



AN OVERVIEW OF TRENDS IN THE REGULATION OF CLINICAL ETHICS COMMITTEES: AN OPINION FROM THE ITALIAN NATIONAL BIOETHICS COMMITTEE ARTICLE

UNA VISIÓN GENERAL DE LAS TENDENCIAS EN LA REGULACIÓN POR LOS COMITÉS DE ÉTICA CLÍNICA: UNA OPINIÓN DEL COMITÉ NACIONAL ITALIANO DE BIOÉTICA

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ABSTRACT:

Keywords:

Clinical ethics committees; Functions and competences; Membership; Collegiality; Location; Italian National Bioethics Committee.

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In 2017, the Italian National Bioethics Committee (INBC) released an opinion paper titled "Clinical ethics committees". Said document advocates for the creation of "clinical bioethics committees" in every suitable setting and lays out a set of guidelines aimed at regulating such committees' functions. The recommendations deal primarily with the independence, requirements for counselling, structures, composition, tasks, placement, coordination, requisite competences, regulations. In the opinion's contents there are: a) the need to entrust counselling and training on ethical issues within clinical practice to different committees than those that deal with ethical assessments of scientific trials and experimentation; b) the laying out of all the various functions and related competencies required of the ethics committees' members; c) the necessity that all counselling practices be carried out by each committee as a whole, rather than by a single expert member; d) Committee's independence. The authors elaborate on each one of the above mentioned aspects and highlight the importance of INBC's recommendations in order to improve the quality standards of care delivered "to each patient's bed".

RESUMEN:

Palabras clave:

Comités de ética clínica; Funciones y competencias; Afiliación; Colegialidad; Ubicación; Comité Nacional Italiano de Bioética

En el 2017, el Comité Nacional Italiano de Bioética (CNIB) publicó un artículo de opinión titulado "Comités de Ética Clínica". Dicho documento aboga por la creación de "comités clínicos de bioética" en cada entorno adecuado, y establece un conjunto de directrices destinadas a regular las funciones de tales comités. Las recomendaciones se refieren principalmente a la independencia, los requisitos para el asesoramiento, las estructuras, la composición, las tareas, la ubicación, la coordinación, las competencias requeridas, las regulaciones. En los contenidos de la opinión se plantean: a) la necesidad de confiar el asesoramiento y la capacitación en cuestiones éticas dentro de la práctica clínica a diferentes comités que aquellos que se ocupan de las evaluaciones éticas de los ensayos científicos y la experimentación; b) la presentación de

las diversas funciones y competencias requeridas por los miembros de los comités de ética; c) la necesidad de que todas las prácticas de asesoramiento sean llevadas a cabo por cada comité como un todo, y no por un solo miembro experto; d) independencia del comité. Los autores detallan cada uno de los aspectos mencionados anteriormente y resaltan la importancia de las recomendaciones de CNIB para mejorar los estándares de calidad de la atención brindada “a la cabecera de la cama de cada paciente”.

1. Introduction

On 31st of March, 2017, the Italian National Bioethics Committee (INBC) has released an opinion paper titled “Clinical ethics committees”, meant to provide lawmakers and the Italian government with several recommendations in light of future regulatory reform on the subject¹. The INBC focused on this issue for various reasons. Firstly, daily clinical practice entails ethical implications that are even more varied and widespread as opposed to scientific experimental activities. There needs to be a national body charged with providing consultancy from an ethical standpoint as to what is “best” to be done when difficult choices and decisions in healthcare arise. Such a need has always gone hand in hand with medical practice, but it has become ever more prevalent over the past decades for various reasons, among which: a) the fast-growing spread of available healthcare services; b) the substantial relevance ascribed to the principle of self determination; c) the multi-ethnic nature of most Western societies, which gives rise to an increased and widespread plurality of views as to the values of human life and health; d) new ethical issues arising from biomedical advancements in many a field, such as organ transplants, life-sustaining treatments, genetics and medically assisted procreation. As a matter of fact, on the heels of hotly debated cases which deeply divided the public opinion as well as the scientific community, there has been an increased sense of awareness in the United States as to the pressing need to institute clinical ethics Committees (CECs), i.e. interdisciplinary Committees made up of experts tasked with the ethical oversight of all those cases deemed morally contentious within the scope of healthcare, with

the sole exception of those having to do with clinical or pharmaceutical trials and research, which fall under the authority of separate research ethics Committees.² Specifically in that regard, Aulisio³ mentions the cases “God Committee”, Quinlan and Cruzan. The former had to do with criteria by which patients were selected in order to undergo dialysis through an innovative, life-sustaining medical device, which was not available to all patients.⁴ Consequently, patients who were not selected and included were unable to enjoy prolonged survival. The other cases, Quinlan,⁵ and Cruzan^{6,7,8} were instead centered on the ability of parents of patients in a vegetative state to require the withdrawal of life sustaining treatments which kept their daughters alive. The second reason which made it necessary for the INBC to intervene is more closely connected to the Italian situation. In Italy, the use of ethics consultancy in clinical practice has long been at the center of a debate. The issue was extensively discussed in one of the earliest papers published by the INBC.⁹ As for regulations, the ministerial

2 Aulisio M.P. “Why Did Hospital Ethics Committees Emerge in the US?” *American Medical Association Journal of Ethics* 2016,8(5): 546-553.

