

Letter to the Editor

The National Ethics Committee: a truly valuable asset for clinical trials?

Dear Editor,

Advances in biomedicine, increased patient autonomy, and higher average life expectancy, have contributed to raising a multitude of questions relating to Clinical Ethics. Though these aspects stand on their own, national or community-level legislation that is unable to meet Ethical demands, or satisfies them only partially, it will never be able to satisfy aims and interests of a rapidly changing society. The Ethical protection of the individual in the context of life and health has been entrusted to independent, impartial bodies: Territorial Ethics Committees. In 2015, Minacori et al¹ posed the following question: Research Ethics Committees and clinical research in Italy: where are we going? After analyzing the Italian legislation regulating Ethics Committees and their practices, the authors noted that though the November 2012 Law had harmonized Territorial Ethical Committee activities at a national level, it neglected to address certain critical points such as the differing deadlines by which the Committees were required to present their opinions, and the drastic reduction of the Committees themselves which had, in fact, hampered their activity. What's more, problems arose from the need for Committee members to receive specific training² and delays in presenting opinions in research institutes extraneous to those in which the Ethical issue had originally arisen. These factors are clearly of critical importance, and EU Regulation 536/2014 was intended to make amendments to many of these weaknesses³. The objective of the EU Regulation can be appreciated in its intent to streamline procedures and impose clear deadlines on clinical trials for drugs; in this sense, the fact that it centralizes authorization procedures for clinical trials and administration through the EU portal could, hypothetically, significantly speed up Ethical review procedures. In case of scientific reviews, Member States that wish to issue a report, which can be shared at EU level, are expected to work together, while Ethical reviews are exclusively the responsibility of each Member State. A current, though possibly distorted understanding of community legislation, has brought about a commonly held belief that legal intervention might be used to close down the Territorial Committees and replace them with a single body, the National Ethics Committee. The ongoing reorganization of the network of Ethical Committees is aimed at making changes to clinical trials of medicine for human use by introducing a specific reference to gender medicine. Many guiding principles and criteria will be taken into consideration: identifying the requisites of centers authorized to conduct the various stages of clinical trials; identifying ways to support the activation and optimization of clinics dedicated to performing Phase I trials with a gender-sensitive approach; simplifying formal requirements, periodic training of the medical personnel involved in the trials; revising the sanction system; reviewing legislation pertaining to non-profit trials and observational studies. The establishment of an Ethics Committee within AIFA (the Italian Medicines Agency) is also proposed. This should be composed of fifteen members who are clinical trials experts, and at least two members should also belong to patient organizations, with the aim of coordinating, orienting, and monitoring the evaluation of Ethical aspects relating to clinical trials of medicines for human use, now delegated to the Territorial Ethics Committees. For instances, when the Territorial Committee is repeatedly ineffectual, this organization can appeal to the Ministry of Health for its suppression. A further reduction of Territorial Ethics Committees is also expected; up to one per region or autonomous province, and up to five interregional committees for Scientific Institutes for Research, Hospitalization and Health Care. In those regions with a resident population over three million, a further Ethics Committee can be identified. These possibilities, however, are causing considerable confusion, not least in the political sphere. Criticisms include doubts on the fact that a restricted number of people

can guarantee that they are able to satisfy all the demands posed by such varied and complex areas of research, and the institution of yet another national body is seen as nothing but a “useless administrative burden”. Taking into account these considerations, some of the most eminent Italian bioethicists have drafted a document on the protection of human subjects in clinical research, the “Carta di Napoli per la Tutela della Persona nelle Sperimentazioni Cliniche”⁴. More specifically, regarding the proposal to form a National Ethics Committee, the document stresses the fact that the activities of the Ethics Committee must always be geared towards the protection of all human subjects participating in a trial. However, as this organization has to express opinions on ethical, scientific and practical aspects relating to clinical trials performed by research structures and hospital facilities at national level, it would simply be unable to carry out its function as guarantor of the safety of our fundamental rights. In the light of these considerations, it must also be said that some ethical issues cannot be studied without taking into account their social context. Though the requirements linked to reviewing experimental protocols are likely to take up most of the Ethics Committees’ resources, the need for Ethical answers in the clinical context is one that is most keenly felt in the country. Furthermore, the average patient has no real idea of the importance of a clinical trial until he or she has to face a serious health problem. Among the demands raised by clinical Ethics, the Ethics of medical consultation, which is increasingly geared towards a therapeutic alliance between patient and physician, are crucial⁵, as are the ways in which healthcare workers put the ethos of their institute into practice⁶. These issues should only be dealt by the Territorial Ethics Committee, which is based in the area in which the Ethical issue originally arose, and not by a National Ethics Committee. In other words, the risks associated with centralized thinking should be avoided, even more in clinical research, with the understanding that listening to more than one opinion can ultimately be seen as a resource and not a source of confusion. It must not be forgotten that the clinical field is still developing and possesses unique characteristics, combining many diverse factors: performing an Ethical evaluation on a real-life case will not be possible unless different professional figures collaborate in the full respect of the defining limitations and characteristics of their field of expertise⁷. A fundamental line of conduct should serve to protect the dignity and fundamental rights of those people who participate in clinical trials without forgetting the demands imposed by clinical Ethics, strengthening and not making light of or ignoring the professional skills shown by the Territorial Committees.

Conflict of interest

The authors declare no conflicts of interest.

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