The legal and forensic value of the guidelines

Francesco Paolo Busardò
Matteo Gulino
Carlo Angioni
Gianluca Montanari Vergallo
Irene Catarinozzi
Laura Iovenitti
Paola Frati

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

Corresponding Author:
Francesco Paolo Busardò
Department of Anatomical, Histological, Forensic and Orthopaedic Sciences, “Sapienza” University of Rome, Viale Regina Elena 336, 00161 Rome, Italy
E-mail: francesco.busardo@uniroma1.it

Summary

Scope: the Authors examine the current jurisprudential context relative to the juridical and forensic value of the guidelines in order to illustrate what are the rules that regulate their use in diagnosis and therapy.

Materials and Methods: the Authors analyze the case decided by the sentence no 8254/2011 of Supreme Court of Appeals considering its clinical characteristics in relation to the legal principle affirmed. The compatibility of this sentence with the principles enshrined in law and the rules of professional conduct are evaluated.

Results and Conclusions: the principle stated by the Supreme Court in the judgment here reported, establishes that guidelines developed by requirements of economic nature cannot influence physicians in their therapeutic choices, and it clashes with the jurisprudence of the Constitutional Court, which emphasizes the need to consider in the health field both the legal aspect and the financial resources in order to achieve a complete protection of the patient. Moreover, the decision under consideration introduces a rule that does not allow doctors to fully exercise their professional freedom in the interest of patients without the risk of receiving administrative penalties or having to respond to legal liability.

KEY WORDS: guidelines, right to health care, medical responsibility.

Background

Health is considered an inalienable right of the individual: it belongs to the person and originates from most universal affirmation of the right to life and physical integrity, representing one of the main expressions. In fact, starting from the basic guidelines established by the International Conference of Health (New York, 1946) and adopted by the World Health Organization (WHO), health is defined as: “a state of complete social well-being and not merely the absence of disease or infirmity”. Health is a fundamental right of every human being (1). In accordance with the declaration of the WHO, the main international conventions establish the right to health as a fundamental right of the individual and of the community and its protection as one of the duties of States. Under the Universal Declaration of Human Rights: “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family” (2).

In Article 32 of the Italian Constitution is stated that: “The Republic safeguards health as a fundamental right of the individual and collective interest, and guarantees free medical care to the indigent. No one can be forced to a specific medical treatment unless required by law. The law may in no case violate the limits imposed by respect for the human person” (3).

This rule shows a dual profile of its vagueness and generality, guaranteeing the right to health, both in its individual and in the collective dimension, and allowing the enjoyment of social rights according to values and criteria of homogeneity and uniformity (4).

This right is realized in a set of rules – which set the funding and organization of health services, by imposing a proper use of resources (5) useful for the promotion, maintenance and restoration of well-being of all people, without differences and ensuring equality of citizens (6). However, the Italian NHS has not been able to deal with the increased costs due to a lack in the strategic use of resources and for inefficiency and waste resulting from a non-optimal and often obsolete management (7).

To solve these problems, with the Legislative Decree no. 502/92 and 517/95 the NHS has been reformed based on the guidelines of corporatization, regionalization of services and competition between public and private. Starting from the creation of public utility (8), have been adopted mainly aimed at saving approaches. These have had the effect of reducing the rate of growth of expenditure, eliminate waste and to achieve good efficiency results (9). This reduction in spending resulted in a change of nature, once inviolable, of the right to health, subject to the financial rules.
The legal and forensic value of the guidelines

So, over the past few years, there has been a change in the role of physician, which has become a qualified employee of a company more and more attentive to costs and bureaucratic and administrative issues. Therefore we can highlight how the economic problems can affect the choices of the physician, which is often found to operate tied to logical and corporate directives on the one hand and the need to protect the right to health of the patient on the other.

As a result, the right to health is found to be increasingly the subject of medico-legal dispute: the physician's professional responsibility has become therefore a phenomenon of vast proportions and strong social impact, so to influence the actions of doctors and the same structures (10).