3 Ibidem

4 Jonsen, A.R. “The god squad and the origins of transplant ethics and policy”. *Journal of Law Medicine and Ethics* 2007, 35(2): 238-40.

5 Smith, W.F. “In re Quinlan: defining the basis for terminating life support under the right of privacy”. *Tulsa Law Journal*, 1976 12(1): 150-167.

6 Gostin, L.O. “Deciding life and death in the courtroom. From Quinlan to Cruzan, Glucksberg, and Vacco - a brief history and analysis of constitutional protection of the ‘right to die’”. *Journal of the American Medical Association* 1997;278(18): 1523-1528.

7 Halper, T. “Privacy and autonomy: from Warren and Brandeis to Roe and Cruzan”. *The Journal of medicine and Philosophy*. 1996: 21(2): 121-135

8 Sacchini, D; Spagnolo A.G. Ethical questions in the treatment of the person in persistent vegetative state. The symbolic case of Nancy Beth Cruzan. *La Clinica Terapeutica*, 2000 151(4): 227-229.

9 Italian National Bioethics Committee, I comitati etici. Roma: Dipartimento per l'Informazione e l'Editoria, Roma, 27 febbraio 1992. http://bioetica.governo.it/media/170632/p8_1992_comitatietici_it.pdf. Accessed April 4, 2017.

1 Italian National Bioethics Committee. 2017. I comitati per l'etica nella clinica. 31 marzo 2017. http://bioetica.governo.it/media/172155/p127_2017_i-comitatietici-per-la-clinica_it.pdf. Accessed April 3, 2017

decreed issued on 8th February 2013 spells out the possibility that ethics Committees might discharge different function from those originally specified, such as the assessment of clinical trials. As stated: insofar as not yet assigned to other bodies, ethics Committees may carry out consultancy-related duties linked to ethical matters pertaining to scientific and healthcare activities, aimed at protecting and promoting personal values. Moreover, the Committees may also propose initiatives in order to provide training for healthcare professionals on bioethical issues. In spite of all of that, thanks partly to the steady increase in statutory responsibilities attributed to ethical research committees, the function of clinical trials assessment has effectively dominated the stage.¹⁰ Only the Veneto Region¹¹ and the Friuli Venezia Giulia Region¹² have adopted measures to promote the establishment of an ethics committee for clinical practice in each healthcare facility. Furthermore, in Italy as in several other countries, the commitment to evaluate clinical trials has proven so prevalent that the Ethics Committees find themselves unable to provide ethics consultancy in healthcare. Predictably, such a situation will be further stressed by the complete execution of a European set of regulations (UE) 536/2014, which came into effect on 16th June 2014. Such norms will in fact mandate that the activity of current ethics committees, which has always been closely focused on research trials rather than healthcare, will be devoted solely to the former. Moreover, the number of ethics committees in Italy is due to be further curtailed.^{13,14}

2. Need to institute a specifically conceived institutional body tasked with consultation and training related to clinical ethics-related issues

The limited practical application of ethics consultation in healthcare settings is an Italian trend which stands in contrast with different initiatives undertaken internationally. In 1978 the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was established in the United States. The three key tasks of the Commission were: 1) an ethical analysis of particularly problematic clinical cases; 2) the drawing up of recommendations and guidelines to address recurrent ethical problems; 3) the promotion or direct management of training programmes to increase ethical awareness among healthcare workers. The final report of the President's Commission was published in 1983.¹⁵ Though the President's Commission and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established in 1974 responding to the disclosure of unethical experiments conducted for decades addressed different areas) were established to address different areas of concern, there are similarities in their results.¹⁶ Though the President's Commission did not recommend the immediate establishment of an ethics committee in every hospital, it supported the formation of interdisciplinary committees to support health professionals in controversial decisions, to promote ethical education and to contribute to the drafting and adoption of guidelines and institutional policies. Many other institutions^{17,18} recommended the

10 Caminti, C.; Diodati F.; Gatti, A.; Santachiara, S.; Spinsanti, S. "Current functions of Italian ethics committees: a cross-sectional study". *Bioethics* 2011,25(4): 220-227.

11 Deliberazione n. 4049/2004 della Giunta della Regione Veneto. January 25, 2005. Bollettino Ufficiale della Regione Veneto 9: 234-252. Deliberazione n. 983/2014 della Giunta della Regione Veneto. July 8, 2014. Bollettino Ufficiale della Regione Veneto 66:469-480

12 Deliberazione n. 73/2016 della Giunta della Regione Friuli Venezia Giulia. February 10, 2016. Bollettino Ufficiale della Regione Friuli Venezia Giulia 6: 224-229.

