

The relationship between medical ethics and the legal system in Italy: food for thought

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Abstract

Relations between ethics in general – and medical ethics in particular – and legal systems are complex and have been extensively examined in the literature. The topic is important not only for ethicists and jurists, but also for members of the public, who benefit from the services offered by the professions. While the Italian Institute of Health does not claim to propose new avenues for exploration of the relations between ethics and legal systems, it offers some food for thought in the ongoing debate.

Key words

- bioethics
- code of ethics
- legal aspects
- medical ethics

FOREWORD

The mission of the Italian National Institute of Health (Istituto Superiore di Sanità, ISS) is the promotion and protection of public health both in Italy and at international level, through “research, surveillance, regulation, control, prevention, communication, consultation and training” [1, 2].

As an “increasingly central actor in national and international decision-making processes” [1] the ISS is particularly conscious of the dynamics between institutions, health professionals and the public, in which the codes of ethics of health professionals are a major point of reference.

The ISS intends to take part in the ongoing debate on the role of “Codes of Medical Practice” in the professional setting and in society, as well as on the relations between codes of medical ethics and legal systems.

In Italy the “Code” is not incorporated in legislation.

Ethics and the law have always been closely entwined and have been abundantly examined in the specialised literature [3]. Without presuming to offer new approaches to the relations between them, the present article offers some food for thought on the issue, with particular reference to Italy.

DEFINITIONS

A code of ethics can be succinctly defined as a written statement of principles or standards of right conduct. Codes of ethics may also contain values, rules and guidelines.

According to “The new dictionary of medical ethics”, codes “serve principally to lay down rights and duties which should underpin professional practice” [4].

The meaning of the term “code” is nonetheless not clearly defined. Pritchard defines a “code” as “a collection of aspirations, regulations, and/or guidelines that represent the values of the group or profession to which it applies”, adding that “codes come in many different forms (... and) bear a variety of names” [5].

In the third edition of the “Encyclopedia of bioethics” Spicer draws a distinction between “(1) professionally generated documents that govern behaviour within the profession; (2) documents that set standards of behaviour for professionals but are generated outside the profession; and (3) documents that specify values and standards of behaviour for persons who are not members of a profession” [6].

Frankel identifies three types of “standards”: aspirational (“a statement of ideals or broadly worded principles to which practitioners should strive”, where “(t) here is no attempt to define with any precision notions of right and wrong behaviour”); educational (“which combine principles with explicit guidelines that can help the individual professional make more informed choices in morally ambiguous situations”); and regulatory (“which include a set of detailed rules to govern professional conduct and to serve as a basis for adjudicating grievances, either between members or between members and outsiders”) [7].

Harrison’s classification is partially identical to Frankel’s, what he calls a “code of ethics” corresponding exactly to Frankel’s “aspirational” standards. What Harris calls “codes of conduct” instead include educational and regulatory clauses (*i.e.* the second and third categories proposed by Frankel) and are prepared for the benefit and regulation of the members of the group. Har-

ris's third category covers "codes of practice", meaning documents written for non-members [8].

At the international level, after the Second World War several institutions drew up codes of conduct and other documents setting out the "duties, principles, rights and responsibilities that are global in the sense that they apply worldwide, without reference to nations or national boundaries" [9]. Some of these documents refer to multiple professional categories while others are specific: "In the ethics of health care, explicit statements of ethical standards have been formulated for physicians and other health professionals, for persons conducting medical experiments involving human subjects, for administrators and for patients and other laypeople who make health care decisions" [10].

Although the law and ethics are clearly distinct, codes of ethics and of professional practice frequently fall into a "grey area" not covered by the statute book, where they provide indications of correct behaviour. Similar indications are also found in other documents, such as guidelines, regulations and statutes.

CODES OF ETHICS IN ITALIAN LAW

In Italy professional orders and colleges (or, in their absence, associations or societies) have at various times issued their own codes of conduct. The Italian legal system considers such codes as "non-pecuniary contracts" [11].

Until fairly recently there were no explicit references to codes of conduct in Italian legislation. They were specifically introduced in Articles 22 and 31 of Law no. 675 of 31st December 1966 on the "protection of persons and other subjects in regard to the processing of personal data" [12], and in the subsequent Legislative Decree no. 196 of 30th June 2003 which approved the "Code for the protection of personal data" [13]. Article 12 ("Codes of Conduct and Professional Practice") of this Code requires that the Italian Data Protection Authority "shall encourage, within the framework of the categories concerned and in conformity with the principle of representation, by having regard to the guidelines set out in Council of Europe recommendations on the processing of personal data, the drawing up of codes of conduct and professional practice for specific sectors, verify their compliance with laws and regulations by also taking account of the considerations made by the entities concerned, and contribute to adoption of and compliance with such codes". In the wake of this law two codes were drawn up concerning the processing of data acquired for purposes of economic, social, behavioural, epidemiological and biomedical research: the "Code of conduct for professions whose activities produce statistics within the national statistics system" [14] and the "Code of conduct and good practice for the processing of personal data for statistical and scientific research purposes", which is addressed to professionals who process data for scientific or statistical purposes outside the national statistics system [15].

