opinions of ethics committees are increasingly appealing to the rule of law and researchers feel the need to clarify their responsibilities. There is a certain need for the law to establish a minimum set of rules, allowing society to function at least satisfactorily in the field of ethical communication, so that at the social level, the freedom of each individual extends only to where the freedom of the other begins.

A person's judicial respect, based on the physical and spiritual inviolability, highlights insufficiently grounded or expressed attitudes and decisions, principles from which the law may develop social consequences. In this connection, it is expected that through the medical communication which has to have an ethical value, the legal norms have to intervene and achieve a referring of macrosocial synthesis, based on clear principles among the various major interests, frequently opposed to the people, conditioning the freedoms of each one in the context of the general interest without vitiating the informed consent.

3. THE SCIENTIFIC VALUE OF RESEARCH, THE COMMUNICATION OF RESULTS AND THE TYPOLOGY OF ABUSE

The scientific medical research makes use of a proper methodology which has to be permanently objectified. Usually, it is described in a document, a formalized protocol which materializes both the preestablished objectives and the procedures aimed at attaining them. In the time prior to the initiation of a research programme, the documentation has to be formally verified in order to establish if the procedures are secure, efficient and that they do not break the ethical and deontological norms of the field. Theoretically, we might say that the transgression of the medical research ethics represents a reality which frequently appears if the procedural norms are not fully respected and if all the incident methodological vectors are not updated.

The topics and the goals of the research in the case of applying a vaccine can be divergent in the perception of the researcher in comparison to those of the subject. The officially stated intention is that of understanding diseases as genesis, evolution and finality, to develop efficient therapeutical schemes and to substantially improve the quality of human life can be hindered by moral opposable intentions (the personal interest: authority, professional awareness, various advantages). Practice, which is comprised of the interventions exclusively aimed at gaining and consolidating a state of well-being for a patient, has to include the hope for a substantial success or at least for a reasonable one. It is only in this endeavour that the scientifical medical research allows for the correct achievement of the goal, respectively of the certainty of the diagnosis and of the correct prophylactic or curative treatment in the case of the affected condition.

The profitability of the human being constituted in time the object of numerous abuses. Statistically assessed and exploited following some convenient progress criteria, this doctrine became a research object, mainly subordinated to the determination of its biophysiological limits. In this context, the trial of German war criminals allowed the elaboration of the Nuremberg Code, the first document with international authority that adopts ethical principles focused on respect, benefit or justice (MEDIA.TGHN.ORG, 1996). The Helsinki Declaration, issued by the Global Medical Association in 1964 represents a document which reconfirms the ethical values materialized in the Nuremberg Code and in the Geneva Declaration by successively adopting amendments and revisions following a consonantal regulation (LEGISLATIE.JUST, 1948).

The EU Council Directives aimed at regulating the good clinical practices in testing the medicinal products (EUR-LEX.EUROPA, 2001) as well as at fulfilling the fundamental requirements for the authorisation of their production and import (EUR-LEX.EUROPA, 2005). Both directives addressed the legal and moral issues of the obligations of the sponsor, the investigator and the ethics committee mandated with the protection of persons, the management of adverse effects, the reporting of results etc.

The 2001/20/EC Directive defines and regulates in a unitary manner a number of essential notions, concepts and procedures used in research (EUR-LEX.EUROPA, 2005). Among the most important ones one can enumerate: the sponsor, the protocol, the investigator, the investigator's protocol. The "Good Clinical Practice" was adopted, having the quality of internationally acknowledged scientific and ethical norms, compulsory to respect in order to maintain the parameters of the study's design as well as the clinical trials (investigations on human subjects carried out methodologically to quantify short-, medium- and long-term pharmacological or pharmacodynamic effects, adverse effects, evaluation of the safety or efficacy of medicinal products / sera / reagents / vaccines).

A substantial part of the population is reserved and considers that the norms mentioned are not respected and that the vaccines based on messenger RNA, respectively Pfizer-BioNTech, Moderna, AstraZeneca and **Johnson** & Johnson may become dangers to medium or distant horizons.

Under the conditions of issuing rules that allow compulsory vaccination, informed consent becomes null, the person's freedom is annulled, his fundamental right and the entire societal structure based on democratic principles

recognized since the French Revolution can collapse with consequences difficult to quantify.