13 Petrini, C.; Gensabella M., "L'autodeterminazione del paziente e il progresso della biomedicina nel parere del Cnb". *Il Sole 24 Ore Sanità*, 2017, May 23, 14-15.

14 Petrini C. "What is the role of ethics committees after Regulation (EU) 536/2014?" *Journal of Medical Ethics*, 2014, 42(3): 186-188.

15 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Summing up. Final Report on studies on the ethical and legal problems in medicine and biomedical and behavioral research. Washington DC, 31 March 1983

16 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Publication OS 78-0012. Washington DC, 18 April 1979.

17 American Medical Association Ethical and Judicial Council. 1985. Guidelines for Ethics Committees in Health Care Institutions. *Journal of the American Medical Association* 253(18): 2698-2699.

18 Ibidem.

establishment of clinical ethics committees. The proposals from the Joint Commission on the Accreditation of Healthcare Organizations¹⁹ are particularly noteworthy. Clinical ethics Committees have long been widespread in hospitals throughout the Western world, albeit in a very inhomogeneous way, and only recently have new committees been instituted in most Eastern Mediterranean Region countries and South-East Asia Region countries.²⁰ Many countries draw a clear distinction between ethics committees for research trials and clinical ethics Committees²¹: the latter are variously known, as “Comités Asistencial de Ética” in Spain, as “Institutional Ethics Committees” in the Netherlands, or as “Clinical Ethics Committees” in the United Kingdom, etc.²² In the United Kingdom committees had largely worked alone until a meeting of committee representatives in January 2001 led to the development of the UK Clinical Ethics Network.²³ Such an international trend toward the creation of such committees appears well-founded for multiple reasons. First of all, research ethics committees operate in partnership with the government bodies that promote and fund research and with the researchers themselves, whereas the clinical ethics committees are primarily centered around healthcare providers and the citizens. From such a distinction a need arose for the two types of committees to have a different composition, thus ensuring a different array of professional competences. Research ethics committees need to rely on such professional figures as pharmacologists, hospital pharmacists, researchers etc. Whilst clinical ethics committees need mostly “socially oriented” profiles (non-medical healthcare pro-

fessionals, family doctors, community representatives or of social or volunteer organizations etc.). One more differentiation was thus laid bare: opinions from research ethics Committees’ opinions are characterized as “binding”, whereas the ones from healthcare ethics Committees are merely “advisory”.²⁴ Such a conclusion has been further buttressed by the INBC in the above mentioned document released in 2017.²⁵ Consequently, the centralization and standardization of the ethical assessment-making process through clearly defined judging criteria is useful for the purpose of clinical trial, but for the providing of care, in which any choice is heavily influenced by each case’s peculiarities and by each hospital’s structural and instrumental means.²⁶

3. Functions and competences

Specific functions as defined in the 1970s by the above-mentioned President’s Commission still constitute an integral part of those attributed to clinical ethics Committees. In 2004 the Ethox Centre of the University of Oxford, jointly with the UK Clinical Ethics Network, has asserted that clinical ethics Committees are meant to serve some or all of the following functions; “1. Providing ethics input into trust policy and guidelines around patient care. 2. Facilitating ethics education for health professionals within the trust. 3. Providing ethics advice for clinicians on individual cases”.²⁷ In 2017, the INBC has laid out such functions: a) to assess from an ethical perspective clinical cases that do not fall within clinical or pharmaceutical research, thus analyzing and debate the nature of moral quandaries which may arise from patient care and therapeutic practices while dealing with ethically and morally charged situations (neonatal or end of life care, for instance) or with vulnerable individuals (minors, incapacitated patients, elderly people, immigrants), unforeseeable events (in-

19 Joint Commission on Accreditation of Healthcare Organizations. 1992. Accreditation manual for hospitals. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations.

20 Hajibabae, F.; Joolae, S.; Cheraghi, M.A.; Salari, P.; Rodney P. “Hospital/clinical ethics committees’ notion: an overview”. *The Journal of Medical Ethics and History of Medicine* 2016,9: 17-26.

21 Slowther, AM. “ Ethics consultation and ethics committees”. In *Principles of health care ethics*, 2 nd edition, edited by R.E. Ashcroft, A.J. Dawson, H. Draper, J.R. McMillan, 2007, 527-532

22 Byk, C., Mémeteau, G. *Le droit des comités d’éthique*. Paris : Éditions Alexandre Lacassagne et Éditions Eska 1997

23 Slowther, A.; Johnston, C.; Goodall, J.; Hope, T. “A practical guide for clinical ethics support”. Oxford: The Ethox Foundation, 2004. http://www.ukcen.net/uploads/docs/education_resources/prac_guide.pdf. Accessed April 28, 2017

