Informed consent in rheumatology care practice

José Marques Filho[1]

ABSTRACT

Informed consent is a mandatory document in human subject research protocols. Its principles have been recently established in the history of Medicine, and the first official document to establish the need for an informed consent from the research subject was the Nuremberg Code (1947). All following documents confirmed that the informed consent is mandatory in human subject research. However, the informed consent, which represents patients' autonomy or self-determination regarding their relationship with their physicians, took a while to be included in medical care practice and medical deontology codes. The convenience of using the informed consent in medical practice is widely discussed today, especially in rheumatology. Our opinion is that the obligation of a signed informed consent provided by the patient for every medical procedure is neither reasonable nor practical. It should be used for more invasive or risky therapeutic procedures. We understand that the informed consent does not guarantee that the patient has been fully informed, which is an essential condition for the current rheumatological practice. Its adoption in routine medical care practice would make medical intervention bureaucratic, and, thus, quite different from the Hippocratic view, which considered the trustful physician-patient relationship fundamental for an adequate medical care practice.

Keywords: informed consent, bioethics, rheumatology.

[Rev Bras Reumatol 2011;51(2):175-183]

INTRODUCTION

Human subject research has been performed throughout the secular history of Medicine with varying degrees of ethics. However, from the formal point of view, it was only after World War II (1939-1945), through the Nuremberg Code, that the formal informed consent of the research subject became mandatory for participating in any biomedical research involving human subjects.[1] This has only occurred because of the abuses against mankind perpetrated in the concentration camps by Nazi physicians, who were triald and convicted at the city of Nuremberg.

All international documents and declarations referring to human subject research, including the important Helsinki Declaration of 1964[1] and, in Brazil, the CNS 196/96 resolution,[2] confirmed that the informed consent is mandatory in human subject research protocols.

Informed consent is the practical expression of respect to the individual's autonomy, and it seems unbelievable that such an elementary right began to be discussed and normalized only in the 1940's. It took even longer for that bioethical milestone to be incorporated into medical practice and ethics codes, and, still nowadays many professionals continue to practice medicine with strong paternalistic characteristics.

Over the past years, the need for and convenience of the formal implantation of the written informed consent in daily practice medical procedures, regarding both diagnostic and therapeutic procedures, have been discussed.

Rheumatology is one of the most recent medical specialties in the history of Medicine acting within two well-defined fields: basic research/clinical trials and care practice.

Regarding research and clinical trials, its rapid evolution, both quantitative and qualitative, is evident, mostly due to the extraordinary advance of knowledge in the area of autoimmunity and the discovery of new drugs. Care practice is a field of Medicine with mostly clinical characteristics, in which the physician-patient relationship acquires particular and fundamental importance.

Because of those characteristics, ethical dilemmas, as in other areas of medical activity, are increasingly common in rheumatologic research and care practice, requiring the rheumatologist to be up-to-date with bioethical reflections and discussions aiming at maintaining a safe, up-to-date, ethical, and, thus, more effective medical practice.

Submitted on 10/27/2010. Approved on 01/16/2011. The author declares no conflict of interest.
Conselho Regional de Medicina do Estado de São Paulo; Centro Universitário São Camilo, SP, Brazil.
1. MSc in Bioethics; Specialist in Rheumatology; Specialist in Internal Medicine; PhD candidate in Bioethics
Correspondence to: José Marques Filho. Rua Silva Jardim, 345, Centro. Araçatuba, São Paulo, Brazil. Zip Code: 16010-340. E-mail: filho.jm@bol.com.br.

CONCEPT OF AUTONOMY AND PATERNALISM

Autonomy is a term derived from the Greek words *autos* (self) and *nomos* (law, rule). It means self-government or self-determination to take decisions that affect one's life, health, integrity, and social relations.

The autonomous subject has freedom of thought. For the existence of an autonomous action, the existence of alternative actions is also necessary. In addition to freedom of choice, the autonomous act assumes freedom of action, the subject can act according to his choices and decisions.

Diego Gracia[3] has pointed out that the principle of autonomy is clearly associated with the consolidation of human rights, mainly due to the philosophical conceptions of Locke, Spinoza, and Kant in the seventeenth and eighteenth centuries. During that period, the basic human rights were established: right to integrity, to liberty, and to property. All human beings are entitled to those rights, which, thus, do not depend on legislation.

The respect to others is based on Kant's philosophy,[4] which states "every man is an end in himself, not the means to the end of others".

It is worth noting that it was only in 1947 that the principle of autonomy was first formalized in a document in the Nuremberg Code, which established basic rules of human subject research, foreseeing the mandatory nature of the voluntary (and autonomous) consent to participate in biomedical research.[1] However, some years were required for the principle of autonomy to be incorporated into medical practice and included in the codes of medical ethics.

