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ETHICS IN RESEARCH AND CLINICAL PRACTICE: A COMPLEX PAIRING

ÉTICA EN LA INVESTIGACIÓN Y LA PRÁCTICA CLÍNICA: UN BINOMIO COMPLEJO

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REVIEW ARTICLE

ABSTRACT

Health research is vital for the advancement of science and development in a country. However, researching with ethics in daily clinical practice is a slow process. Several factors play a critical role at the beginning of any investigation: the workplace, the right time, the resources with which it is counted, the number of study subjects that could be involved and even the socio familiar environment of the researcher. All these factors are directly or indirectly related to ethical problems between the doctor researcher and the patient or research subject; even more in countries like Peru, where the low educational level of the population increases a certain position of power of the doctor. Likewise, the appearance of new areas in Medicine such as palliative care, assisted human reproduction, gene therapy and tissue engineering make this pairing even more complex.

Key words: Medical research; Bioethics; Physician patient relationship. (source: MeSH NLM)

RESUMEN

La investigación en salud es vital para el avance de la ciencia y el desarrollo de un país. Sin embargo, investigar con ética en la práctica clínica diaria es un proceso lento. Diversos factores juegan un rol crítico al inicio de cualquier investigación: el centro laboral, el momento adecuado, los recursos con los que se cuenta, la cantidad de sujetos de estudio que se podría involucrar y hasta el entorno sociofamiliar propicio del investigador. Todos estos factores están relacionados de forma directa o indirecta con problemas éticos entre el médico investigador y el paciente o sujeto de investigación; más aún en países como el Perú, donde el bajo nivel educativo de la población acrecienta cierta postura de poder del médico. Asimismo, la aparición de nuevas áreas en la Medicina como los cuidados paliativos, la reproducción humana asistida, la terapia genética y la ingeniería de tejidos hacen aún más complejo este binomio.

Palabras clave: Investigación médica; Bioética; Relación médico paciente. (fuente: DeCS BIREME)

INTRODUCTION

AAlthough many people think that any time in the past was better, in general, life has become simpler over time. At the moment you don't wait days to receive a letter because you have instant messaging, you don't need to go to a library to get information because almost everything is on the Internet. This connectivity in the world is undoubtedly due to the development of science and technology. However, all that scientific-technological development was achieved through many years of research.

According to the World Health Organization, research can improve health and life quality of individuals and populations[1]. Research in recent decades has really been a breakthrough in the field of health, so it is, that the life expectancy of Peruvians in 1998 was around 68 years and twenty years later it was increased to 75 years[2]. This increase is due to the development of new diagnostic tests and treatments, as well as the identification of multiple risk factors for disease necessary to develop prevention approaches and

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improve the quality of life of the population. So health research encompasses theoretical justification but also practical importance.

There are two valid approaches to health research: quantitative and qualitative. The first allows the measurement and control of certain variables in order to generalize the results obtained, with the possibility of repetition and comparison between similar studies. The second provides details about the data, illustrates the environment, and offers a more flexible view. Although in Medicine the quantitative approach prevails, the qualitative does not cease to be part of our daily life. The doctor-patient relationship is based not only on objective issues such as laboratory tests and imaging tests, but also on very subjective issues such as clinical interviews. It is on this path that Medicine opens up endless opportunities for research through both approaches that end up being complementary. For example, when we study the determinants of the quality of life of terminal patients, we find quantitative, but also qualitative, questions. And it is these subjective facts that generate this ethical dilemma that leads us to the question, how far can we investigate with human beings?

Today, the age of evidence-based medicine leads to providing the best possible treatment for patients. However, when one is faced with difficult-to-handle pathologies such as advanced-stage neoplasms or orphan rare diseases or disorders refractory to medical treatment; serious ethical mistakes can be made in the pursuit of appropriate therapy, many of which could be covered up under the name of research.

DOCTOR-PATIENT RELATIONSHIP

The relationship of a doctor-researcher to a research subject remains essentially a doctor-patient relationship. Some authors have described the power in favor of the doctor in the doctor-patient relationship[3,4], a common panorama in underdeveloped or developing countries such as Peru, where the low educational level of the population increases a certain position of power of the physician and relegates even more the patient's own decisions. Added to this is the emergence of new areas in medicine such as palliative care, assisted human reproduction, gene therapy and tissue engineering, which makes this relationship even more complex.

