

# The static evolution of the new Italian code of medical ethics

G. MONTANARI VERGALLO, F.P. BUSARDÒ, S. ZAAMI, E. MARINELLI

Department of Anatomical, Histological, Forensic and Orthopaedic Sciences, Sapienza University of Rome, Rome, Italy

**Abstract.** – Eight years since the last revision, in May 2014 the Italian code of medical ethics has been updated. Here, the Authors examine the reform in the light of the increasing difficulties of the medical profession arising from the severity of the Italian law Courts.

The most significant aspects of this new code are firstly, the patient's freedom of self-determination and secondly, risk prevention through the disclosure of errors and adverse events. However, in both areas the reform seems to be less effective if we compare the ethical codes of France, the United Kingdom and the United States.

In particular, the non-taking into consideration of the said code quality standards and scientific evidence which should guide doctors in their clinical practice is to say the least questionable.

Since these are the most significant changes in the new code, it seems inevitable to conclude that the 2014 edition is essentially in line with previous versions.

Now more than ever it is necessary that medical ethics acknowledges that medicine, society and medical jurisprudence have changed and doctors must be given new rules in order to protect both patients' rights and dignity of the profession. The physician's right to refuse to perform treatment at odds with his own clinical beliefs cannot be the only mean to safeguard the dignity of the profession. A clear boundary must also be established between medicine and professionalism as well as the criteria in determining the scientific evidences that physicians must follow. This has not been done in the Italian code of ethics, despite all the controversy caused by the Stamina case.

## Key Words:

Medical ethics, Italian code, Patient's self-determination, The minor's consent, Advance directives, Clinical risk prevention.

## Introduction

Eight years after the previous version, in May 2014 the new code of medical ethics came into

force. During this eight-year period, the way people tend to see medicine and doctors as the answer to all their expectations was further strengthened.

More and more often the doctor is seen as a provider of services rather than a physician who, by virtue of his extensive studies and continuous updating, performs a very difficult activity.

Indeed, in the easiest case scenario the doctor has to make difficult decisions in a short time, running risks and being misled by clinical and instrumental results is frequent and the margin of error is always lurking in the background<sup>1</sup>.

Moreover, the increasing severity of the Italian courts makes it more and more difficult to treat patients implementing the belief that medicine can cure the vast majority of illnesses.

This has resulted in a misunderstanding and even a trivialization of the medical profession.

Faced with this situation, you do not need to be a doctor to understand that this can generate a question of professional identity.

Doctors now have to ask themselves: "What is my work in today's society?", "Can I still practice medicine without having to use adjectives, such as defensive?", and also: "How do I figure out which scientific standard I must follow in order to be ethically irreproachable?"

In this paper, the authors aim to examine how the long awaited new Code deals with the justified questions previously mentioned, trying to highlight the new trends and what has already been expressed in the previous version of the code, regarding the following issues: the ethical responsibility of the patient, the patient's self-determination, the minor's consent, the advance directives and the clinical risk prevention. Finally, a brief comparison with the code of medical ethics of other countries, such as France, the United Kingdom and the United States, will be done.

### ***Where is Italian Medical Ethics Going?***

The new code seems to be moving towards an increasing emphasis on risk prevention as well as an apparent increase in the freedom of self-determination of the patient. In the next subsections we will consider these issues individually.

#### ***Ethical Responsibility of the Patient***

Section 33 of the new Code reaffirms the duty of understandable and comprehensive information on prevention, diagnosis, prognosis, possible diagnostic and therapeutic alternatives and the foreseeable risks and complications. But it immediately adds a rule that was not contained in the Code of 2006: the physician must inform «*on the behaviours that the patient will have to adopt in the healing process*» as well.

The latter provision, on the one hand, extends the duty to inform and, therefore, the scope of medical responsibility. On the other hand, requires patients to stick to the behaviours specified by the physician as needed to improve their health conditions.

The duty to adopt certain behaviours limits the freedom of the patient, but this limitation does not appear to be ethically unacceptable.