So the medical professional liability in Italy and of course the rest of Europe, has become a very topical issue for the growing consideration that, at the social level, is now dedicated to the right to health as a fundamental right worthy of the highest protection.

At the same time, however, the increasing demand for health services determines the incessant increase of harmful circumstances (11). The situation is complicated for two reasons: a) the evolution of technology and scientific research – exploiting the results in terms of profit – b) the need to balance the protection of the right to health with the inevitable problem of limited economic resources.

On the one hand the new acquisitions in the field of diagnosis and treatment have improved outcomes and reduced the risks associated with certain medical and surgical acts. On the other hand, claims for compensation for supposed medical errors or the countless deficiencies from in the management of the National Health Service are increasing (12).

The Italian legislation, in this context, is generic and lacking and the penal law has been expressed through certain stages of development (13). Initially it was in favour of doctors, then progressively more critical to the health professionals (14, 15), up to become imbalanced in favour of patients.

Currently, the law has become a “subsystem” with respect to the rules of the penal code (16-18) and civil (19) about guilt: the judges have the role of mediators between the lack of regulations and rich and heterogeneous case law (20).

In fact, the legislature is not willing to act in this context, resulting in an “empowerment” of the judiciary that is gradually assuming the role of mediator.

The case that we intend to comment – in which the pair between the need to protect the right to health and the limits imposed by the Regional Decrees and guidelines – is difficult to solve, provoking a discussion in both medical and legal field.

The Case

The case goes back to June 9, 2004, a time when Mr. X was transported to the hospital where in urgency, while performing a coronary angiography, was subjected to a coronary angioplasty with application of drug-eluting stents, after myocardial infarction with severe respiratory failure. Subsequently, on June 14 was then transferred from the ICU to the Cardiology with a diagnosis of pulmonary edema, acute myocardial infarction with pre-existing conditions such as hypertension in current smoker. In the subsequent days was subjected to multiple investigations including ECG holter.

Nine days after admission, the patient showed asymptomatic, with negative objectivity, with disappearance of erythema previously expressed, and therefore was discharged with a letter to the treating physician which stated the diagnosis of acute anterior myocardial infarction and edema extended acute pulmonary edema, with prescription drug therapy, perform an ergonometer test after two months and a myocardial scintigraphy after six months.

His medical history showed that the patient in question were smoker, hypertensive, suffering from severe hypercholesterolaemia, hypertriglyceridaemia, obesity, all indicators of a dysmetabolic syndrome.

The following night the resignation of the subject was seized with coughing and dyspnoea, and transported to the hospital, arrived there in cardiac arrest. Cause of death determined by autopsy, was an arrhythmia (fibrillation tachycardia).

The doctor was accused of having discharged the patient – with results of recent myocardial infarction extended to nine days after surgery of interventricular artery angioplasty – causing death due to heart attack, occurred a few hours after the discharge.

The role of the guidelines has been instrumental in establishing liability. For the judges of first instance this conduct was not considered free from fault because even though the value of these rules – as general guidelines related to an abstract case – the doctor should have assessed specifically the case entrusted to his judgment, to detect any particularity, to take the most appropriate decisions even if departing from those rules (21).

From the history was evident that the patient had a coronary risk, aggravated by the severity of the infarction. In the subsequent degree of judgment, the physician was acquittated as the magistrate positively evaluated compliance with the guidelines by the physician. Moreover, the level of residual cardiac mechanical function (ejection fraction 29%) was within the parameters established by the standards, and there were not signs predictive of adverse electrical events. At the discharge the patient was asymptomatic for days with markers of necrosis normalized.

The judge concluded for acquittal because the patient’s condition – though critical – were no different or more severe compared to those of other patients in the same clinical conditions and therefore such as to require a different treatment.

With sentence no. 8254 of 2011, the Italian Supreme Court overturned the decision of the Court of Appeal of Milan, explaining as follows: “in the practice the physician must, with knowledge and belief, pursuing the sole purpose of caring for the sick using the current diagnostic tools and therapeutic, without being influenced by regulations or guidelines that are not relevant.
to the tasks entrusted to it by law and the resulting responsibilities”.