On daily practice, one can state that autonomy and paternalism are complementary in the physician-patient relationship, and, thus, neither total autonomy nor absolute paternalism can exist. Therefore, the more symmetrical that relationship, the greater the degree of autonomy, and, the more asymmetrical that relationship, the more evident is paternalism; in practice, that relationship behaves as a pendulum.[5]

According to Hossne,[6] the principle of autonomy was one of the most important bioethical achievements of the century and triggered the appearance of new conflicts in the physician-patient relationship, which should be faced and reflected by both agents of that special relationship.

For the Greek thinkers, the nature of all things – *physis* – could be understood by use of observation and reason – *logus*. In Medicine, the nature of diseases could also be understood by the same process, known as technique, in Greek – *teknê* –, which, in the case of Medicine, would be *teknê iatrikê*, that is, the medical technique (or, in Latin, *ars medica*). That technique could be learned and taught. Physicians, capable of mastering the technique and art, acquire great power, and can, thus, set the rules for the patients' life and treatment.

According to Diego Gracia,[3] the physician-patient relationship of that time is comparable to that between the Greek ruler and citizens, in which, according to Plato's *The Republic*, the ruler (a philosopher), knowing what is best for the people, should have absolute power, and the citizen should obey the ruler's orders without questioning. Likewise, the physician, by mastering the medical technique and art, should give orders and the patient should comply obediently. This is the perfect definition of the physician's paternalism, an attitude that dictated his behavior throughout most of the history of Medicine, and that was first challenged only in the mid-twentieth century.

The characteristic paternalism of the medical profession, according to which the physician holds knowledge and knows more about the patient than the patient himself, originates from the notion that the infirm is "*infimus*", lacks firmness, and does not have the formal knowledge held by the physician.

According to the philosopher Franklin Leopold,[7] paternalism results from the asymmetric character of the physician-patient relationship, characterized by patient's frailty and physician's strength. In this disproportional relationship, the care provided nullifies the subject, objectifying him, and knowledge inconspicuously changes into power, yielding deplorable consequences, as the subject is deprived of his singular individuality.

VULNERABILITY

Philosophy has considered vulnerability as an essential anthropological dimension of human existence. To be vulnerable means to be susceptible to damage. To be alive is a biological improbability, highly vulnerable to perturbations and death, and, thus, vulnerability is a condition intrinsic to human life.[8] In addition to this intrinsic vulnerability, some individuals are affected by several unfavorable circumstances, which make them even more vulnerable.

Severe diseases jeopardize the integrity of the human subject. According to Drane and Pessini,[9] "disease is the enemy of action, liberty, and self-determination", and, "in severe disease, one suffers a wide damage, accompanied by the devastating loss of the power to remediate the damage suffered".

If choice, initiative, decision making, and responsibility are influenced by the patient's illness, the physician should promote and stimulate the patient's participation in diagnostic

and therapeutic decisions, and stimulate the patient's self-determination.

All those limitations are more marked in chronic, symptomatic and progressing illnesses, and characterize the vulnerable state of the sick person.

One of the major characteristics of rheumatological diseases is chronicity, and many of them, in addition to causing pain, limit, in varied degrees, the patients' daily activities.

WRITTEN INFORMED CONSENT

There are several denominations to refer to the informed consent, such as "awareness and consent", "post-information consent", "written informed consent", which are aimed at demonstrating that the patient is properly informed and agrees with the procedure proposed by his physician or multiprofessional team. That consent can be either informal or formal. The former should always be registered in the medical record by the assistant doctor, while the latter constitutes a legal instrument denominated in most Brazilian texts *Termo de Consentimento Livre e Esclarecido* (written informed consent).

In a recently published article, Hirschleimer *et al*.[10] have defined the informed consent as follows: "it is the register in the medical record of the patient's, or his legal guardian's, decision, taken after being informed, authorizing a specific medical treatment or procedure, being aware of its risks, benefits, and possible consequences. The informed consent should document that the patient was informed about the existing treatment options".

For Hewlett,[11] the consent is morally accepted only when based on the following four elements: information, competence, understanding, and willingness. Information is the basis of the patient's autonomous decisions. It is, however, not sufficient. Proper explanation is fundamental to the patient's consent or refusal of the proposed measures or procedures. Thus, the explanation has to be adapted to the patient's cultural, social and psychological circumstances. Technical and scientific terms should not be used. On the contrary, the information should be simple, approximated, intelligible, and provided within patterns accessible to the patient's intellectual and cultural level.

The right to informed consent obliges us to inform the patient about everything that may be relevant in his process of decision making. The difficulty lies in defining which information is relevant, which, obviously, varies with the clinical situation and each patient. One solution would be to inform the patient about everything he considers necessary to make his own decision.