Codes of conduct are also mentioned in Law no. 42 of 26th February 1999 [16], which contains provisions applying to healthcare professionals (though it refers only to nursing, technical and rehabilitation personnel

and in Law no. 251 of 10th August 2000 [17], which regulates the nursing, technical and rehabilitation healthcare professions as well as obstetricians. This law reiterates the meaning of codes of conduct but is not addressed to all healthcare professionals.

The issue of codes of conduct is addressed in part of a bill currently before Parliament, the "Decree enabling the Government to legislate in the matter of clinical drug trials, together with measures to update essential levels of care, and to reorder the healthcare professions and the managerial levels of Health Ministry employees" [18]. The bill envisages that the national healthcare professional federations emanate a "code of conduct, approved by their respective national councils and addressed to all members of professional associations in Italy". The bill further expects the associations of healthcare professionals and their respective national federations to "promote and ensure: the independence, autonomy and responsibility of the professions and of professional practice: professional/technical quality; enhancement of the social function (of healthcare); the protection of human rights and of the ethical standards of professional practice indicated in the codes of conduct, in order to ensure the protection of individual and collective health".

THE "CODE OF MEDICAL CONDUCT" IN THE ITALIAN LEGAL SYSTEM

The earliest "Code of Medical Conduct" in Italy was drawn up by a committee established by the Federazione Nazionale degli Ordini dei Medici (FNOM, National Federation of Physicians' Associations) in 1953 and approved in 1954 [19]. Although the code was initially conceived above all as a means of reciprocal guarantees, over the years it has increasingly become a guide for physicians.

The current version was adopted by the National Federation of Physicians' and Dentists' Associations (FNOMCeO) on 24th May 2014. On 19th June 2016 [20] Article 56, regarding "informational advertising in the health sector" (which had been challenged by the Data Protection Authority on 24th September 2014) [21] was amended.

Article 1 of the Code defines the nature of the Code, identifies the subjects to whom it is addressed and formalises its compulsory nature for all members of the Associations: it "defines the set of regulations, informed by principles of medical ethics, that govern the professional conduct of surgeons and dentists (...) listed on their professional registers. In agreement with the ethical principles of humanity and altruism and with the civil principles of subsidiarity, it commits the physician to protect individual and collective health by monitoring the dignity, decorum, independence and quality of the profession. It also regulates the private conduct of physicians where this is relevant and affects the decorum of the profession. Physicians must know the Code and comply with the guidelines attached to it: they must take the professional oath, which is a constituent part of the Code".

Article 2 ("disciplinary authority") confirms, among other things, the duty of each member to know the con-

tents of the Code: “Non-compliance with, or breach of the Code or of the Oath, even when due to ignorance, constitutes a disciplinary offence and shall be considered in accordance with the procedures and terms established by the professional association”. This article corresponds to Article 5 of the Criminal Code, which states that “ignorance of the law does not excuse” (*ignorantia juris non excusat*). The article was reviewed by the Constitutional Court, which in its decision no. 364/88 [22] declared it to be partially unconstitutional because of its failure to exclude “unavoidable ignorance”. The Court pointed out that each person is duty-bound to be acquainted with basic legal precepts and that any person who operates in a specific professional field who is ignorant of the criminal laws regulating that field is culpable. While these provisions refer to criminal laws, they can be applied to Article 2 of the “Code of Medical Conduct”.

Later versions of the “Code of Medical Conduct”, down to the current one, tended to follow the evolution of legislation, adapting the code to new laws. But good practice was, at least until recently, considered an extra-legal matter. With its ruling no. 10842/03 [23], the Court of Cassation affirmed that: “unless they are incorporated into legislation (...), provisions laid down in codes of conduct drawn up by professional associations have neither the essence nor the characteristics of laws such as those subject to Article 12 of the Civil Code, but are an expression of the powers of self-government of the Associations (or Colleges), so that their authority (...) derives not only from professional custom but also from the regulations issued by the above Associations (or Colleges) to set down the duties of correct behaviour with which their members should comply and to regulate their disciplinary function”. In other words, the Court stated that none of the ethical provisions issued by professional associations can be considered as laws of the land unless they are transposed into legislation, because they lack the essential requisites.

This approach, however, was overturned by the same Court in its ruling no. 26810/07, which stated that breaches of regulations laid down in professional codes should be treated as breaches of the law. In other words, the Court considered such codes as rules of law with which members of professional associations must comply and which complement objective law for the purposes of identifying disciplinary offences [24]. With this ruling breaches of regulations contained in codes of good practice are considered in the same way as ordinary legislation, and carry the same consequences.

This approach was again confirmed by the Court of Cassation in ruling no. 16145/08, which stated that disciplinary measures “are to be treated as legislation supplementary to general clauses, which are to be interpreted taking account of different legislative sources, albeit of infralegislative rank, such as regulations of professional ethics” and that the “Code of Medical Conduct” “represents a legal source that can be qualified as a ‘legal standard’ whose legitimate interpretation is a *quaestio iuris*” [25].