24 Italian National Bioethics Committee. 1997. I comitati etici in Italia: problematiche recenti, cit.

25 Italian National Bioethics Committee. 2017. I comitati per l’etica nella clinica. 31 marzo 2017, cit.

26 Ibidem.

27 Pegoraro, R.; Petrini C. Committees: Clinical Ethics Committees. In *Encyclopedia of Global Bioethics*, edited by H. Ten Have, 2016, 623-633.

cidental findings); b) to set forth exemplifying models for informed consent, provided that: a) it is necessary to personalize each piece of information according to each patient and real life situations; b) the request for consent is part of a doctor's duties and nobody else may be delegated for that purpose; c) to propose and to supervise bioethics training activities; d) carry out, whenever possible, activities aimed at raising awareness of bio-ethical issues among the people. Lastly, clinical ethics Committees should be entrusted with the identification and definition of moral or cultural problems that arise in care and therapeutic activities with the task of proposing possible solutions and carrying out appropriate mediation thus laying the foundations for full implementation of the ideals of therapeutic alliance.²⁸ Recently, on an international level, ethics Committees' activities have come to comprise organizational ethics, that is ethical issues related to healthcare organization such as professional integrity, among others, allocation of resources, rights and duties of providers, business and service plans and the relationship among institutions within a social setting.^{29,30,31,32} Consequently, several scholars think of clinical ethics Committees as useful tools in order to improve the quality of healthcare services as well.³³ In addition to all those aspects, according to the UNESCO, a well thought-out clinical ethics Committee may serve broader functions too: resolution of possible conflict among healthcare professionals or between the professionals and the patients or their family members; the carrying out of bio-ethical research within the institution; participation in debates

centered on legislative reform about bio-ethical issues, whether at a local, regional or national level.³⁴ In light of the above mentioned functions, according to the INBC, clinical ethics Committees should be able to rely on multiple competences. Among these, the following ones stand out as necessary: a solid grounding in ethics and moral theories; medical clinic, with reference to the diseases treated in the respective institution; social and cultural background of patients, with the implementation of specific forms of cultural mediation; codes and documents of ethics as deemed relevant to each healthcare profession; elements of bio-law and healthcare regulations; national and international sets of guidelines with regard to medical ethics-related topics; organization of healthcare services. Initiatives aimed at the proper training and the timely updating of all members of the ethics Committees are essential.³⁵ Such a conclusion is reasserted in the paper "Core competencies for clinical ethics committees", released by the UK Clinical Ethics Network in 2010.³⁶

4. Membership

The composition should be multidisciplinary, composed of members from different professional backgrounds. Medical and nursing profiles are undoubtedly required, but other figures should or may be represented as well (according to the circumstances): law, business/administration, religion, philosophy, social issues. Particularly important is patient representation. In fact, the above mentioned mediatory function among various social and cultural extractions within clinical practice makes it necessary to get involved the beneficiaries of said activities.^{37,38} More precisely, in accordance

28 Italian National Bioethics Committee. 2017. I comitati per l'etica nella clinica. 31 marzo 2017, cit.

29 Førde, R.; Hansen T.W. "Do organizational and clinical ethics in a hospital setting need different venues?" *HEC Forum* 2014,26(2): 147-58.

30 Magelssen, M.; Pedersen R.; Førde R. "Novel Paths to Relevance: How Clinical Ethics Committees Promote Ethical Reflection". *HEC Forum*, 2016 28(3): 205-16.

31 McClimans L.; Slowther A.M.; Parker M. "Can UK clinical ethics committees improve quality of care?" *HEC Forum* 2012,24(2): 139-47.

32 United Nations Educational, Scientific and Cultural Organization. 2005. Guide No. 1. Establishing Bioethics Committees. Paris: UNESCO. <http://unesdoc.unesco.org/images/0013/001393/139309e.pdf>. Accessed April 7, 2017.

33 Larcher, V.; Slowther A.M.; Watson A.R. "On behalf of the UK Clinical Ethics Network. Core competencies for clinical ethics committees". *Clinical Medicine* 2010,10(1): 30-33.

34 Geppert, C.M.; Shelton W. "Health Ethics Committees as Mediators of Social Values and the Culture of Medicine". *American Medical Association Journal of Ethics* 2016,18(5): 534-539.

35 Italian National Bioethics Committee. 2017. I comitati per l'etica nella clinica. 31 marzo 2017, cit.

36 Førde, R.; Hansen T.W. "Do organizational and clinical ethics in a hospital setting need different venues?" *HEC Forum* 2014,26(2): 147-58.

37 Magelssen, M.; Pedersen R.; Førde R. "Novel Paths to Relevance: How Clinical Ethics Committees Promote Ethical Reflection". *HEC Forum*, 2016 28(3): 205-16.

