

COMMENTARY

Clinical ethics and the role of clinical ethics committees: proposals for a revival

Carlo Petrini¹ and Walter Ricciardi²

¹Bioethics Unit, Office of the President, Istituto Superiore di Sanità, Rome, Italy

²President, Istituto Superiore di Sanità, Rome, Italy

Abstract

The issue addressed in the paper published by the Italian National Bioethics Committee (NBC) entitled “Clinical ethics committees”, is highly significant for many reasons. One of these is the fact that the ethics committees charged with assessing clinical trials have so much responsibility and such a heavy work-load that they have little time available for other tasks such as engaging directly with patients “at the bedside”, as a result of which the role of committees responsible for assessing clinical cases is especially important. According to the NBC, the opinions of clinical ethics committees should be formulated jointly and are non-binding. The NBC offers practical proposals not only for the Italian context. While the Italian National Institute of Health (Istituto Superiore di Sanità – ISS) is not involved directly in treating patients, its role in providing guidance is crucial to the national health service and it has always paid special attention to these issues.

Key words

- bioethics
- clinical ethics
- ethics committees

On 31st March 2017 the Italian National Bioethics Committee (NBC) unanimously approved a document entitled “Clinical ethics committees” [1]¹. The issues related to such committees are of some importance on the Italian bio-political scene, as the question of how to provide guidance on clinical ethics “at the bedside” is still unresolved. This is due in particular to developments in legislation governing ethics committees in much of the European Union. In Italy, as in many other European nations, current legislation [2] governing the establishment, organisation and functioning of ethics committees assigns to these bodies a crucial role in the assessment and authorisation of trials of drugs and medical devices, a role that is further emphasised in Regulation 536/2014 of the European Parliament and the Council of Europe [3], which lays down precise and binding rules for the assessment and authorisation of clinical trials. The time devoted by these committees to assessing trials leaves them little time for other issues such as clinical ethics, in particular.

For this reason the document approved by the NBC focuses on committees dedicated specifically to issues of clinical ethics. It proposes minimum requisites con-

cerning their independence, the procedures for consultation, their structure, composition, tasks, location, coordination, responsibilities and regulation. The NBC argues that clinical ethics opinions should not relieve physicians of their responsibility and should be formed jointly, in other words not by an individual expert. This is not intended in any way to belittle the valuable role in bioethics of experts or of the ethical guidance services provided in some healthcare facilities. The decision to dedicate the document exclusively to clinical ethics committees does not imply a failure by the NBC to recognise the importance of such experts and guidance services in a healthcare setting [4]: in fact, the document cites examples from other countries, where such centres are known by varying names, including the particularly evocative term “clinical space” used in France. The NBC document does not devote too much space specifically to experts in bioethics or to clinical ethics centres solely because to do so would call for a separate document, which the Committee hopes to be able to produce in the future.

In reiterating the need for ethics opinions to be formed jointly, the NBC is adhering strictly, at a time of extremely delicate ethical decisions, to three basic principles of clinical bioethics: interdisciplinarity, pluralism and the physician/patient or healthcare team/patient relationship. The need to safeguard the physician/patient relationship is also one of the reasons why the NBC deems it essential that the opinions of clinical ethics

¹ The NBC Working Group that drew up the document was coordinated by Carlo Petrini, co-author of the present paper, and by Salvatore Amato and Cinzia Caporale.

committees should be considered as a guide and are not binding. Another requisite considered indispensable by the NBC is the independence of clinical ethics committees from the structures that establish them and from the institutions in which they operate.

The practical suggestions proposed by the NBC for the establishment and functioning of clinical ethics committees are particularly helpful. It is specifically recommended that the committees should include at least one of each of the following professional experts: clinical physician, bioethicist, nurse, jurist, health risk expert, patient representative, epidemiologist. The specialist areas that the NBC considers should be represented include, in particular: the foundations of ethics and moral theories; clinical medicine, with a special focus on the diseases treated in the specific facility; the socio-cultural background of patients, with the provision of specific forms of cultural mediation; ethical codes and documents relating to healthcare providers; elements of bio-law and healthcare regulations; national and international guidelines on issues of medical ethics; the organisation of health services. Members of these committees should not only have the appropriate training and experience, but should also have constantly attended refresher seminars.

Clinical ethics committees can provide a valuable contribution to the strengthening and improvement of relations between physicians and patients: the opinions

and guidance they offer can help to formulate helpful suggestions for solutions to the most challenging situations.

Although the Italian National Institute of Health (Istituto Superiore di Sanità – ISS) is not a treatment facility directly involved in the care of patients, its responsibilities include both clinical trials and clinical practice [5], so that the issue of clinical ethics committees is of considerable importance. Another reason these committees are accorded particular attention concerns their potential role in the interpretation and application of guidelines. The recent Italian legislation on the safety of treatment and the professional liability of healthcare providers [6] assigns both a key role in clinical practice to guidelines, and crucial responsibility for guidelines to the ISS. The latter publishes guidelines “after checking that the approved procedures meet the standards defined and made publicly available by the ISS and that the scientific proof offered in support of the recommendations is relevant”.

While the primary focus of the NBC document is on Italy, it also offers a broad overview of clinical ethics committees and refers to the experience of other nations. It is thus useful as a reference document beyond Italy for patients, physicians, healthcare professionals and facilities, patient associations, national and regional health safety bodies, community groups operating in the biomedical field, and legislators.

REFERENCES

1. Italian Bioethics Committee. Clinical ethics committees. 31 March 2017. http://bioetica.governo.it/media/172267/p127_2017_clinical-ethics-committees_en.pdf
2. Ministero della Salute. Decreto 8 febbraio 2013. Criteri per la composizione e il funzionamento dei comitati etici. *Gazzetta Ufficiale – Serie Generale* n. 96, 24 aprile 2013.
3. European Parliament and Council. Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. *Official Journal of the European Union* L 158, 27 May 2014.
4. Petrini C. Towards clinical bioethics (or return to clinical ethics?). *Clin Ter* 2013;64(6):e523-7.
5. Ministero della Salute. Decreto 24 ottobre 2014. Approvazione dello statuto dell'Istituto Superiore di Sanità, ai sensi dell'articolo 2 del Decreto Legislativo 28 giugno 2012, n. 106. *Gazzetta Ufficiale – Serie Generale* n. 268, 18 novembre 2014.
6. Italia. Legge 8 marzo 2017, n. 24. Disposizioni in materia di sicurezza delle cure e della persona assistita, nonché in materia di responsabilità professionale degli esercenti le professioni sanitarie. *Gazzetta Ufficiale – Serie Generale* n. 64, 17 marzo 2017.