

Guidelines and best practices: remarks on the Gelli-Bianco law

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Abstract

The paper's authors aim to elaborate on the innovations brought by law n. 24/2017, issued by the Italian Parliament with a close focus on art. 5, which pertains to the drafting of guidelines and the adoption of best practices. The guidelines constitute in fact an element of innovation brought by the above-mentioned law, and compliance with them can shield from possible liability those health care professionals who find themselves embroiled in professional accidents while in the fulfillment of their duties. Besides, there are several critical aspects within the law that need to be highlighted as well. As far as best practices are concerned, the lawmakers who drafted the legislation make no mention as to the standards of evidence needed in order to characterize any given professional behavior as "best practice". The reform appears unlikely to be effective in providing doctors with clear behavioral standards, thus reducing the margin for liability claims against them. *Clin Ter 2018; 169(2):e82-85. doi: 10.7417/CT.2018.2059*

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Elements of novelty in the law "Gelli-Banco"

Following prolonged and contentious parliamentary proceedings (1), Italian lawmakers have provided a new legislative framework aimed at regulating so called medical (and in a broad sense, health care-related) liability, and have enacted law n. 24/2017, denominated "provisions on patient care safety and professional liability of health care providers" (2,3). The law's main purpose is to restore the balance in patient-doctor relationships, staving off liability claims, which have adversely affected the health care system and given rise to defensive medicine practices, i.e. doctors (out of concern that they may be sued for indemnity payments), recommending a diagnostic test or medical treatment that is not necessarily the best option for the patient, but one that mainly serves the function to protect the doctors themselves against possible claims of medical malpractice, by proving that all viable therapeutic options have been used, thus avoiding any possible charges (4).

Such a law, known as Gelli-Bianco bill, has been crafted for the main purpose of ensuring the so-called treatment safety, set forth in article 1 as a key element in the preservation of the constitutionally protected right to enjoy good health. The regulation mandates that safety must be guaranteed through proper prevention tools and health care risk management, in conjunction with the most effective use of structural, technological and organizational resources available. It further spells out the obligation of health care professionals to contribute to risk prevention while administering health care procedures.

Health ombudsmen are appointed as guarantors of the right to health care, on a territorial basis.

In pursuance of article 3 of the new piece of legislation, the Italian Ministry of Health has instituted a national "observatory", meant to provide oversight of sound health care practices. Such a newly-established body is tasked with collecting data (from "regional centers for health care risk management", instituted according to article 2 of the new law) about risks and adverse occurrences, in addition to the causes, scope and recurrence of financial burdens stemming from litigation (5). Furthermore, guidelines are provided based on the counsel of scientific societies and technical associations of health care professionals in order to define suitable measures aimed at preventing and managing health care risks, as well as overseeing the implementation of good practices and the training and updating of health care personnel (6).

The above mentioned provisions, in addition to art. 4 (*data transparency*), bears witness to the lawmakers' concern with the repercussions of so-called health care risk not only on the system of care and protection, but on financial sustainability as well, as evidenced in article 4, which calls for data-collection with regards to indemnity payments awarded.

Article 6 is designed to regulate medical liability for health care professionals, by repealing subsection 1 of Balduzzi law (7) and crafting a new article into the Italian Criminal Code: art. 590-sexies (negligent liability for death or injuries in health care), which states: if death or injuries have been caused by lack of skill, conviction is to be ruled

out, provided that the guidelines published by the National Health System had been complied with, or, in the absence of these, best health care practices, based on the assumption that such recommendations were well-suited to the specific case.

Articles 7 to 13 deal with aspects of tort law and indemnity payments. Article 7 specifically deals with civil liability of health care facilities (whether private or public) and individual professionals.

Health care institutions exercising their functions, according to the Italian Civil Code, articles 1218 and 1228, must answer for negligence or wrongdoing from health care staff (doctors, nurses or technicians) who operate within the facilities even though the latter have been chosen by the patients, and are not employed directly by the hospital. Such provisions hold valid in cases of professional services administered “*intra moenia*” (services performed by doctors within the facilities but outside of hospital working hours), or in conformity with an agreement, as part of research trials or through so-called telemedicine. As for health care professionals, they are liable for their actions according to article 2043 of the Italian Civil Code, unless they prove to have acted in pursuance of contractual agreements between them and their patients.