In this regard, it is undisputed that the information and the subsequent acquisition of consent are aimed at establishing a “therapeutic alliance” between doctor and patient<sup>2</sup>. The concept of therapeutic alliance goes beyond a mere contract between opposing parties each pursuing its own interest. Through the informed consent, in fact, doctor and patient reach an agreement that puts them on the same side (just like two allies) as bearers of the same interest to the best benefit for the patient.

As doctor and patient are allies and have an equal relationship, both must behave in an appropriate manner to achieve the best therapeutic results. Obviously, patients can refuse treatments. But when they consent, they also accept to behave in the way indicated by the doctor. Thus through consent, the patient assumes a moral duty of fairness in order to avoid making the doctor’s efforts useless, for example by means of rehabilitation or diagnostic and pharmacological treatments after discharge. Therefore, the new version of section 33 appears to be ethically correct.

The code of medical ethics of the American Medical Association is the one that clearly gives the patient the responsibility for their own choices in the field of health care.

*Opinion 10.02* states that «*patients have the responsibility to communicate openly, to partici-*

*pate in decisions about the diagnostic and treatment recommendations, and to comply with the agreed-upon treatment program*»<sup>3</sup>.

#### ***The illusory Increase in Patient’s Self-Determination***

Over the last 40 years, the importance of personal freedom has grown in society. So the rules of professional conduct should not remain indifferent to these developments. Indeed, the latest editions of the Italian code of ethics were characterized by a steady and significant growth of patient’s self-determination.

In this respect, the role of the child and the relevance of advance directives seem to be ambiguous in the new Code.

#### ***The Minor’s Consent***

In 2006, the Italian Code of medical ethics introduced the duty both to inform the child compatibly with his age and to take into account his will. The physician was obliged to inform the Court only when the legal representative of minors or adults who lack legal capacity refuses a treatment which cannot be postponed<sup>4</sup>.

Instead the current version of section 37 states that the Court must be involved in the decision even when the necessary treatment is refused by the minor provided that he is informed and advised.

But this provision cannot be interpreted as an improvement of the protection of the minor’s freedom. The reason is that section 37 adds that, despite the opposition of the minor or his legal representative, the physician should promptly proceed to perform any treatment deemed as necessary and urgent without informing the Court.

The French Code of Medical Ethics considers the protection of a child’s health more important than his freedom of self-determination. In fact it establishes that, in case of an emergency, the doctor must provide the necessary care even without consent of the legal representative. But if the opinion of the child can be obtained the physician must take it into account as far as possible<sup>5</sup>.

The child’s freedom is better protected by the General Medical Council in the Explanatory guidance of the Good clinical practice.

First, at the age of sixteen, teenagers are presumed to be able to make their own decisions in the field of health care. Even children under 16 years can be considered capable depending on their maturity and ability to understand<sup>6</sup>.

Moreover, the explanatory guidance establishes that doctors «*should usually abide by any decision*

young people have the capacity to make themselves» although they must encourage minors to involve their parents in important decisions<sup>7</sup>.

However, only in Scotland relatives cannot authorize the treatment refused by a minor capable of making a decision. Conversely in England, Wales and Northern Ireland the doctor «*should seek legal advice*» where he considers that «*treatment is in the best interests of a competent young person who refuses*»<sup>8</sup>.

### *The Relevance of Advance Directives*

Consistent with the opinion of the Italian National Committee for Bioethics<sup>9</sup>, the new section 38 of the code provides that advance directives must meet the following requirements: *a)* must be written, signed and dated by a capable person; *b)* must be preceded by written medical information; *c)* must be medically and logically consistent with the patient's condition; *d)* the doctor bases his conduct on the respect of dignity and quality of life<sup>10</sup>.

However, the doctor is not obliged to follow these advance directives. The situations in which it is more difficult to comply with the previously expressed will, are: *a)* when there is a considerable length of time between the manifestation of the will and the time of treatment; *b)* when the patient makes the advance directive before falling ill; because there is a risk that the subject could be less aware of the choice he/she has made; *c)* the anticipated rejection, even regarding specific treatments, still lacks precise references in curing the illness, therapeutic alternatives and the exact consequences of the refusal<sup>11</sup>.