38 McClimans L.; Slowther A.M.; Parker M. "Can UK clinical ethics committees improve quality of care?" *HEC Forum* 2012,24(2): 139-47.

to the INBC, The composition of ethics Committees in clinical practice should reflect the various professionals and figures involved in decision-making, assisting, on a case-by-case basis and when needed, a stable nucleus of other expert components. The stable nucleus should be composed of members who take part in all deliberations (members of the medical and hospital staff, representatives of patient associations, lawyers and bioethicists) and members who take part only in those decisions in which their presence appears to be necessary based on the beliefs or needs of the patient (e.g. religious, cultural mediators, psychologists, social workers).³⁹ The permanent pool of experts should comprise at least one member for each one of the following figures: clinical doctors, bioethicist, nurse, jurist, healthcare risk management expert, patients representative, epidemiologist. The intervention of the additional experts should be called upon whenever a case being assessed presents new or peculiar traits and for whose resolution the professional competencies in the permanent pool of experts may not be enough.⁴⁰

5. Collegiality

Oft times, ethical consultancy is not merely provided through clinical ethics Committees, but by individual ethics consultants as well, bioethicists specialized in clinical bioethics, either from outside the healthcare facilities or operating as part of the hospital's staff. In several countries, among which the United States,⁴¹ said professionals follow specifically devised training paths and their own code of ethics. In Italy, the National Group of Clinical Ethics and Healthcare Ethics Consultation adopted on 10th December 2013 the Documento di Trento. According to the scholars involved, since there are relatively few experiences of institutionalized ethics consultancy, to entrust such practices

to individual consultants rather than a preconstituted committee appears to be a better suited, more sensible choice. The clinical ethics Committee, whenever available, would play the role of reviewer of consultancy already administered, with the goal of dealing with different issues on a more general level, often arising from the consultancy practices themselves, and of devising recommendations and sets of ethical guidelines.⁴² For instance, ethical guidelines on the refusal on the part of Jehova's Witnesses to receive blood transfusions should lay out exactly when the treatment should be necessarily administered and specify the responsibilities of each party involved (doctors, patients, relatives, legal counsel, etc.).^{43,44} In fact, producing guidelines necessarily calls for the participation of a multidisciplinary pool.⁴⁵ Although it is undoubtedly harder to manage the proper functioning of collegial organizations, the choice to entrust the consultancy phase to an individual professional has itself its downsides. Yet, it seems highly unlikely that consultants, operating separately and individually, could provide opinions that mirror the existing ethical plurality of views on a given clinical issue.⁴⁶ A multidisciplinary approach is needed to provide the doctor with thorough consultancy. It is also unlikely, though, for a single professional to be able to rely on a wide-ranging set of skills and expertise in a number of different disciplines and subjects.⁴⁷ Besides, entrusting the consultancy to a single profile would enhance the risk of a disparity in judgement, depending on which consultant is called upon to intervene. The INBC posits that ethics consultation should fall upon clinical ethics Committees and should be administered by the com-

39 Italian National Bioethics Committee. 2017. I comitati per l'etica nella clinica. 31 marzo 2017, cit.

40 Ibidem.

41 American Society for Bioethics and Humanities. 2014. Code of Ethics and Professional Responsibilities for Healthcare Ethics Consultants. http://www.asbh.org/uploads/files/pubs/pdfs/asbh_code_of_ethics.pdf. Accessed May 28, 2017.

42 Gruppo Nazionale di Etica Clinica e Consulenza Etica in ambito Sanitario. Documento di Trento. *Medicina e Morale*, 2014, 62(1): 156-159.

43 Herreros, B.; Ramnath V.R. "Bishop L. "Clinical ethics protocols in the clinical ethics committees of Madrid". *Journal of Medical Ethics* 2014, 40(3): 205-208

44 Cameron, M.E. "Value, be, do: guidelines for resolving ethical conflict". *Journal of Nursing Law* 2000,6(4): 15-24. 12.

45 Petrini, C. "Toward Clinical Bioethics (or a return to Clinical Ethics?)". *La Clinica Terapeutica*, 2013,164(6): 523-527

46 Mori, M. "Per un ripensamento della consulenza etica nelle strutture sanitarie italiane". *Medicina e Morale* 2015, 64(6): 959-985.

47 Petrini, C.; Gensabella M. " L'autodeterminazione del paziente e il progresso della biomedicina nel parere del Cnb", cit.

mittee in its entirety, so as “to be able to guarantee a plurality of visions and competencies which are necessary in a society with a high degree of technological complexity and composite cultural background such as ours”. Nevertheless, this general rule should not be rigidly applied, because there might be situations that are incompatible with the proper functioning of a collegial organization, which is necessarily slower and more complex compared to an intervention from a single consultant. In particular, For cases of urgency or in cases where it is necessary to obtain information directly from the patient or care practitioners, the Committee may envisage delegating part of its functions to more restrictive bodies while maintaining supervision over their work. The multidisciplinary and pluralistic nature of ethical counselling must always be guaranteed.⁴⁸ That does not mean denying or questioning the value of ethics consultation services within healthcare facilities: it is nonetheless a reminder as to the need for shared evaluations, so as to encompass the broad scope of multiple competencies which are unlikely to be found in a single professional expert.⁴⁹ The opinion from the INBC does not spell out what professional background each member of the expert pool should have. Hence, each individual clinical ethics Committee could from time to time decide who to appoint. In spite of all that, in consideration of the clinical ethics committee’s opinion and its contents, it seems sensible that within such narrow groups a relevant role should be played by the bioethicist. Such professional profile is contained within the decree from 8th February 2013 as an integral part of the ethics Committees. Nevertheless, in Italy such a profession has not been clearly defined yet, from a regulatory standpoint. Thus, it is unclear what kind of training and credentials needs to be attained in order to be considered a bioethicist and then deliver ethics consultation services in research and clinical practices. It is an extremely relevant point, since