On the other hand, it is always worth emphasizing that there is a great conceptual difference between the informed consent and the formal informed consent, signed by both the physician and the patient. While the former has an ethical and deontological character of respect to the patient's autonomy, the later has a more legal, although also ethical, character, and is formalized between the parties of a professional relationship.

LEGISLATION

The guidelines relating to the obligation of the formal informed consent in human subject research are very well defined in national and international codes, declarations, and decrees. Historically the initial milestone was the Nuremberg Code (1947), confirmed by all later documents, such as the Helsinki Declaration (1964) and all its versions, the Belmont Report (1979), the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Brazilian translation in 1993), and, in Brazil, the CNS 196/96 Resolution (*Resolução* CNS 196/96).[1] However, legislation stating that the formal informed consent is mandatory in medical care practice is more recent and still relatively conspicuous.

Spain is one of the few countries that passed a law determining that formal informed consent is mandatory in medical care practice. The 41/2002 Law determines that formal informed consent is mandatory in surgical procedures and invasive exams.[12]

In Brazil, the Federal and Regional Councils of Medicine lack resolutions normalizing the formal informed consent; however, in official opinions, they admit that the use of the formal informed consent is ethical and legal and can be applied to medical care routine.

The only Brazilian rules determining that formal informed consent is mandatory in medical care practice are as follows: the SAS/MS 865/2002 decree, which determines that formal informed consent is mandatory for dispensing special drugs for the treatment of rheumatoid arthritis; and the later decrees, which regulate dispensing of special drugs for the treatment of other rheumatological diseases.[13]

It is worth noting that formal informed consent has been contemplated in the Brazilian legislation since the 1988 Code of Medical Ethics, as well as in the civil code and state laws of some Brazilian states.[14]

FINAL CONSIDERATIONS

Throughout the history of Medicine, the physician-patient relationship has occurred in an asymmetrical and monotonous

form, following the Hippocratic assumptions, according to which the physician is obligated to benefit his patient, protecting him to the fullest extent, even against truth and hard reality, in a way similar to that of a father-son relationship, in the old model known as paternalism.

The great transformation occurred approximately six decades ago, with the recognition of the patient's autonomy and the progressive passage from a purely paternalistic relationship to a decision-sharing relationship, during which the physician-patient relationship became more symmetrical. Thus, the patient's consent to diagnostic and therapeutic procedures has become the maximum expression of respect to his autonomy.

The specialized literature has shown that there are basically two views concerning the formal informed consent in medical care practice. The first, a more legal view, follows a model known as defensive medicine, in which the authors emphasize the importance of the document signed by the patient, whose major objective is to serve as evidence should a legal or ethical dispute happen.[15] The second, with more consistent arguments based on published texts, is a philosophical and practical view, based on bioethical milestones. According to that view, the patient's consent is seen as a continuing process in the physician-patient relationship, with information and explanations that aim mainly at protecting and stimulating the patient's self-determination in respect to the ill subject's dignity.[16-19]

It is worth noting that this is also the view of Beauchamp and Childress, in their classic book *Principles of Biomedical Ethics*:[20] "It is essential that the informed consent be understood as a process over time, avoiding the common view that the signed consent form is the essence of the consent".

Recent studies[21,22] have shown that the jurisprudence of the Brazilian Court recognizes the physician's duty to inform the patient. The information can be registered in a formal term or in the medical record, a document recognized as fundamental for formalizing the medical acts communicated to patients and well described when accomplished. Based on those studies, one can say that the formal informed consent is not required, but informing the patient is mandatory.

Finally, agreeing with Moura Junior:[23] "What improves the physician-patient relationship? Humanized care, marked by good personal relationship and dedication of required time and attention. To know how to listen to the patient, clarify his doubts, understand his expectations, and explain in a simple and objective way the diagnosis, treatment, benefits and possible complications, in addition to prognosis. To let the patient choose whenever there is more than one alternative. To be constantly up-to-date, and to be aware of the limits of Medicine. To tell the truth in face of the lack of a certain treatment or its low efficacy."

Finally, we think that the formal informed consent should be understood as an ethical and legal requirement in the current medical care practice. It is neither reasonable nor necessary to obtain the patient's signature for each and every medical procedure. The literature has shown that there is no guarantee that that practice prevents future legal disputes. In addition, it can create an atmosphere of suspicion of the professional attitude, which is absolutely inadequate in the therapeutic relationship between physicians and their patients.

Accepting that the formal informed consent is mandatory in all rheumatological procedures can lead to bureaucratization of the physician-patient relationship, which, being one of the pillars of medical practice, is mainly characterized by trust and mutual respect.