4. COMMUNICATING THE MEASURES TO PROTECT PATIENTS' HEALTH

The measures aimed at protecting the health of the individuals include the following standard norms:

- avoiding repetitive trials without an express motivation, for people and animals (EC. EUROPA.EU, 2001);
- harmonizing the technical and organisational nature and of marketing for the optimal usage of medicinal products (DIXON Jr., 1998).
- monitoring all the nonconforming reactions with the exception of those included in the investigator's brochure (forms of manifestation);
- the reactive functioning of the research ethics committees (with experience in the field);
- the creation of a certain data basis, scientifically agreed on, which can be accessed by all states if the confidentiality norms are respected.

The national legislative framework is very well configured. Among the norms in the field one can enumerate the law on good research practice (LEGISLATIE.JUST, 2004) and the law which protects the animals used for scientific purposes or for other experimental purposes (LEGISLATIE. JUST, 2002), together with the law regarding the rights of the patient (LEGISLATIE.JUST, 2003) and the law which protects personal data (LEGISLATIE.JUST, 2001), the deontological codes (annexes 1, 2, 3) (LEGISLATIE.JUST, 2001) and all the orders and rules for good practice in the clinical study (LUCHIAN & LUCHIAN, 2011).

The regulations of the National Medicines Agency, through express orders (LEGISLATIE. JUST, 2006a; LEGISLATIE.JUST, 2006b), transpose the European norms (2001/20/EC, 2005/20/EC), adopted by our country and the "Rules of good practice in the clinical trial represent a set of quality requirements in the ethical and scientific fields, internationally acknowledged, which have to be respected during the planning, execution, recording and reporting phases of the clinical trials. Respecting these rules guarantees the protection of the rights, safety and comfort of all participants in the clinical trials, as well as the credibility of the results of these clinical studies" (LEGISLATIE. JUST, 2006b).

In a research perimeter restricted by the rules presented, the rights, safety and well-being of participants, including environmental protection can really be ensured and the results of the study remain credible and unhindered.

5. INFORMED CONSENT DURING THE PANDEMIC

In a world with a difficult to control dynamics, the meanings and the directions in which it leads are difficult and sometimes even impossible to intuit. But nothing that is related to this development influents more than the development of human knowledge. In the hypothesis that science is mainly directed by utility, the whole evolution history of the human society confirmed that it may produce or lead to conflicts generated mainly by financial interests.

In those respective challenges in which science frequently appears in the equidistance of certain moral rules and legal norms, various principles with the value of norm have to be instituted. In the absence of some universally valid procedures, regardless of the existing configuration, medical research implies some risks (physical, social, psychological, emotional and financial) which belong to the institutions or to the individuals included in the programme. Regardless of the chosen path, the great research beneficiaries remain the society, the applied medicine, the researcher or the participating subjects (LUCHIAN & LUCHIAN, 2011).

The Belmont Report, drafted in USA, adopted by the European Union presents "The ethical principles" and later on details "the guides" for protecting human subjects. Defining the boundaries between practice and research, this report states the procedural norms, the methodology and the potential applications which result from them (HHS, 1979).

The preoccupations of the WHO in the field of bioethics facilitated the appearance of a "Guide," which represents a fundamental document on the area of the problems of the informed consent and of the safety of all patients (CIOMS, 2016).

These procedures aimed at the unitary definition of continental and national policies in reference to research ethics on human subjects, preserving the cultural specificity and economic possibilities of the countries with limited resources (thematic, point research), stimulating the approach of transnational studies for drafting GCPs (Good Clinical Practice), applied mainly in Europe, the USA and Japan.

The pharmaceutical component (SINGH, 2015) of research (medicines, vaccines, serums, reagents) was regulated and a set of important rules was established regarding all the virtual and specific procedures of laboratory research practice. The European Parliament issued the above-mentioned Directive 2001/20/EC regarding "the implementation of good clinical practice" for the research which refers to testing pharmaceutical products aimed at human usage. Subsequently, the 2005/28/EC directive will insert the detailed principles and guides of GCPs in the research of substances and of the authorization conditions for the production, distribution, sale or import of these products.