Legislators have set out to regulate aspects related to out-of-court settlement and insurance implications as well (see article 8, citing “*mandatory settlement attempts*”). Article 10 subsection 1, specifically mandates that all health care institutions, whether public or private, have compulsory insurance in order to cover third parties for damages caused by personnel operating within the facilities. Subsection 3 mandates that such workers buy insurance, sustaining the costs themselves, to cover damages arising from “*major guilt*” (8).

Article 15 pertains to the appointment of technical consultants and expert witnesses in civil and criminal trials centered on health care liability claims.

The judicial organ is due to appoint expert witnesses, to be chosen among those registered in professional orders cited in subsections 2 and 3 of article 15, devoid of any conflict of interest, either in the current proceedings or other related ones. Furthermore, in the process of appointing expert witnesses, the courts will make sure that they have the requisite skills and expertise which may have been acquired through specific training programs.

New guidelines and best practices

Drawing on what has been well-established practice for years in other countries, particularly English-speaking ones, Italy has, through this new legislation, devised a system of accreditation, oversight and upgrading of existing guidelines. They need to be crafted by public and private bodies and institutions, as well as scientific and technical orders and associations listed in a specific registry. In that regard, article 5, subsection 1, mandates health care professionals - administering preventive, diagnostic, therapeutic, palliative, rehabilitation or forensic-medical procedures - to abide by the recommendations laid out in the guidelines, but for different peculiarities in individual cases (9-11).

It is necessary to clearly lay out the requirements that scientific bodies or societies need to meet in order to legitimately issue binding guidelines for doctors. The Italian Ministry of Health, therefore, released a decree on 2nd August 2017. Overall, such requirements include: a) to be seated in at least 12 Italian regions; b) to be representative of at least 30% of specialists for any given area of medicine; c) to have a charter created by public deed, abiding by an array of prescriptions, among which: 1) a statement of independence of the body or society and of its legal representatives, certifying their non-involvement in any business activity, with the sole exception being the activities comprised in the national medical training program (ECM); 2) no trade union related purposes should be pursued; 3) members are required to actively partake in the body’s or association’s activities and in its decision-making process; 4) being non-profit in nature; 5) an obligation to release and divulge all scientific activities undertaken by the newly-formed association, via an official website, properly updated at all time; 6) a set of measures ought to be put in place for the purpose of dealing with possible conflicts of interest that may arise; 7) the creation of a scientific committee designed to verify and oversee the nature and quality of all research activities performed and of the scientific production, according to sets of standards and bibliometric indicators with scientific validation and acknowledgement by the international scientific community (12).

Discussion

The above cited prescriptions arguably prove that Gelli law discounts the importance of so-called “best accredited practices”: the Balduzzi decree had equated them with the official guidelines, whereas the current legislation lessens their impact as merely “ancillary” indications, which become relevant only “in absence” of guidelines acknowledged and identified within the law itself.

Lawmakers have gone to great lengths to spell out a set of requirements in order to gain access to the roster of accredited scientific societies and technical associations, and yet the criteria based on which the official guidelines will be crafted still appear murky, from the standpoint of contents. The only clear element is that the new array of guidelines is due to be vaguely vetted by the Italian National Institute of Health (13). In fact, any set of guidelines and eventual updates will have to be encapsulated into the National Guidelines System (NGS) and released on the National Institute of Health’s website, after a thorough review of the methodologies applied according to clearly defined standards set forth by the Institute itself. Neither the newly-enacted piece of legislation nor the ministerial decrees spell out any set of criteria that scientific societies ought to abide by in order to devise guidelines and the Higher Health Institute at the following oversight stage (14).