Over the years, scientific rigor in the world affected not only the researcher but also the research subjects. This can be seen in the doctor-patient relationship, that paternalistic relationship of yesteryear where the doctor decided on the future of the health of the individual turned a few decades back towards a medicine based on the autonomy of the patient who currently demands to know everything related to his health[5]. This last type of doctor-patient relationship, it is undoubtedly the result of ethics in time, which is based on the universal principles described in the Belmont Report of 1978: autonomy, charity, non-maleficence and justice[6]. Autonomy is based on the right to freedom of the person; it is important to highlight as an autonomous person that individual with the capacity to discern about his personal interests and to act accordingly[7]. Charity guarantees well-being and frames all acts of goodness potentially derived from research[8]. Non-maleficence explains that it is necessary to avoid any kind of physical or psychological, economic or moral damage to the research subjects. In this sense, there would be maleficence in some research when the experiment contemplates a greater risk in comparison to the benefit that the research subject may receive[9]. Justice establishes an equitative distribution of the charges and benefits of research among all individuals involved in the problem being investigated. Therefore, a fair selection of those involved in research should be ensured[10]. These four universal principles must be taken into account in the development of all health research and must be reflected in a document: informed consent. This document is extremely necessary for both researchers and research subjects, as it ensures respect for the research subjects involved.

INFORMED CONSENT

Although it is clear that clinical trials are an essential research design to improve medical treatments; before initiating any, researchers have the obligation, legal and ethical, to obtain the informed consent of research subjects[11].

The outline of informed consent in the health field was born around 1900, when Dr Walter Reed produced a document that included risks and payments related to participation in a study on yellow fever. And although this text was rather drafted as a contract, it is considered a precursor to modern informed consent[12]. With the advent of the Nuremberg Code in 1947, the obligation to seek informed consent was explicitly raised, as was the freedom of the participant to terminate any experiment[13].

The American College of Physicians defines informed consent as the explanation to an attentive and mentally competent patient of the nature of his illness, as well as

the balance of its effects and the risk of recommended diagnostic and therapeutic procedures, and then ask for his approval to be submitted to these procedures. It also adds: the presentation of the information must be understandable and unbiased (…), the patient's collaboration must be achieved without coercion and (…) the physician must not take advantage of his potential psychological dominance over the patient[14]. Thus, informed consent should rather be understood as a gradual and continuous process between the research subject and the researcher, which begins with the fulfillment of the right to information, it continues with the autonomy of the patient who must decide whether to accept or reject their participation in the research and culminates with the proper filling of document[15]. Both researchers and research subjects are the protagonists in this process. However, the application of informed consent in clinical practice is notoriously difficult as noted in international literature[16].

At the time of informed consent, there are two useful perspectives: the doctor's and the patient's one. The first allows to include all information that the doctor considers important and that must be presented to a reasonable patient for informed consent. The second-most used, by the way-uses all the information a reasonable patient would want and need to know to make an informed choice. Indeed, there is great confusion about how much information should be summarized in informed consent and how to do so.

On the other hand, there are three learning styles that should be considered in the informed consent process. There are research subjects who understand and learn better visually, they would like to see an image or a photograph or some demonstrative example of what is proposed. Others understand and learn better auditively, they would prefer to listen very carefully to pre- and post-operative recommendations or instructions or alternatives to care and the risks and complications inherent in any procedure or treatment. And finally there are others who are kinesthetic apprentices who rather seek to relate how this whole process affects them personally. Thus, as the objective of informed consent is to obtain a high level of understanding, this can be achieved by combining the three learning styles throughout the informed consent process[17].

NEW FIELDS OF MEDICINE

Health research is of great social interest as it generates development and life quality for people. In recent years, new areas of medicine have attracted the attention of society, as they offer a potential beneficial alternative to conventional treatments. However, ethical dilemmas in research increase with the development of science and polarize the scientific and non-scientific community on issues such as: assisted human reproduction and the beginning of life, palliative care and end-of-life care, gene therapy and possible changes in the natural selection of the species, in vitro management of biological products of human origin and their marketing, tissue engineering for possible organ transplants, among other problems; They raise different views in favour of those who believe that alleviating the pain or symptoms of an illness justifies it and other views that believe it is appropriate to respect the limits of nature. Many ethical aspects had yet to be clarified, and the debate would continue in Peru until clear rules were established.

CONCLUSION

The ultimate purpose of medical research is the production of new knowledge for decision-making. This new scientific knowledge is the result of an ordered process that includes theory, method and technique. Therefore, it requires a lot of responsibility and ethics on the part of the researcher or the research group, since its results have a direct or indirect impact on population life. The important thing before starting an investigation is to keep in mind that any clinical experiment must be subject to ethical principles and within the legal framework, in order to prevent potential risks. The fundamental rights of research subjects, such as the right to life, physical integrity and humane treatment, cannot be tacitly and under any circumstances violated. In addition, research must meet minimum requirements such as the fact that there is no alternative method that is effectively comparable to the experiment, that the benefits outweigh the potential risks, the research subject is informed of his rights and that the same subject has freely given his consent with the open possibility of withdrawing from the research at any time.

In short, ethics in the framework of the binomial medical research and clinical practice is a constant challenge due to the multiple factors that affect its purposes, the characteristics of the population to study, the socio-cultural norms and even the skills of researchers. However, respect for the patient and commitment to scientific truth should provide the necessary balance to achieve this objective.

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