The Ethics Committees analyse and grant the approval for every study. These approvals are obtained before the beginning of the actual research activities, and monitoring is carried out throughout their development. These tests will not influence human integrity. The research holder must fully assume the factual responsibility for maintaining the well-being of the subjects and the research review activities and the adopted code of conduct will ensure and guarantee rigorously, in stages, all the necessary protection measures.

Research on underage subjects and in the case of those who are mentally ill is performed after all the compulsory tests on valid people are performed or if they cannot be performed on adults and aim at acquiring data and information relevant to the health of children or people with disabilities. The study is carried out strictly in compliance with their decision and the written consent of the parent (legal representative).

Studies concerning women of reproductive age or those who are pregnant represent priorities generated by the necessary therapeutic specificity. Their inclusion in the study samples is made with much discernment, through volunteering, usually on the basis of a thorough analysis in order to avoid any possible legal dysfunctions (protective norms, customs), religious ones (confessional prohibitions) and especially those of a medical nature (contraceptive methods, risks to the fetus).

In order to ensure the adequate documentary protection, the clinical trials will take place in compliance with all the existing laws and regulations. The beneficiary of the research will uphold all the unanimously accepted ethical principles, such as: The Nuremberg Code, The Belmont Report, The Declaration of Helsinki, whose latest version includes the amendments adopted in Washington (2002, CIOMS).

They will be associated with the explanations issued by "The Council for International Organisations of Medical Sciences," which established "The International Ethical Guidelines for Biomedical Research Involving Human Subjects", respectively "The Ethical guidelines for biomedical research involving human subjects" - CIOMS and "The International Conference on Harmonization Good Clinical Practice" - ICHGCP, "The Guidelines for the International Conference on the Harmonization of Good Clinical Practice", adopted in "… the interest and well-being of the human being which has to prevail over the unique interest of the society and of science."

The informed consent during pandemic gains new valences, representing the decision of a person to benefit from a certain therapy or to participate in a test after he or she receives all the necessary information, understands and analyses them and agrees in this regard "without being subjected to coercion, influence, induction or intimidation" (CIOMS, 2001). The individual's capacity to make a free and explicit decision defines the voluntary decision.

The main forms of consent vitiation in the current practice are coercion and manipulation, with all their known specific or particular forms. Consent can be materialized in a standardized form, including the subject's right to unconditionally withdraw at any time, in the event of adverse, unpredictable or little prior encountered events. The regulation in its essence must be understood as an effective freedom, and the consent given to carry out an intervention

can change over time and cannot be later used later against that particular person.

Consent represents an essential requirement in any therapy. The expressing of consent for a medical intervention has to fully fulfill all the criteria included in the norms which cover all the medical acts and especially the interventions which take place with the purpose of prevention, diagnosis, treatment and rehabilitation.

Rewarding participants can take many forms, starting with the payment of transport costs, expenses for food and clothing, free medicines and medical services, the payment of time for research, but without exceeding certain levels that determine interest for these reasons. The amount of payments is a distinct activity that is designed, endorsed motivated and nominally approved by the ethics committee.

The legal and medical lack of competence refers to people who do not understand the information due to a lack of capacity, who do not express their will, respectively all people uncapable of making a coherent decision and of explaining it.

The American National Bioethics Advisory Commission drafted the competency standards for the mentally ill, which differ according to their level of involvement, understanding and participation. In the case of severe limitation of the understanding capacity through the lack of maturity (newly born, children), or of mental disability some special determination measures will be used.

Assessing risks and benefits. The results expected from the documentary phase of the study have to trace the well-being of the society, a benefit which is impossible to obtain through other means and which cannot be random. Research has to include the definition of the risks in the forms allowed by the configuration of the study, according to the degree of difficulty and of novelty. No experiment should take place if it is susceptible of serious major consequences, such as death, illness or disability, and therefore the risk should not exceed the daily significance of the matter in study. The procedures with the purpose of diagnosis, either therapeutic or preventive, applied on the subjects have to rich at least the confirmed parameters with the standard procedures used in practice. The gradual increase of the risks should not exceed the known or anticipated permissive values. Risk assessment aims at quantifying probabilities, including the measure of the evil that may appear, in comparison with the dimensions of the anticipated benefits. The quantifiable result of the medical benefit has to substantially be larger than the rum of the existing risks.