it affects the quality of the clinical ethics Committees’ opinions. As a consequence, the Italian Bioethics Committee has seen fit to defer its resolution until a future and specific opinion can be formulated.

6. Location

Although the choice of the location may not be a crucial decision, the organizational context may play a significant role. A committee in an administrative structure may be perceived as a bureaucratic encumbrance. A committee in the head office (Director, President) may be perceived as an imposed authority. The best place for a clinical ethics Committee to be located may vary according to the circumstances and may change in any given institution: Considering the particular function that ethics Committees in clinical practice are called upon to carry out, they should have territorial roots. In small towns, a dimension linked to the local hospital facility may be envisaged. In larger locations, where there are Universities with University Hospitals, it may provide ethics Committees at the level of individual structures, selected on the basis of institutional ties or the nature of the activities carried out. However, excessive fragmentation should be avoided to allow each Committee to have a comprehensive picture of the problems and to avoid any disparity in treatment. Coordination between clinical ethics Committees is desirable, possibly through the establishment of a national network.⁵⁰ At any rate, by virtue of the mediatory functions that ethics committees are meant to serve, the independence of their members is a key element.⁵¹ Therefore, said members should not be an integral part of the single institution for which the committee perform its consultation activities.⁵² Such precautions notwithstanding, there might still be undue influence on the committees’ work. That’s why the INBC has called upon the legislators to preserve and

⁵⁰ Italian National Bioethics Committee. 2017. I comitati per l’etica nella clinica. 31 marzo 2017, cit.

⁵¹ Petrini, C. “Toward Clinical Bioethics (or a return to Clinical Ethics?)”, cit.

⁵² Sabin, J.E. “How Can Clinical Ethics Committees Take on Organizational Ethics? Some Practical Suggestions”. *Journal of Clinical Ethics* 2016,278(2): 111-116

⁴⁸ Italian National Bioethics Committee. 2017. I comitati per l’etica nella clinica. 31 marzo 2017, cit.

⁴⁹ Carnevale, F.A. “Let’s Not Forget about Clinical Ethics Committees!” *Journal of Clinical Ethics*, 2016, 27(1): 68-70.

guarantee the independence of clinical ethics Committees' members, not just with respect to the bodies that constituted them, but with regards to the institutions within which they operate.⁵³ In light of the kind of activity clinical ethics Committees perform, the issue of whether their opinions should be binding or merely advisory appears to be particularly pressing. On the one hand, a given committee's recommendations may risk being pointless, without the proper tools in order to ensure their implementation. On the other hand though, compelling physicians to comply with the standards of conduct conceived by the clinical ethics Committees would run counter to the right to respect for professional dignity and independence, in addition to being an undue interference with the notion of professional responsibility, which falls upon doctors, and which doctors cannot shirk. If committee eventually came to replace doctors, the bond of trust between the latter and their patients would ultimately be compromised. As a matter of fact, patients need to be able to trust the professionals who formulate a diagnosis and devise a therapy. If doctors are swayed by the indications of outsiders, their credibility is eventually diminished in the eye of their patients. Consequently, «the clinical ethics Committee can provide authoritative guidance which, however, is not binding and does not take away from the doctor and the healthcare team the autonomy and responsibility of decision making».^{54,55} A reasonable compromise has been adopted in Spain, where ethics committees' opinions and guidelines are non-binding, but doctors are required to explain and substantiate their possible refusal to abide by said recommendations.⁵⁶ A similar solution might bring the unintended consequence of pressuring doctors into accepting the committee's indications.

