

LETTER

Comments on

“Clinical ethics and the role of clinical ethics committees: proposal for a revival” by Petrini and Ricciardi

Dear Editor,

The very interesting Commentary “Clinical ethics and the role of clinical ethics committees: proposal for a revival” by Petrini and Ricciardi [1], must be commended for addressing the relevant issue of “clinical ethics”, the role of current and future ethics committees, and, in particular, for drawing attention to the CNB (Comitato Nazionale di Bioetica – Italian Bioethics Committee) influential document on the topic [2].

Still, considering the importance of the matter, we would like to add some further remarks. The first document defining the duties of ethics committees in Italy concerned only the assessment of clinical trials and biomedical research in general [3]. The legislator started considering ethical aspects, in addition to those involved in controlled clinical trials and biomedical research on human beings, only since the Ministerial Decree dated 12 May 2006, Article 1, paragraph 3 [4]. The same point was later reiterated with the Ministerial Decree dated 8 February 2013 [5].

Despite that, until now ethics committees are mostly engaged in the assessment of clinical trials and biomedical researches. This means that they can mostly consider those requirements that validate a research from a scientific point of view, contextualizing them in the ethical framework of bioethics’ evolution since the Belmont Report and the due observance of the principles of beneficence, autonomy, and justice [6], formally reasserted by the Helsinki Declaration [7] and the Oviedo Convention [8]. Such requisites mainly consists of: i) the relevance of the clinical question and the pertinence of primary and secondary outcomes to be recorded on an adequate target population; ii) the accordance with scientific methodology and, consequently, the appropriate clinical and statistical planning of the study; iii) the benefit/risk ratio for the human beings involved; iv) finally, the procedures of obtaining informed consent, not limited to the adequacy and completeness of the written text.

Current ethics committees also play an important role in the evaluation of “observational studies”. They must primarily ascertain the actual observational nature of the proposed studies, thus avoiding the enrollment of unaware subjects in an experimental study. Therefore, they must also guarantee the accordance of study procedures to “the usual standard of care”, in order to avoid additional burdens for the patient. Finally, issues of privacy and adequate information to subjects enrolled must be considered. This last point is sometimes quite problematic since, in non-interventional studies, the information could be often deemed non-essential and thus it is sometimes inaccurate or even missing altogether.

One should finally remember the role of the ethics committees in the approval of the therapeutic use of a medical product subjected to clinical trial, the so-called expanded access/compassionate use, according the Ministerial Decree dated 8 May 2003 [9], recast and replaced by Ministerial Decree dated 7 September 2017 [10].

In addition, current ethics committees have often undertaken educational and training tasks, planning seminars and workshops, mainly focused on ethical topics [11].

In light of the above, recent proposals for the establishment, along with the already existing research ethics committees, of “new ethics committees” devoted to “clinical ethics” shall be welcomed.

However, it cannot be denied that the institution of such “new ethics committees” raises some concerns, especially considering the problems with respect to: i) their actual

composition; ii) the expertise that shall be required for their members; iii) their interaction with Legal Medicine Services in hospitals and health care institutions; iv) the cost burdens and the problem of who shall take upon itself those burdens; v) their effective independence from the institution that provides for the payments of the members; vi) the extent of their dissemination (regional, with no knowledge of the local reality, or local, at each hospital with tremendous economic and organizational demands).

In our opinion, with respect to the issue of the composition and structure of the new ethics committees, it is extremely important to openly address the very specific recommendation of the CNB regarding the multidisciplinary and pluralistic character of clinical ethics consultation, which “is exclusive task of the committees and must be provided by the committee in its entirety” [2]. The CNB thus disavows the individual ethics consultant model and reiterates the need for ethics opinions to be formed jointly in the deliberative setting of clinical ethics committees. This setting provides a wealth of different perspectives and the varied, complementary qualifications of their members, and acknowledges, at the same time, the need to safeguard the physician/patient/relatives or health care team/patient/relatives relationship, avoiding any delegation to the “expert” outside of the profession of the moral responsibility that is integral to the medical and healthcare professions themselves.

One last comment concerns the inclusion of an “epidemiologist” in the clinical ethics committees. In addition, we suggest that also a “clinical epidemiologist or a biostatistician” should be included, for her/his specific expertise in the evidence based medicine (EBM), focused on the evaluation of the evidence of health interventions, which is crucial to assess their appropriateness and therefore their ethical soundness at the clinical level.

These are just two instances of a complex of thorny issues that seem far from being resolved, especially if one considers the ongoing debate in literature about the pros and cons of different models of clinical ethics consultation [11] and the long gestational and finalization process of the CBN document [2].

As a matter of fact, in the beginning, clinical ethics committees and clinical ethics consultants were allotted the tasks of the ethical analysis of particularly problematic clinical cases; the drawing up of recommendations and guidelines to address recurrent ethical problems; the promotion and management of training programs to increase ethical awareness among healthcare workers [12]. These actions should be primarily addressed to clinical staffs and place the ethicists “in a role supportive of the clinical practitioners”, helping them to “make explicit the values inherent in their decisions”, even undertaking the more committed role of personal counsellors.

