Guidelines, good practices and best clinical health practices: valuable guidance for physicians and judges?

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Abstract

Enactment of law n. 24, 8th March 2017, (so-called “Gelli-Bianco” law), has given rise to substantial innovations in the realm of medical liability: on the one hand, an attempt has been made towards redefining the boundaries of professional liability, for the purpose of curbing the use of “defensive medicine”; on the other hand, there is the effort to delineate good medical conduct by means of “institutionalization” and a greater degree of consistency of guidelines and good clinical health care practices. There are, however, thought-provoking cues concerning the relationship between the two concepts, which can be sensibly developed, even in light of international scientific literature. This paper has been designed to critically analyze both principles and their relation within the framework of the newly enacted piece of legislation denominated “Gelli-Bianco”, in light of the Italian jurisprudence while at the same time, searching for common ground in international law, particularly Anglo-Saxon countries, aiming to clarify the lawmakers’ ultimate goal as well as the law’s practical scope of application.

Key words: law n. 24/2017, guidelines, defensive medicine, medical treatment safety

Introduction

In the realm of medical Italian liability, law n. 24, from 8th March 2017, (so-called “Gelli-Bianco” law), currently in effect, represents an updated replacement of the previous “Balduzzi” law, n. 189, passed on 8th November 2012. One of the most significant innovations has to do with the possible criminal developments of medical liability. Lawmakers have attempted to stem the application of criminal liability for doctors. A guiding principle in drafting the new legislation was an intention to curb the use of “defensive medicine”, which doctors may resort to out of fear of medico-legal consequences, in order to ward off lawsuits, by prescribing unnecessary or redundant tests and screening procedures, for no other reason than preventing possible claims (1).

Specifically, the Gelli-Bianco law, in art. 6, subsection 2, asserts that: «Insofar as an adverse even has occurred on account of negligence, medical liability shall be ruled out as long as recommendations laid out in the specific set of guidelines have been complied with as prescribed by law, or in absence of these, the good clinical health care practices, provided that such prescriptions have proved to be suitable for the specific case».

Negligence, in order to result in non-liability, must be tied to the sound application of guidelines or best clinical practices. In order to further clear up such a concept, an in-depth analysis of both concepts is necessary.

The connection among guidelines, good practices and best clinical health care practices

The conception of guidelines has been clearly defined for many years (2, 3), both in health care settings and legal ones, as a set of non-cogent rules, laid out on scientific grounds as recommendations, aimed at the improvement of clinical performances, patient outcomes and the use of resources. A standardization of medical procedures has thus been pursued, based on so-called Evidence Based Medicine (4), i.e. medical practice grounded in a statistically significant body of proof.

In order to enable health care providers to gain access to more clearly defined standards of conduct, lawmakers have put in place a mechanism devised to select binding guidelines, as stated in article 5: «Health care operators, while providing services for preventive, diagnostic, therapeutic palliative, rehabilitation, and forensic medical purposes, must abide by the recommendations laid out in guidelines, except for individual case specificities, released under subsection 3, and devised by public bodies and institutions and scientific associations of health care professionals registered in a specific database instituted by decree of the Italian Health Ministry, to be issued within ninety days from the enactment of the new legislation, to be updated biennially...». 
It is noteworthy that the obligation to comply with guidelines applies to forensic medicine services as well, which was not the case in the previous law, where there was a mere reference to health care operators “in the fulfillment of their duties”.

Nonetheless, guidelines cannot comprise and contemplate all possible clinical situations. Bearing that limit in mind, the legislators have firstly spelled out that: «In absence of the above-mentioned recommendations, health care operators shall abide by good clinical practices».