7. Conclusions

The encouragement on the part of the INBC to spread sound training practices and ethics consultancy in healthcare through specifically conceived collegial organizations appears sensible. In fact, the current Italian and international situations make such organizations necessary from three different standpoints. Firstly, an awareness on the part of patients to be able to refuse medical treatment and to be entitled to the most exhaustive information available makes contrasts between them and their doctors more likely. Thus, the range of cases which can be characterized as ethically contentious is no longer occasional or rare, as it was decades ago, but rather frequent. Furthermore, the international economic crisis has made the issue of limited resources ever more pressing. That has undoubtedly caused ethical evaluations to comprise every aspect of healthcare services and the administration of finite resources, rather than being circumscribed to single ethical issues. As a consequence of that, ethical assessment activities happen on a daily basis. Lastly, a need has arisen to reduce the incidence of lawsuits. Trials, as it is well-known, are a waste of resources and stem from a failure in the therapeutic relationship. Such a scenario makes a greater presence of clinical ethics Committees all the more needed; they can help doctors establish a better relationship with their patients, thus preventing the arising of unfounded litigation, which might, for instance, stem from a failure on the part of the patient to acknowledge a doctor's right to conscientious objection. With reference to the risk of litigation, clinical ethics Committees' role in elaborating models of informed consent and a sensitization of doctors as to the need to inform each patient on an individual basis may turn out to be quite useful. For the committees to be able to effectively discharge all these duties, they need to rely on a multidisciplinary set of competences and skills. That makes their collegial nature absolutely necessary. In addition to that, it is equally necessary for all members to cooperate when dealing with any issue, with the possibility to exempt individual members who may have competencies ill-suited to

⁵³ Italian National Bioethics Committee. 2017. I comitati per l'etica nella clinica. 31 marzo 2017, cit.

⁵⁴ Ibidem.

⁵⁵ Dörries A., P. Boitte, A. Borovecki. "Institutional challenges for clinical ethics committees". *HEC Forum* 2011,23(3): 193-205.

⁵⁶ Herreros, B.; Ramnath V.R. "Bishop L. "Clinical ethics protocols in the clinical ethics committees of Madrid", cit.

the topic at hand. Nevertheless, the collegial nature of the committees and their authoritativeness should not result in their opinions being considered binding on healthcare practitioners, since the latter's independence and professional dignity need to be preserved. That does not discount the importance of the committees. In fact, through their traditional functions of training and updating of personnel on clinical ethics-related issues, the committees constitute a source of enrichment and spur critical thinking, thus spreading among practitioners greater awareness as to the ethical value of recommended behavioral standards.

Lastly, as laid out in the document examined herein, it is vital that the clinical ethics Committees be able to operate according to science and conscience, with no undue influence from outsiders. The INBC has chosen to make clinical ethics Committees the core of its released document. For that reason, it has seen fit not to deal with the issues of ethics consultation services or the individual experts possibly operating in healthcare facilities. The broad scope of such issues would have been unfit to be included within a single paper. Having decided to devote the article to the topic of clinical ethics Committees, and having ascribed to them such a relevant role, does not in any way deny the value of other services or bioethics experts, whose roles may well be extremely valuable: Nonetheless, the INBC has meant to highlight the need for a multidisciplinary approach, which bioethics service providers may not necessarily be able to offer, and the importance of collegial work, which cannot be supplanted by a single expert.

Author contributions

The authors significantly contributed to the production of this manuscript. They substantially contributed to the conception and design of the article, were involved in drafting (ER) or revising the draft critically for important intellectual content and have approved the final version for publication.

Conflict of interest

No conflicts of interest to declare.

References

- American Medical Association Ethical and Judicial Council. 1985. Guidelines for Ethics Committees in Health Care Institutions. *Journal of the American Medical Association* 253(18): 2698-2699.
- American Society for Bioethics and Humanities. 2014. Code of Ethics and Professional Responsibilities for Healthcare Ethics Consultants. http://www.asbh.org/uploads/files/pubs/pdfs/asbh_code_of_ethics.pdf. Accessed May 28, 2017
- Aulisio M.P. "Why Did Hospital Ethics Committees Emerge in the US?" *American Medical Association Journal of Ethics* 2016,8(5): 546-553.
- Byk, C., Mémeteau, G. *Le droit des comités d'éthique*. Paris : Éditions Alexandre Lacassagne et Éditions Eska 1997.
- Cameron, M.E. "Value, be, do: guidelines for resolving ethical conflict". *Journal of Nursing Law* 2000,6(4): 15-24. 12
- Caminti, C.; Diodati F.; Gatti, A.; Santachiara, S.; Spinanti, S. "Current functions of Italian ethics committees: a cross-sectional study". *Bioethics* 2011,25(4): 220-227.
- Carnevale, F.A. "Let's Not Forget about Clinical Ethics Committees!" *Journal of Clinical Ethics*, 2016, 27(1): 68-70.
- Deliberazione n. 4049/2004 della Giunta della Regione Veneto. January 25, 2005. Bollettino Ufficiale della Regione Veneto 9: 234-252. Deliberazione n. 983/2014 della Giunta della Regione Veneto. July 8, 2014. Bollettino Ufficiale della Regione Veneto 66:469-480
- Deliberazione n. 73/2016 della Giunta della Regione Friuli Venezia Giulia. February 10, 2016. Bollettino Ufficiale della Regione Friuli Venezia Giulia 6: 224-229.
- Dörries A., P. Boitte, A. Borovecki. "Institutional challenges for clinical ethics committees". *HEC Forum* 2016,23(3): 193-205
- Førde, R.; Hansen T.W. "Do organizational and clinical ethics in a hospital setting need different venues?" *HEC Forum* 2014,26(2): 147-58.