Moreover, the last subsection of section 38 adds that the doctor, «*in relation to the clinical conditions, must in any case proceed to perform all the treatments which are deemed necessary and urgent*». Therefore, the importance of advance directives does not seem apparent in the new code.

These rules do not allow to clearly solve cases of advance refusal of blood transfusions by Jehovah's Witnesses. On the one hand, this advance directive should be respected when it satisfies the above conditions set by the first three subsections of section 38. On the other hand, however, the last subsection of the same article seems to allow the doctor a wide freedom of action because blood transfusions are usually necessary and urgent treatments. However, the physician must also take into consideration the provisions of section 35 (informed consent and dissent), according

to which the doctor does not undertake or continue any diagnostic procedures and/or therapeutic interventions without the previous obtaining of informed consent or in the presence of informed dissent, therefore because a blood transfusion is a "therapeutic intervention" the doctor cannot administer it if the patient has expressed his dissent in written form to that procedure.

The French Code recognizes the importance of advance directives as well. But in cases of urgency it requires the physician to perform the treatment without consulting the relatives<sup>12</sup>.

The rules applied in the UK are more inspired to the principle of autonomy.

In cases of advance refusal it must be presumed that the person was capable of refusing when he made the decision, unless there are reasons to believe otherwise.

However, in an emergency situation, where there is not sufficient time to properly investigate, treatment should be performed anyway as long as there is the opportunity of prolonging the patient's life, improving his condition or the managing of his symptoms<sup>13</sup>.

The Code of Medical Ethics of the American Medical Association is even more intended to protect the freedom of choice. According to the last section of the Opinion 2.20, a proper substituted judgment or best interests analysis is sufficient to discontinue life-sustaining medical treatment even if the patient is not terminally ill or permanently unconscious<sup>14</sup>.

Even with respect to the treatment of the patient in a final compromised state of consciousness, the solution adopted by the new Code is far from clear.

In this case, the current Code requires the doctor to continue pain therapy and to perform treatment of supportive care only "until deemed proportionate, taking into account the advance health care directives".

However, the lack of clarification regarding the evaluation of the concept of "ethical inappropriateness" and "quality of life", which depend on the moral relativity of the patient, leaves in this way all the responsibility to the physician<sup>15</sup>. Therefore, it appears to be contradictory the obligation of the physician to take account the advance health care directives.

According to the French code, which is much clearer, the physician must refrain from any unreasonable obstinate investigation or treatment and can choose to continue or not to undertake those treatments which appear useless, dispro-

portionate or have no purpose other than artificial life support<sup>16</sup>.

The approach American Medical Association is also mainly focused on therapeutic freedom. The surrogate's decision is almost always accepted by the doctor unless one of the following conditions occur: (1) in case of the unavailability of a family member willing to be the patient's surrogate decision maker; (2) when there is a disagreement among family members and no decision maker is designated in an advance directive; (3) when a health care provider thinks that the family's decision is not at all what the patient would have decided if competent; and (4) when a health care provider believes that the decision cannot reasonably be judged to be in the best interests of the patient<sup>17</sup>.

#### *Growing Importance of Clinical Risk Prevention*

The 2006 version of the Code, section 14, required the physician to detect, report and assess errors in order to improve the quality of care through the understanding of the causes of adverse events and the implementation of the behavior necessary to prevent future errors.

Instead, the current Code requires doctors to perform four specific obligations: *a*) compliance to good clinical practice; *b*) attention to the information process and acquisition of consent as well as the communication of an adverse event and its causes; *c*) the ongoing development of training activities on care safety procedures; *d*) detection, reporting and evaluation of sentinel events, errors, near misses and adverse events.

So the new code provides a clearer obligation in disclosing errors<sup>18</sup>.

However, the regulation of the general medical council is much more detailed. In fact, under the section significantly entitled «*Show respect for the patient*», subsection 55 states that doctors must: *a*) honestly offer an apology when the patient suffers harm or distress under their care; *b*) give complete and prompt reasons for what has happened<sup>19</sup>.