In our opinion, this role should not escalate to a more substantial patients advocacy, which places the ethicist “between the practitioner and his context of performance”, interfering with the health care professionals’ attention and performance [13]. This kind of interference, in the complex and unstable clinical setting, might also lead to “a replacement of the privacy of the doctor- patient relationship [13]”, a reduction of “the freedom to care and comfort in seeking cure”, and a potential risk “for ethical leverage through financial-legal consequences” [13]. A more positive role of the ethicist, besides offering her/his expertise in the ethical analysis of particularly problematic clinical cases in multidisciplinary committees, could be the educational one. Given the rather desultory and mainly abstract training in Bioethics that prospective physicians and healthcare providers receive in Italian universities, an effective interaction with clinical ethics committees and consultants could enhance in clinical staff, physicians, and, especially, physicians undergoing specialized training, the ethical expertise that is part-and-parcel of their professional responsibility. This is particularly true in such areas as intensive care unit, coronary care unit, stroke unit, oncology [14], and paediatrics [15], where more often medical and health care personnel confront complex and dramatic moral dilemmas [16].

Finally, given the importance of validating medical actions, and generally all kind of actions taken in medical settings, according to EBM, ethical consultation should be critically evaluated following a standardized approach [17]. It might be an approach pragmatically oriented on the outcomes, that nevertheless allows the assessment of the distinction between the interactions linked to the usual medical practice and the further contribution given by the ethical consultation. Even if this kind of research is mainly qualitative and raises formidable methodological problems, such as those regarding the control group and “sham interview”, it is desirable to strive to obtain answers as objec-

tive as possible, especially taking into account the investments that the introduction of such a practice in the public health involves.

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REFERENCES

1. Petrini C, Ricciardi W. Commentary. Clinical ethics and the role of clinical ethics committees: proposals for a revival. *Ann Ist Super Sanità*. 2017;53(3):183-4.
2. Italian Bioethics Committee. Clinical ethics committees. 31 March 2017. Available from: http://bioetica.governo.it/media/172267/p127_2017_clinical-ethics-committees_en.pdf.
3. Italia. Decreto Ministeriale 18 marzo 1998 relativo alle Linee guida di riferimento per l'istituzione e il funzionamento dei Comitati etici. *Gazzetta Ufficiale – Serie Generale*. n. 122, 28 maggio 1998.
4. Italia. Ministero della Salute. Decreto 12 maggio 2006 Requisiti minimi per l'istituzione, l'organizzazione e il funzionamento dei Comitati etici per le sperimentazioni cliniche dei medicinali. *Gazzetta Ufficiale – Serie Generale*. n. 194, 22 agosto 2006.
5. Italia. 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.
6. Belmont. Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Available from: www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html#toc.
7. Dichiarazione di Helsinki 2013. Available from: <https://retecomitatietici.apss.tn.it/wp-content/.../02/dichiarazione-helsinki-2013>.
8. Convenzione di Oviedo 1997. Available from: www.isss.it/binary/coet/cont/convenzioneoviedo.
9. Italia. Ministero della Salute Decreto 8 maggio 2003 Uso terapeutico di medicinale sottoposto a sperimentazione clinica *Gazzetta Ufficiale – Serie Generale*. n.173, 28 luglio 2003.
10. Italia. Ministero Della Salute Decreto 7 settembre 2017 Disciplina dell'uso terapeutico di medicinale sottoposto a sperimentazione clinica. *Gazzetta Ufficiale – Serie Generale*. n. 256, 2 novembre 2017.
11. i) Workshop: Il Comitato Etico di Niguarda e La Sperimentazione Clinica: Milano, 27 Settembre 2006; ii) Workshop del Comitato Etico dell'azienda Ospedaliera Ospedale Niguarda Ca' Granda: Sperimentazioni Cliniche: Nuovo decreto Ministeriale CTA, 29 Settembre 2008; iii) A.O. Ospedale Niguarda Ca' Granda: Validità del consenso informato ed applicabilità nelle situazioni critiche. Lo stato dell'arte degli aspetti normativi e le sfide per il futuro, 27 Settembre 2012; iv) Convegno: Quale prospettive per i Comitati Etici in Italia?, 1 dicembre 2017, ASST Papa Giovanni XXIII, Bergamo.
12. Altisent R, Martín-Espildora N, Delgado-Marroquín MT. Health Care Ethics Consultation. Individual Consultant or Committee Model? Pros and Cons. *Am J Bioeth*. 2013;13(2):25-7. Available from: <http://dx.doi.org/10.1080/15265161.2012.750394>.
13. Lyon-Loftus GT. What is a clinical ethicist? *Theoretical Med* 1986;7:41-5.
14. Guidelines for ethics committees in health care institutions. Judicial Council. *JAMA*. 1985;253:2698-9.
15. American Academy of Pediatrics, Committee on Bioethics, Institutional ethics committees. *Committees on Bioethics. Pediatrics*. 2001;107:205-9.
16. Giannini A. Il ruolo della consulenza di etica clinica in ospedale. *Medicina e Morale*. 2015;6:1061-76.
17. Tulskey JA, Fox E. Evaluating ethics consultation: Framing the questions. *J Clin Ethics*. 1996;7:109-15.