Therefore, the latter are obviously outweighed by guidelines, whereas in the previous law, n. 189/2012, repealed upon the enactment of the new one, good practices and guidelines were considered to be on a par: both contributed to the determination of standards of care that physicians needed to meet while handling individual cases. Furthermore, legislators have taken steps to safeguard the doctor’s decision-making autonomy (5). In fact, the guidelines are binding for doctors «except for individual case specificities». Thus, if any given case presents traits that would make guidelines unfit to achieve the patient’s best interest, the obligation to comply with them is overridden (6). Consequently, doctor conduct in similar situations shall be assessed according to good practices. The important caveat «except for individual case specificities» is meant to preserve doctor discretionary power in the decision-making process. Law n. 219 from 22nd December 2017 has further reasserted that patients cannot demand from doctors any treatment that run counter to laws, professional ethics or good clinical health care practices (7, 8, 9, 10).

It appears that the legislators have acknowledged the impossibility to constrain the doctors’ work through overly restrictive rules, which would severely limit their scope of action and make it impossible to adapt recommendations to the peculiarities of each real-life case. Guidelines and good practices, as previously pointed out by the Italian Supreme Court of Cassation in multiple rulings (11), do not merely constitute “instructions” to be followed no matter what, nor are they dogmatic imposed rules, but rather pliable tools to be molded according to each clinical case scenario. Doctors cannot and should not be up in a position to operate having to select the diagnostic and therapeutic options that best suit his or her cautionary needs, even to the detriment of different, more effective practices, which may not yet have been included in the guidelines, or other choices that would be more effective for a given case.

The weight carried by guidelines seems to have grown on an international scale. In Anglo-Saxon legal doctrine, for instance, the standard to be applied in case of medico-legal claims was the so-called Bolam test (12), according to which doctors cannot be charged with negligent conduct as long as they are found to have acted in compliance with practices acknowledged or deemed to be appropriate by a scientific or medical community (a responsible body of medical opinion) (13). The degree of ability and competence required of health care operators in order to shield them from liability in court is not undefined or generic, but rather related to the specific profession, and must meet the average standards (ordinary skill) supposed to befit any operator in the fulfillment of their professional duties. Recent legal trends have apparently leaned towards stricter assessment standards, which would live up to the Bolam test, for which courts of law would apply a more interventionist approach: one of such strategies is the creation and application of guidelines (14), as highlighted in a 2006 study published in the Medical Law Review Journal. The same article, however, despite the assumption that such tools will gain ever greater relevance in medico-legal proceedings, warns of the danger related to a decrease in the discretionary power of doctors.

The principle of «Good clinical practices» is even more controversial, from a scientific as well as legal standpoints: a current definition which came to be adopted in legal doctrine is «protocols, strict and predefined codes of diagnostic and therapeutic conducts that are designed to lay out procedures that health care operators must rigorously abide by in a given situation» (15). Nevertheless, from a medical and forensic practice perspective one is bound to point out a lack of clarity in some respects, or even confusion at times, especially in the juxtaposition with guidelines: the legislators have in fact refrained from indicating the degree of relevance and weight that scientific evidence must carry in order to be included in the elaboration of good practices, nor are any sources or scope of knowledge given to draw upon. There is, in legal doctrine, a duality of interpretation that can be essentially summed up in two antithetical positions of those who lean towards a clearly-defined distinction between the two elements, guidelines and good practices, and those in favor of a total juxtaposition (16).

A further moot point has to do with good clinical health care practices and their counterparts on an international level. The definition appears to be borrowed from Anglo-Saxon literature, where however two phrases are found that could engender considerable confusion as to the original form of what the Italian law indicates: «Good Clinical Practice» and «Best Clinical Practice».

Based on what international literature asserts, the phrase «Good Clinical Practice», which dates back to the early 1990s (1, 17), is meant as a high ethical and quality standard in the field of research, planning, execution, registration and reporting of clinical trials where human subjects are involved. Such a standard has been conceived to provide safeguards for those involved and to preserve the credibility of such trials: yet, the title, which has been borrowed by the Italian lawmakers upon drafting the national regulations (18) betrays a substantial element of confusion, lacking any distinction between “good practices” and “guidelines”, with the latter intended as precondition for the creation of good practices.