This applies in particular to the guidelines provided by the health administration to ensure cost effectiveness of the hospital: the physician’s ethical duty to put the health of the patient before any other need.

Discussion and Conclusions

The gradual spread in recent years of recommendations, guidelines and protocols demonstrates the need for the scientific community to order medical knowledge in operational and strategic systems aimed to raising the standards of quality (22).

This trend is common to most European countries and meets the first difficulty where it is not possible to find a universal definition of guidelines, although it is generally considered as “criteria developed in a systematic way in order to help the decisions of doctors and patients with regard to most appropriate health care” (WHO), or clinical behavior recommendations produced through a systematic process in order to assist physicians and patients to decide what are the most appropriate method of support specific clinical circumstances. Their non-binding character that makes them profoundly different from protocols determines legal and medico-legal implications of relevant entities where this is used to continue the investigation of an alleged professional liability (22, 23).

Since the innumerable variants interact with their practical application – like the inevitable obstacles of organizational, behavioral, the need for the rationing of resources or even the expectations of patients – guidelines should be considered a useful tool in certain situations (but not always), taking account of ability, cultural background, common sense and sensitivity of the physician. To the coroner, the recommendations of the guidelines – although important to ensure uniformity in professional behaviors in the light of the best available evidence and knowledge – must be translated into daily clinical practice by physician and centered on the specific patient, in view of its individual peculiarities and its demands (22, 24).

According to this, it is basically inspired by the decision of the Supreme Court, which considered guilty the doctor who had followed the guidelines, since he had not exercised his cultural autonomy of a patient considered to be “special”, and had not checked the health condition of the patient, which made him a patient at risk. For the judge, in fact, the adherence to guidelines can not add nor remove the right of the patient the possibility of obtaining medical services most appropriate since they represent a tool based on criteria of cost management and not to the actual needs of the individual patient. There is a certain incongruity with the current reorganization of the Italian National Health Service that from 1992 is strongly marked by policies of privatization and healthcare cost containment (22-24).

The same evolution of the Italian Constitutional Court marks this trend so much so that several times claimed that the right to health “from the point of view of welfare is subject to the decisions of the ordinary legislator, that is configured as a conditional right to the decisions of the legislator through balance with other constitutionally protected interests among which is included the consideration of the organizational and financial resources available” (25) or as “in the presence of limited resources it is unthinkable to be able to spend without limit because it is the expense that must be commensurate with the actual financial resources, which influence the amount and level of health care”. That judgment has the purpose to prevent “waste of resources completely incompatible with the national interest that, in the current difficult situation of public finances, can not be reflected by the optimal utilization of available resources” (26). It is generally agreed that, although the protection of health has a constitutional basis, it is still subject to large areas of political and administrative discretion, with regard to the dual profile of content of the performance and the implementation of services.

The right to health as the other social rights has undergone a process of relativization that has characterized it as “Right financially affected” (27). This setting is not easily compatible with the statement made by the Court of Cassation, which stresses that no one is allowed to precede the economic logic to the logic of protection of health, adding that the decision to discharge a patient must have medical nature, non-statistical, and should be related to the physical and mental condition of the patient, to the prognosis about the clinical course and the opportunity to continue care at home. The logic of care must be based on the protection of health and the choice of the physician must be related to the conditions of the patient.

Even more peremptory is the affirmation of the Court when it states that “nothing is known, however, about the contents of these guidelines or the authority from which they come or their level of scientific or the aims to which they are pursued or is not known whether the same represent a further guarantee for the patient or if they are just a tool to ensure cost effectiveness of the management of the hospital”.

It would be appropriate that the law Courts take into account the condition of the physicians, tied between company guidelines and their real possibility of being able to carry out their work professionally.

References

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17. Art. 42 c.p. “ Nessuno può essere punito per un’azione od omissione preveduta dalla legge come reato, se non l’ha commessa con coscienza e volontà “.
19. Art. 2236 c.c. “ Se la prestazione implica la soluzione di problemi tecnici di speciale difficoltà, il prestatore d’opera non risponde dei danni, se non in caso di dolo o colpa grave “.