The American Medical Association provides the mandatory application and development of mechanisms for error detection and analysis of their causes. But the obligations are different depending on whether there is a medical liability.

Even when the standard of care has been met or the proof of causal link is lacking, the physician must at least show concern for the damage suffered by the patient. Such behaviour can never be construed as an admission of liability.

Instead, when an error occurs physicians should explain «*the nature of the error and the measures being taken to prevent similar occurrences in the future*» because it may decrease the risk of liability<sup>20</sup>.

Therefore, the rules approved by the American Medical Association require the revelation only in cases of actual liability. That seems to be an interesting middle ground between full disclosure and the possibility of defences based on silence.

In fact, in the international literature some studies have shown the usefulness of error disclosure for the purpose of reducing disputes, provided that the disclosure is made with particular procedures<sup>21</sup>, while others have reached the opposite conclusion<sup>22</sup>.

On the one hand, the general revelation of all adverse events and their causes, raises concerns for the following two reasons: first, in cases as complex as that of the medical liability, the demonstration of both error and causal link is unlikely to be reached. In any case, it would require so much time it would be incompatible with the purpose of preserving the patient's confidence.

Secondly, disclosure may involve the risk of losing insurance coverage<sup>23</sup>.

On the other hand, choosing not to reveal even the slightest cases of error is anachronistic in terms of ethics. The solution of hiding an actual liability would violate the principles of bioethics: because silence is aimed at preventing the injured patient from getting compensation, thereby violating the principles of beneficence, non-maleficence and justice; and the principle of autonomy because if the doctor hides an error, the correct decision-making process of the patient would be altered<sup>24</sup>.

## **Conclusions**

Since these are the most significant changes in the new code, it seems inevitable to conclude that the 2014 edition is essentially in line with previous versions.

Now more than ever it is necessary that medical ethics acknowledges that medicine, society and medical jurisprudence have changed and doctors must be given new rules in order to protect both patients' rights and dignity of the profession. The physician's right to refuse to perform treatment at odds with his own clinical beliefs cannot be the only mean to safeguard the

dignity of the profession<sup>25</sup>. A clear boundary must also be established between medicine and professionalism as well as the criteria in determining the scientific evidences that physicians must follow. This has not been done in the Italian code of ethics, despite all the controversy caused by the Stamina case<sup>26,27</sup>.

Although the ethical codes of France, the United Kingdom and the United States are not deeply detailed, they are certainly more advanced than the Italian one.

The French Code states that the physician must provide the patient care based on data acquired by science<sup>28</sup>.

The importance of data and scientific knowledge as daily guidance of the doctor is even more evident in the rules of the General Medical Council: the physician must «*provide effective treatments based on the best available evidences*»<sup>29</sup>.

The American Medical Association explains more fully the role of the doctor in the medicine of the XXI century. According to the Opinion 9.14 of the American Code of Medical Ethics, physicians should be active in developing the quality of health care by: *a) knowing best care practices; b) controlling the quality of the treatments they perform through quality improvement tools such as peer review; c) demonstrating dedication to developing and disseminating performance improvement measures*<sup>30</sup>.

Clearer rules of conduct do not restrict the freedom of the physicians, they are intended to give doctors reference points in order to reduce the increasing risk of litigation. Doctors who are increasingly facing a risk of liability feel isolated and this has fostered defensive medicine, which has caused both a waste of resources together with a deterioration of patient care.

In this respect, the regulation of the American Medical Association is very effective: *a) treatments should not be performed simply because patients insist on them; b) denial of treatment should be based on acceptable standards of care, «not on the concept of “futility,” which cannot be meaningfully defined»*<sup>31</sup>.

Moreover, according to the Opinion 2.095, in order to determine whether a treatment should be considered as within the standard of care, physicians should consider the following ethical principles: «(1) *degree of benefit (the difference in outcome between treatment and no treatment)*, (2) *likelihood of benefit*, (3) *duration of benefit*, (4) *cost*, and (5) *number of people who will benefit*»<sup>32</sup>.