Legislators, however, in law n. 24/2017, have attempted to stray from the previous acceptance, which appears associated with a different age and setting, by adding the adjectives “clinico-assistenziali” (“clinical-health care related”). The more befitting definition is undoubtedly «Best Clinical Practice», which is reminiscent of the concept of «Best Practice» adapting it to a medical setting. Good practice should be intended as an organization approach associated to industry and ever more frequently identified with management and administration, a set of praxeological rules aimed at the improvement of firms and businesses with a degree of stability in time. It could also be intended as a system of work optimization for the purpose of achieving better performances, higher quality in one’s work based on
the reliability of effectiveness testing: it is safe to say that it is a quality-centered formula.

From a wide-ranging review of international literature (19), although not recent, it is possible to cut out an appropriate definition of “good practice” to be applied to the health care setting, which goes beyond merely quality-based considerations: it represents the “best way” to identify, collect, assess, spread and implement information, and to monitor outcomes of clinical treatments and interventions on individual patients or groups. Information needs to be well-grounded in terms of safety, effectiveness, convenience, ethical and social values and the overall quality of the interventions made. The ultimate goal is the improvement and preservation of public health, along with risk containment and the optimization of resources.

Well before law n. 24/2017 was enacted, another set of good practices was well-known in Italy. There has been, since 2008, an observatory focused on good practices for patient safety, which has as its stated mission to gather and spread the best experiences in various fields of medicine, by yearly meetings in close cooperation with the Ministry of Health and the Technical Committee of Regions and Public Administration, fostering information exchange and clinical risk management strategies, and constantly aimed at the advancement and improvement of public health. More recently, through law n. 24/2017, a National Observatory of good practices relative to safety in health care within the National Agency for Regional Health Care Services (AGENAS). The two bodies share the same objectives, such as the gathering of data on a regional basis concerning clinical risks and adverse events, the devising of measures aimed at clinical risk containment and management, the monitoring of best practices toward greater treatment safety, as well as the training of health care personnel; yet, the latter body has the peculiarity of having been phased in by national law. The National Observatory has been instituted via a ministerial decree on 29th September 2017, which also mapped out the body’s structure, composition, priorities and ultimate stated purposes (20). It is worth noting that under article 2, subsection 3, the decree identifies as major contributors to the observatory the same profiles tasked with the definition of guidelines, with the addition of professional figures from different federations and associations, or experts on specific relevant subjects: «In order to properly discharge the duties spelled out under subsection 1, letter e), the Observatory may draw upon the expertise of scientific societies and technical-scientific associations of health care professionals and experts in all relevant subjects, including patient associations.»

The connection between guidelines-good practices and malpractice

“Gelli-Bianco” Law entails that doctors may be deemed incompetent despite their compliance with guidelines and good practices befitting a given clinical case. Such development poses a glaring contradiction that could make the whole reform untenable. Yet, the Supreme Court Joint Sections managed to set forth a case-based analysis: the failure to comply with guidelines or good practices should not be punished if their execution takes places with only minor variations from an optimal implementation (21).

Such a legal trend is applied to both guidelines and good health care practices, since only those are mentioned in article 6 of the “Gelli-Bianco”. A breach of good safety practices, however, under article 3 of the same law, would necessarily lead to criminal liability. In fact, such practices fall under the category of cautionary rules, designed to lower the risk of adverse events, such as those procedures put in place to prevent hospital-acquired infections (22,23).

Under British codes, liability is generally found if a violation of the “standard of care” is proven. Such a principle is commonly interpreted as a procedural, quality, diagnostic and therapeutic standard, widely accepted and applied by a large share of the scientific community, and whose violation, however, does not necessarily constitute proof of medical negligence. There might be, in fact, different sets of recommended practices, just as widely acknowledged by a different part of the scientific community, or more innovative ones and better suited to specific cases, that might warrant a medical conduct disregarding the generically defined “standard of care”. Conversely, it is possible, however rarely, that full compliance with a “common practice” may not necessarily prove the doctor defendant’s innocence, since such a practice may be deemed by the courts to be negligible in and of itself (24).