Furthermore, the above-mentioned requirements set in order to be listed in the ministry-sanctioned registry that enables scientific societies to issue guidelines have drawn criticism from scholars and experts, since they supposedly neglect the phase of scientific quality verification, while give too much weight to formal aspects and the national

coverage of the new organizations. According to the official requirements, in fact, a new scientific society that failed to cover at least 12 Italian regions and to represent at least 30% of specialists in a given area would be barred from releasing state-sanctioned guidelines even if it could indeed boast a top-rated scientific production and valuable international connections, which the decree fails to consider altogether (15).

A release from the Italian Ministry of Health, issued on 23rd October 2017, is set to clarify some practical ambiguities within the decree, although it failed put to rest all criticisms. All of the law's shortcomings are in fact unsolved, among which the lack of any mandate for scientific societies and bodies to devise guidelines in conformity with the highest international quality standards, to best look after patients' health (16).

Gelli law has been enacted to meet the needs of doctors in terms of clarity and certainty, but now seems to be leading to some sort of "state-medicine", liable to hinder medical progress and penalize patients as well. (17) Let's picture, for instance, the case of a doctor who may be acquainted with innovative medical practices and treatments, still not contemplated by official guidelines: they could not be adopted, in favor of possibly less effective treatment compliant with the guidelines.

Conventional wisdom has led many to express doubts and concern over the increase in the number of experts who play a role in the drafting of official guidelines, due to the risk that some individuals may be included with interests other than the patients' health protection (e.g. economic interests) (18). Such concerns, which are far from unfounded, in our view, are not the only ones: there is a risk that an element of financial sustainability in health care risk management may sway and interfere with the elaboration and contents of the guidelines (19,20). Currently, it is in fact difficult to predict how to balance financial considerations against health care safeguards, and to what extent the former are likely to affect the latter in the identification of a set of guidelines by which doctors and other health professionals will have to abide.

Guidelines used to be hazy and ill-defined under the previous legislation, Balduzzi law. The reform, however, seeks to make such binding prescriptions clearer, unequivocal and easily consultable. Such changes are arguably for the better. Nonetheless, based on the requirements set by the Italian Health Ministry, it cannot be ruled out that several different bodies may be licensed to issue guidelines, which may even be at odds with each other. How can two sets of legally binding guidelines be in disagreement with one another, thus mandating different conducts and practices?

As for the relief provided for doctors' legal positions, it does not cover every case.

In fact, if damages arise from instrumentation used by doctors to perform any treatment or from the health care facilities as a whole, article 2051 of the Italian Civil Code applies. On the basis of the above-cited article, it is not enough to prove that no wrongdoing or misconduct ever took place, but evidence is required of the event's accidental nature (21,22).

Gelli law draws a clear distinction between officially sanctioned guidelines and best practices, in that the latter are distinctly separate from the former by virtue of their

not being officially categorized and referred to only as replacement of official guidelines. Other than that, the notion of "best practices" with regards to clinical care is still hazy and ill-defined (23,24). It is therefore necessary to wait for them to be established on a case-by-case basis, whenever the official guidelines turn out to be inapplicable and different sets of recommendations and suggestions, grounded in medical science, lend themselves to be adopted in any particular instance (25-27).

Conclusions

It is worth raising concerns and doubts over the actual possibility that the official guidelines and the mention of best medical practices may constitute clear behavioral standards for health care professional, leading to a lower incidence of litigation against them. The guidelines openly refer to the treatment of individual diseases, but not uncommonly, patients suffer from multiple ones. The application of such guidelines in highly renowned institutions may hamper the development of innovative medical practices, whereas it might turn out hard to achieve in other hospitals. Best medical practices, on the other hand, are not as well-defined in terms of contents: lawmakers fail to either outline them or point out exactly what scientific evidence criteria are to be met in order to view any doctor's behavior as compliant with the standards of "best practice" in court, whether in tort or criminal law, according to article 6. (25) Such a scenario is bound to give rise to far-reaching ramifications in terms of inconsistencies in judgments and risks of contrasting rulings for a single case. The deriving circumstances appear to run counter to the need for certainty of judgment, which is strongly felt in all sectors; better clarity of rules may in fact increase the likelihood of out-of-court settlements, leading to a better-functioning judicial system (28).

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