Quantifying the beneficence represents an obligation which belongs to the fundamental goals of research; it refers to all favourable situations, in relationship to the risks involved and to those in which the presumed benefice has to be abandoned due to the level which became unacceptable. Basically, bio-human research has to be differentiated completely from the known medical practice (individual therapy) and this one from that of public (community) health.

The publishing and valuing of results is done by respecting the correctness rigors and those belonging to unethical research are forbidden and sanctioned. Regardless of the nature of obtained results in relationship to those expected, the assessment of the research's conclusions represents the object of a detailed analysis activity, followed by presentations, articles published in specialised journals or other specialized papers.

At the end of the research, every participant has to be offered full access to the most efficient measures of prophylaxis, diagnosis or treatment which were confirmed during the research (The World Medical Association, 2002).

6. RESTRICTIONS AND CONTROL NORMS IN THE SCIENTIFIC RESEARCH ETHICS

At the institutional level, the need to have an ethical control in research was supported by "The ad-hoc committee of experts bioethics", which later become "The bioethics steering committee" (CDBI). Following the activity which took place, the following committees appeared: "The European Convention for the Protection of Human Rights and Dignity of the Human Being Against the Applications of Biology and Medicine", Oviedo-1997, the additional protocol to the "Convention on the Prohibition of the Cloning of Human Beings", Paris-1998, "The

Additional Protocol to the Convention on Transplantation of Organs and Tissues of Human Origin", Strasbourg-2002, "The Universal Declaration on the Human Genome and Human Rights", UNESCO-1997, "The Universal Declaration on Bioethics and Human Rights", UNESCO-2005, and others.

The protection norms for the rights of the people involved in the biomedical research are concentrically developed, present a general declaration or convention and are followed by a radial system, based on rules, principles and additional protocols, referring to the aspects presented.

The national and European protection system distinguishes between the substantive rules contained in the "Conventions" and the "Protocols," the need to create an appropriate structural system and the need to train a group of specialists compatible with the future imperatives.

The Genetic Technologies are subscribed to the effects of "The Convention on Human Rights and Biomedicine" developed by the European Council and later on completed with "The forbiddance of human cloning" and "The Additional Protocol on Biomedical Research." The EU Parliament adopted the associated resolution respectively "The Convention in the interest of Biotechnology and Genetics" through which the unity of the European protection system of the human being is ensured. In this normative planetary and continental complex, the use of vaccines from the messenger RNA range becomes dangerous, with insufficient testing on human subjects regarding possible medium- and long-term negative effects.

The ethical and legal specialized literature distinguishes the traditional theory in which the human being has rights and obligations from birth to death from the extended liberal conception which states that the rights are acquired by the human embryo and belong even to the deceased person. In this reference space, for actual causes, "The European Convention on Human Rights" decided to institute some control norms specific to the granting of corresponding rights, but through a firm regulation of the person's consent.

Responsible medical communication and research have to combine professional and scientific qualities with those of an ethical nature. One has to be very well trained so that every medical act, every procedure is performed with the highest moral and professional probity. The practice of medical research represents an art based on science and in order to be perfect it has to stem from the respect for life and for human essence. Although medical science and technique have very much evolved during recent times, human spirituality remained pretty much the same, as well as human suffering which has also not changed to much (LUCHIAN, 2008).

European conventions succeed in judiciously combining legal norms with ethical considerations and scientific discoveries, while combining the responsibilities of the lawyer, the governor, the scientist and the doctor in order to produce appropriate solutions to the problems they face and will continue to face, the individual, society and, in general, humanity. Society members must accept responsibility, including the risks of honest participation in promoting common health, justified by the specificity of human body fragility, emotional and genetic interrelationships, lack of an appropriate alternative and unanimity in the desire to benefit from medical knowledge, all contributing to the creation of this "duty of participation", conceived as a universal value by Rosamond Rhodes.

The informed consent will be mandatory, strictly voluntary, obtained only in the absence of coercion or illegal influences. The absence of coercion implies the exclusion of any form of threat, conditioning or reward or of any means and forms of adjuvant. Any abuse of authoritarian, political-administrative, professional or restrictive positions in any form of individual rights and freedoms by the application or suggestion of actual or potential sanctions must be excluded[12].

The obligation to apply any individual or mass therapy annuls human freedom.

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