The recent Italian code of ethics does not take into consideration the fact that law Courts require the physician to apply the maximum prudential measures without considering costs, whereas the American Medical Association shows that the decision to carry out a treatment is correct only if its cost is evaluated.

---

### Authors' contributions

GMV, FPB and EM have made substantial contributions to conception and design of the manuscript; SZ performed the bibliography research. All Authors have been involved in drafting the manuscript and revising it critically for important intellectual content and all of them have given final approval of the version to be published.

---

### Conflict of Interest

The Authors declare that they have no conflict of interests.

### References

- 1) FEDERSPIL G, VETTOR R. I limiti della medicina: probabilità, errori e linee guida. In Aa.Vv. Il rischio in medicina oggi e la responsabilità professionale. Milan: Giuffrè, 2000: 97.
- 2) LAVIN M. What doctors should call their patients. J Med Ethics 1988; 14: 129-131.
- 3) American Medical Association. Code of Medical Ethics, Opinion 10.02 - Patient Responsibilities (2001), available online at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion1002.page?>
- 4) CALCAGNI C, CECCHI R. Deontologia medica. Dalla deontologia ippocratica alla bioetica. S.E.U., 2008: 109.
- 5) CONSEIL NATIONAL DE L'ORDRE DES MÉDECINS. Code de déontologie médicale, art. 42 (article R.4127-42 du CSP) (2012), available online at: <http://www.conseil-national.medecin.fr/sites/default/files/codedeont.pdf>.
- 6) GENERAL MEDICAL COUNCIL. Consent guidance: Involving children and young people in making decisions, art. 55 (2008), available online at: [http://www.gmc-uk.org/guidance/ethical\\_guidance/consent\\_guidance\\_involving\\_children\\_and\\_young\\_people.asp](http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_involving_children_and_young_people.asp).
- 7) GENERAL MEDICAL COUNCIL. 0-18 years guidance: Young people who have capacity, art. 29 (2007), available online at: [http://www.gmc-uk.org/guidance/ethical\\_guidance/children\\_guidance\\_29\\_capacity\\_to\\_consent.asp](http://www.gmc-uk.org/guidance/ethical_guidance/children_guidance_29_capacity_to_consent.asp).
- 8) GENERAL MEDICAL COUNCIL. 0-18 years guidance: If a young person refuses treatment, art. 31 (2007), available online at: [http://www.gmc-uk.org/guidance/ethical\\_guidance/children\\_guidance\\_30\\_33\\_refuse\\_treatment.asp](http://www.gmc-uk.org/guidance/ethical_guidance/children_guidance_30_33_refuse_treatment.asp).