The Constitutional Court also affirmed that “membership of an Association creates a professional obligation to behave in a manner compatible with the

objectives pursued by the Association” [26] and that, given that current legislation entrusts professional associations with disciplinary authority over their members, the regulations contained in codes of practice are *de facto* also legal rules that form the basis for charges of illicit conduct.

Put briefly, the Italian “Code of Medical Conduct” contains extra-legal rules applicable within the professional category, but of which legal doctrine and case-law in the matter of professional duty are increasingly taking note.

This trend is set to accelerate if and when a bill currently before Parliament becomes law. This bill, “Provisions concerning the professional responsibility of healthcare personnel” [27], does not explicitly mention the “Code of Medical Conduct”, but gives special consideration to guidelines. Health professionals are required, in the exercise of their healthcare duties – except in very specific circumstances – to comply with rules of good clinical practice and care and with the recommendations laid down in guidelines drawn up by scientific associations and research institutions listed in a Health Ministry decree and included on a special register.

THE CODE OF MEDICAL CONDUCT AND THE LEGAL SYSTEM: FOOD FOR THOUGHT

Although there may be even major differences between the approaches to medical ethics of different nations, medicine, like disease, knows no boundaries: a common feature in all the codes of medical practice drawn up in the last century is an explicit reference to the Hippocratic tradition [28], which forms the backbone of most such codes [29].

This is certainly true of the “Principles of European Medical Ethics” [30] adopted by the European Conference of Medical Orders (CEOM) on 6th January 1987 (to which an Appendix was added on 6th February 1995), and of the European Charter of Medical Ethics” [31] adopted on 11th June 2011 by the CEOM in the wake of the “Sanremo consensus document” [32] promoted by the FNOMCeO.

Among the useful features of codes of ethics are their ability: to encapsulate in a single document all the indications concerning the values, principles and standards that each profession should pursue; to draw a clear line between what is and what is not tolerated; to encourage the public’s trust in the different professions.

Some of these benefits could be enhanced if the texts of these codes were incorporated into legislation [33]. According to Paul Honigman “For medical ethics to be effective, they must be incorporated either directly or indirectly in the law of the land, at least in a democratic society. ‘Indirectly’ means that the state may delegate to a subsidiary body the responsibility for ensuring that ethical standards are maintained and enforced. Medical ethics which are divorced from the law of the land are likely to be merely academic and lacking in effectiveness. This does not mean that there can never be occasions when in moral and idealistic terms it is the duty of the medical practitioner to uphold abstract principles of medical ethics even if the law of the land dictates otherwise” [34].

In some nations the codes of medical practice have been variously incorporated into legislation.

In France, for instance [35], the “Code de déontologie médicale” was updated a number of times before the current version of 7th May 2012 [37] was ratified by a decree of the Conseil d’État and incorporated in the “Code de la Santé Publique” (in Articles R.4127-1 to R.4127-12). It is nonetheless worth noting that the code is included not in the legislative section of the “Code de la Santé Publique” but in the regulatory section.

In Germany the professional order of each Land adopts a code of medical conduct in accordance with the relevant laws of the specific Land (which also specifies which issues the code may address). In this way the code of conduct assumes the characteristics of the source of law typical of public law institutions, to which category professional orders belong [38].

In Italy several rulings concerning professional liability (in both civil and criminal proceedings) have treated the “Code of Medical Conduct” as a set of rules in common law against which the conduct of individual physicians can be measured [39].

The possible incorporation of the complete text of the “Code of Medical Conduct” into legislation might make it more binding on physicians, though the transposition of rules of good practice into legal regulations could prove problematic [40].

At this point it is worth recalling that opinions expressed in legal literature and case law, and even in current legislation, may conflict with standards of good practice and place physicians in seriously difficult positions.

Nor should it be forgotten that the art of medicine differs from other professions, as the Constitutional Court aptly pointed out in its ruling no. 282 of 22nd June 2002 [41] (which declared the constitutional illegitimacy of Law no. 26 passed on 13th November 2001 by the regional government of the Marche, which had suspended the application of electroconvulsive treatment, lobotomies and other psychosurgical therapies). The Court referred explicitly to the “Code of Medical Conduct” to support the view that “as the practice of

medicine is based on the acquisition of scientific and experimental knowledge that is continually evolving, the underlying rule in this field consists in the autonomy and responsibility of the physician”, who “must adapt his decisions to scientifically validated data and methodologically sound evidence” (as established in Article 12 of the 1996 “Code of Medical Conduct” then in force). The Court then stated that decisions taken by regional lawmakers that are not based on “acquisitions of specific technical-scientific knowledge that has been validated by the competent authorities” but are based on “assessments of a purely political nature” cannot override “fundamental principles based on current state legislation”, and concluded that the “Code of Medical Conduct” presents a “meeting-point between the physician’s professional decisions and his duty to take account of scientific and experimental evidence”.

In light of all the above there is good reason to pursue the search for ways to improve the relations between ethics and the law, bearing in mind the complex nature of both. But it would be inappropriate to transform the code into legislation, as this would lead to over-legislation. As we have seen, the fact that the “Code of Medical Conduct” has not been incorporated into legislation does not prevent it being recognised as being legally binding.

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