Therefore, it is apparent that guidelines and “standard of care” are closely intertwined, although there cannot be a total degree of assimilation between the two, given the less strict nature of the “standard of care”. In fact, the definition of any medical treatment as standard does not relieve judges of their duty to verify whether there could be different diagnostic or therapeutic options that are just as reasonably tenable. Nevertheless, on the heels of law n. 24/2017, the non-compliance with guidelines befitting the peculiarities of any given case should constitute sufficient grounds to convict the physicians, even though the treatment specified in the guidelines were not the only one acknowledged by the international scientific community.

In that regard, misunderstandings should be cleared up. The failure to comply, on the part of doctors, with the guidelines spelled out in law n. 24/2017 is not in itself tantamount to liability. The above cited ruling from the joint sections of the Italian Supreme Court has confirmed that liability is found only in cases where it is proven that the guidelines were well-suited to the specific case and its peculiarities (25). That highlights a distinct difference between the guidelines under law n. 24/2017 and other documents codifying leges artis, i.e. binding rules to be strictly enforced with no exception, and without the discretionary power to adjust according to individual cases. Protocols are usually viewed as falling under this category. Yet, good safety practices should belong to it as well, since law n. 24/2017 codifies the necessity to adapt only guidelines and good practices (and not good safety practices) to individual cases (5). Besides, strict leges artis may be found within documents denominated “guidelines”, such as those laid out by ministerial decree in order to regulate in depth every single practice of medically assisted procreation (26, 27, 28).
Conclusions

In conclusion, it is safe to assume that although “good practices” are clearly outweighed by guidelines in the prescriptions of law n. 24/2017, it is impossible to unequivocally outline elements in order to conclusively distinguish between them on the basis of their contents. On the contrary, at the international level, the common goals of guidelines and good practices have led to a merging rather than a differentiation, or even to a reversal of their respective intrinsic values compared to the Italian Gelli law. Hence, good practices are not trumped and outweighed by guidelines, but the latter ought to contribute to the definition of what a good practice really is for any given case (“Guidelines FOR good practices”). By the same token, in the Italian legal landscape, a theory has taken hold according to which good practices and guidelines share the same scientific groundwork to draw upon, such as accredited medical manuals, scientific literature, i.e. the overall knowledge and attainments underpinning medical science as a whole and ultimately, “clinical practice” (29).

On that basis, it appears sensible to conclude that law n. 24/2017 does not provide doctors with a valuable frame of reference to guide the choice of treatment in the patient’s best interest. In fact, ascribing a binding valence to guidelines laid out in such a law and limiting the scope of medical liability for those doctors who abide by them, may lead health care professionals to see as a priority the compliance with guidelines, rather than the pursuit of the best clinical solutions for patients. Furthermore, the reliability of the guidelines is often undermined by conflicts of interest (30). Consequently, it would have been preferable to give impartial public institutions the task of drafting guidelines, rather than scientific societies.

Lastly, the reform does not appear to be useful to judges, either: by making it necessary to adapt the guidelines to any single case’s peculiarities, trials will have to verify whether the indications expressed in the guidelines were or were not the best suited for the case in question. As mentioned before, the issue of adaptation to single cases is a distinctive trait of guidelines. It appears therefore inappropriate, on the part of the legislator, to keep using guidelines as a yardstick to verify medical liability. It would be advisable to draw upon the Anglo-Saxon approach of using guidelines as a mere tool in order to determine what constitutes good practice in any given case. That would not necessarily lead back to greater uncertainty for doctors and an increased likelihood of being held liable. In fact, the above mentioned precept of responsible body of medical opinion appears suitable in order to contain the risk of legal claims. In order to avoid legitimizing shoddy practices, on the other hand, it seems reasonable to demand that doctors prove that their choices are grounded in sound clinical motives, possibly based on solid scientific evidence.

The ultimate effects of the reform will have to be conclusively assessed only after the Observatory has become fully operative and the law-mandated sets of guidelines have been released.

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