- 9) COMITATO NAZIONALE PER LA BIOETICA. Dichiarazioni anticipate di trattamento (2003), available online at: [http://www.governo.it/bioetica/testi/Dichiarazioni\\_anticipate\\_trattamento.pdf](http://www.governo.it/bioetica/testi/Dichiarazioni_anticipate_trattamento.pdf).
- 10) BUSARDÒ FP, BELLO S, GULINO M, ZAAMI S, FRATI P. Advance health care directives and "public guardian": the Italian supreme court requests the status of current and not future inability. *Biomed Res Int* 2014; 2014: 576391.
- 11) CACACE S. The refusal of medical treatment, to avoid any misunderstanding. *Riv It Med Leg* 2014; 36: 547.
- 12) CONSEIL NATIONAL DE L'ORDRE DES MÉDECINS. Code de déontologie médicale, art. 37 (article R.4127-37 du code de la santé publique) (2012), available online at: <http://www.conseil-national.medecin.fr/article/article-37-soulagement-des-souffrances-limitation-ou-arret-des-traitements-261>.
- 13) GENERAL MEDICAL COUNCIL. End of life care: Doubt or disagreement about the status of advance refusals, art. 72-73 (2010), available online at: [http://www.gmc-uk.org/guidance/ethical\\_guidance/end\\_of\\_life\\_advance\\_refusals\\_doubt\\_or\\_disagreement.asp](http://www.gmc-uk.org/guidance/ethical_guidance/end_of_life_advance_refusals_doubt_or_disagreement.asp).
- 14) AMERICAN MEDICAL ASSOCIATION. Code of Medical Ethics, Opinion 2.20 - Withholding or Withdrawing Life-Sustaining Medical Treatment (1994), available online at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion220.page?>.
- 15) PATUZZO S, TAGLIARO F. The new Italian code of medical ethics (2014): ethical and legal issues. *Riv It Med Leg* 2015; 37: 843.
- 16) CONSEIL NATIONAL DE L'ORDRE DES MÉDECINS. Code de déontologie médicale, art. 37 (article R.4127-37 du code de la santé publique), available online at: <http://www.conseil-national.medecin.fr/article/article-37-soulagement-des-souffrances-limitation-ou-arret-des-traitements-261>.
- 17) AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS, OPINION 2.20 - Withholding or Withdrawing Life-Sustaining Medical Treatment, art. 4, available online at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion220.page?>.
- 18) TURILLAZZI E, NERI M. Medical error disclosure: from the therapeutic alliance to risk management: the vision of the new Italian code of medical ethics. *BMC Med Ethics* 2014; 15: 57.
- 19) GENERAL MEDICAL COUNCIL. Show respect for patients, art. 55 (2013), available online at: [http://www.gmc-uk.org/guidance/good\\_medical\\_practice/respect\\_patients.asp](http://www.gmc-uk.org/guidance/good_medical_practice/respect_patients.asp).
- 20) AMERICAN MEDICAL ASSOCIATION. Code of Medical Ethics, Opinion 8.121 - Ethical Responsibility to Study and Prevent Error and Harm (2003), available online at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8121.page>.
- 21) IEDEMA R, SORENSEN R, MANIAS E, TUCKETT A, PIPER D, MALLOCK N, WILLIAMS A, JORM C. Patients' and family members' experiences of open disclosure following adverse events. *J Qual Health Care* 2008; 6: 421-432.
- 22) STUDDERT DM, MELLO NM, GAWANDE AA, BRENNAN TA, WANG YC. Disclosure of medical injury to patients: an improbable risk management strategy. *Health Aff* 2007; 1: 215-226.
- 23) GRAZIADEI M. What we wrong? Tort law, personal responsibility, expectations of proper care and compensation. In Graziadei M. *European tort law* 2008. Springer Wien, 2009: 2-24.
- 24) EDWIN AK. Non-disclosure of medical errors an egregious violation of ethical principles. *Ghana Med J* 2009; 1: 34-39.
- 25) SIEGHART P. Professional ethics - for whose benefit? *J Med Ethics* 1982; 1: 25-32.
- 26) FRATI P, FRATI G, GULINO M, MONTANARI VERGALLO G, DI LUCA A, FINESCHI V. Stem cell therapy: from evidence-based medicine to emotion-based medicine? The long Italian way for a scientific regulation. *Stem Cell Res Ther* 2013; 5: 122.
- 27) BUZZI F, TASSI G. Judges' «supremacy» subjection of medical science and weakness of administrative and political governance regarding health-care treatments improperly qualified as «compassionate». *Riv It Med Leg* 2014; 36: 415.
- 28) CONSEIL NATIONAL DE L'ORDRE DES MÉDECINS. Code de déontologie médicale, art. 32 (article R.4127-32 du CSP) (2012), available online at: <http://www.conseil-national.medecin.fr/article/article-32-qualite-des-soins-256>.
- 29) GENERAL MEDICAL COUNCIL. Good medical practice, art. 16 (2013), available online at: [http://www.gmc-uk.org/guidance/good\\_medical\\_practice/apply\\_knowledge.asp](http://www.gmc-uk.org/guidance/good_medical_practice/apply_knowledge.asp).
- 30) AMERICAN MEDICAL ASSOCIATION. Code of Medical Ethics, Opinion 9.14 Quality (2009), available online at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion914.page>.
- 31) AMERICAN MEDICAL ASSOCIATION. Code of Medical Ethics, Opinion 2.035 - Futile Care (1994), available online at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2035.page?>.
- 32) AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS, OPINION 2.095 - The Provision of Adequate Health Care, available online at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2095.page?>.