- Geppert, C.M.; Shelton W. "Health Ethics Committees as Mediators of Social Values and the Culture of Medicine". *American Medical Association Journal of Ethics* 2016,18(5): 534-539.
- Gostin, L.O. "Deciding life and death in the courtroom. From Quinlan to Cruzan, Glucksberg, and Vacco - a brief history and analysis of constitutional protection of the 'right to die'". *Journal of the American Medical Association* 1997;278(18): 1523-1528.
- Gruppo Nazionale di Etica Clinica e Consulenza Etica in ambito Sanitario. Documento di Trento. *Medicina e Morale*, 2014, 62(1): 156-159.
- Hajibabae, F.; Joolae, S.; Cheraghi, M.A., Salari, P.; Rodney P. "Hospital/clinical ethics committees' notion: an overview". *The Journal of Medical Ethics and History of Medicine* 2016,9: 17-26
- Halper, T. "Privacy and autonomy: from Warren and Brandeis to Roe and Cruzan". *The Journal of medicine and Philosophy*. 1996: 21(2): 121-135.
- Herreros, B.; Ramnath V.R. "Bishop L. "Clinical ethics protocols in the clinical ethics committees of Madrid". *Journal of Medical Ethics* 2014, 40(3): 205-208
- Italian National Bioethics Committee. 2017. I comitati per l'etica nella clinica. 31 marzo 2017. http://bioetica.governo.it/media/172155/p127_2017_i-comitati-etici-per-la-clinica_it.pdf. Accessed April 3, 2017
- Joint Commission on Accreditation of Healthcare Organizations. 1992. Accreditation manual for hospitals. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations
- Jonsen, A.R. "The god squad and the origins of transplantation ethics and policy". *Journal of Law Medicine and Ethics* 2007, 35(2): 238-40
- Larcher, V.; Slowther A.M.; Watson A.R. "On behalf of the UK Clinical Ethics Network. Core competencies for clinical ethics committees". *Clinical Medicine* 2010,10(1): 30-33.
- Magelssen, M.; Pedersen R.; Førde R. "Novel Paths to Relevance: How Clinical Ethics Committees Promote Ethical Reflection". *HEC Forum*, 2016 28(3): 205-16.
- McClimans L.; Slowther A.M.; Parker M. "Can UK clinical ethics committees improve quality of care?" *HEC Forum* 2012,24(2): 139-47.
- Mori, M. "Per un ripensamento della consulenza etica nelle strutture sanitarie italiane". *Medicina e Morale* 2015, 64(6): 959-985.
- Pegoraro, R.; Petrini C. Committees: Clinical Ethics Committees. In *Encyclopedia of Global Bioethics*, edited by H. Ten Have, 2016, 623-633
- Petrini C. "What is the role of ethics committees after Regulation (EU) 536/2014?" *Journal of Medical Ethics*, 2014, 42(3): 186-188.
- Petrini, C. "Toward Clinical Bioethics (or a return to Clinical Ethics?)". *La Clinica Terapeutica*, 2013,164(6): 523-527
- Petrini, C.; Gensabella M., "L'autodeterminazione del paziente e il progresso della biomedicina nel parere del Cnb". *Il Sole 24 Ore Sanità*, 2017, May 23, 14-15.
- President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Summing up. Final Report on studies on the ethical and legal problems in medicine and biomedical and behavioral research. Washington DC, 31 March 1983
- Sabin, J.E. "How Can Clinical Ethics Committees Take on Organizational Ethics? Some Practical Suggestions". *Journal of Clinical Ethics* 2016,278(2): 111-116
- Sacchini, D.; Spagnolo A.G. Ethical questions in the treatment of the person in persistent vegetative state. The symbolic case of Nancy Beth Cruzan. *La Clinica Terapeutica*, 2000 151(4): 227-229
- Slowther, AM. " Ethics consultation and ethics committees". In *Principles of health care ethics*, 2nd edition, edited by R.E. Ashcroft, A.J. Dawson, H. Draper, J.R. McMillan, 2007, 527-532
- Slowther, A.; Johnston, C.; Goodall, J.; Hope, T. "A practical guide for clinical ethics support". Oxford: The Ethox Foundation, 2004. http://www.ukcen.net/uploads/docs/education_resources/prac_guide.pdf. Accessed April 28, 2017.

Smith, W.F. "In re Quinlan: defining the basis for terminating life support under the right of privacy". *Tulsa Law Journal*, 1976 12(1): 150-167.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for

the Protection of Human Subjects of Research. Publication OS 78-0012. Washington DC, 18 April 1979.

United Nations Educational, Scientific and Cultural Organization. 2005. Guide No. 1. Establishing Bioethics Committees. Paris: UNESCO. <http://unesdoc.unesco.org/images/0013/001393/139309e.pdf>. Accessed April 7, 2017.

