



Οι Κλινικές Κατευθυντήριες Οδηγίες ως το βασικό κριτήριο για τη θεμελίωση του «Σφάλματος» στην Ιατρική Ευθύνη: Πλεονεκτήματα, προβλήματα και προτάσεις

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ΠΕΡΙΛΗΨΗ

Στην πλειονότητα των έννομων τάξεων, το σφάλμα αποτελεί το θεμελιώδες κριτήριο για τη θεμελίωση της ιατρικής ευθύνης. Η αξιολόγηση της συμπεριφοράς του ιατρού για την εδραίωση ή την απόρριψη του σφάλματος βασίζεται στο απαιτούμενο πρότυπο επιμέλειας που καθιερώνεται από τη νομοθεσία. Εξαιτίας της εγγενούς αοριστίας της έννοιας του σφάλματος, τα δικαστήρια αντιμετωπίζουν δυσκολίες να επιλύσουν τις σχετικές υποθέσεις και οι ιατροί δεν γνωρίζουν τι ακριβώς απαιτεί ο νόμος από αυτούς. Αυτό έχει οδηγήσει στη συζήτηση σχετικά με την ανάγκη να διευκρινιστεί περαιτέρω η έννοια του σφάλματος και να υιοθετηθούν πιο συγκεκριμένα πρότυπα επιμέλειας. Πράγματι, κάποιιο υποστηρίζουν πως ο νόμος θα πρέπει να λάβει υπόψη τις κλινικές κατευθυντήριες οδηγίες καθιστώντας τις το απαιτούμενο σε κάθε περίπτωση πρότυπο επιμέλειας. Παρά τα πλεονεκτήματα ενός προτύπου επιμέλειας βασισμένου σε αυτές, τα προβλήματα που προκύπτουν από τη συγκεκριμένη προσέγγιση είναι σημαντικά και σίγουρα εμποδίζουν την εφαρμογή της προς το παρόν. Το άρθρο καταλήγει με κάποιες προτάσεις που αποδεικνύουν πως θα πρέπει να γίνουν πολλά βήματα ακόμα, προτού οι κατευθυντήριες οδηγίες αποτελέσουν το θεμελιώδες κριτήριο διαπίστωσης του ιατρικού σφάλματος.

Λέξεις Κλειδιά: Ιατρική, ευθύνη, σφάλματα, λάθη, κατευθυντήριες, οδηγίες.

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Clinical Guidelines as the fundamental criterion for the establishment of "Fault" in Medical Liability: Advantages, issues and proposals

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ABSTRACT

In most jurisdictions, fault is the fundamental criterion of imputation of medical liability. The evaluation of physician conduct for the assertion or the rejection of fault is based on the required standard of care established by legislation. Due to the vagueness and case-specific character of the notion of fault, the courts face difficulties to resolve the relevant cases and physicians do not know what the law expects of them. This has led to discussion of the need to clarify the concept of fault and to adopt more specific standards. In fact, some claim that the law should take advantage of clinical guidelines by adopting them as the legal standard of care. Despite the superficial advantages of a guideline-informed standard of care, the problems arising from this approach are significant and certainly hinder its current application. The article closes with some proposals, which show that there is still a long road ahead before guidelines become the fundamental criterion to establish "fault".

Keywords: Medical, liability, fault, errors, mistakes, clinical, guidelines.

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INTRODUCTION

The way the law deals with death or personal injury resulting during the provision of medical treatment has undergone significant changes over the years.¹ Higher expectations of successful outcomes, more complex care and the use of more advanced medical technologies and procedures have had an impact on liability of clinicians both in creating new problems and in raising the standards of care. Despite the differences in health service arrangements, the issues faced by the law are similar across different jurisdictions. ¹ At this point,, it is essential that a terminology clarification in respect of the Greek language be made. Fault is what Greek legal theory calls “σφάλμα” and refers to medical malpractice (=ιατρικό σφάλμα), which –according to the legal theory- is the physician’s conduct that does not conform with the diligence/care, which is required by the medical profession and is necessary in the particular case (=for the particular patient); usually because the doctor does not follow his/her professional standard or because he/she violates the rules of medical science and art (*leges artis*).² The standard of care (=πρότυπο επιμέλειας) and tort liability (=αδικοπρακτική ευθύνη) will also be key notions in our analysis.

Fault is undoubtedly the most traditional, the most widespread and the most important criterion of imputation or foundation of

responsibility;³ the blame is addressed to the agent of a damaging event if he/she has not shown due care in order to avoid damage. ³ This blame is commonly called “fault”. Fault has often been characterized as “the cornerstone” of tort liability.³ Civil liability of physicians is not an exception to the above rule. Fault constitutes the fundamental criterion in the establishment of medical responsibility. Most legal systems have adopted the fault-based system of medical liability with only a few exceptions.⁴ Medical liability is linked to the presence of two main elements: (1) the recognized *standard of care* and the boundaries of the *fault* notion (when the physician’s conduct is negligent according to a generally accepted standard of care) and (2) the burden of proof regulation. ⁵

The patient has the right to obtain compensation only if the physician has committed a fault (either an act or an omission). ⁵ Either in contract or in tort, fault represents the starting point for the patient’s claim. ⁵ The fault can be considered as deviating from the standard of care. ⁵ With reference to the standard of care, the medical professional has to fulfill his duties appropriately, with diligence and in accordance with the current state of medical art. ⁵

For the fault of the physician to be ascertained, it is necessary to analyze and



evaluate his/her conduct in the execution of a specific treatment or diagnosis.⁵ The evaluation of this conduct will be based on the required and established by the legislation (or case-law) standard of care.⁵ In general, the physician has to fulfill his duties by following a professional standard of care, based on a standard of experienced physicians in their specific medical field.⁵

The article will focus on the element of “fault” for two reasons: firstly, it is one of the most problematic areas of medical liability and secondly, it has an “international” character and the article aims at reaching conclusions, which can be applied in various legal systems. The notions of “fault” and the “standard of care” despite the minor dissimilarities (concerning their definition and content) are essentially the same in all countries with fault-based system of medical liability. Nevertheless, despite their use in law and medicine to determine whether medical care provided was negligent or not, the precise meaning of these concepts is often unclear for both medical and legal professionals.⁶

In the following sections after explaining why these notions are highly problematic, we will evaluate the possible positive and negative consequences of making clinical guidelines the legal standard of care and, finally, we will make specific proposals for the introduction of guidelines in the legal landscape.

The Transnational Character of the Article

At this point, it should be noted that the article deliberately makes no reference to specific national legislation or case law. The author intends to give a supranational character to the conclusions reached and the proposals made, so that they may be applied in varying degrees in multiple jurisdictions. Particularly, we will try to draw the general framework regarding the place of guidelines in the approaches of *fault* and the *standard of care* in medical liability legal theory. Furthermore, the fundamental principles governing the use of guidelines in the legal system and practice will be defined. All the remarks, conclusions and proposals will be general enough so as not only to apply to most legal systems, but, at the same time, leave room for adjustments to the special characteristics and the legal culture of each jurisdiction.

Some might claim that this is practically infeasible due to the significant differences both in the legal and the medical fields among western countries. Nevertheless, this is not absolutely accurate. Certainly, there are variations both in the way medicine is practiced and in the way the law responds to adverse events and medical errors. Most variations in the former field are a consequence of differences in health care budget and, thus, in medical equipment, medical technologies etc. Differences in the

law of medical liability are inevitable due to the fact that despite their similar roots, legal systems are never identical, even if they belong to the same category (common law or civil law). Nevertheless, despite the differences, the way particular conditions are treated in modern health care systems is generally similar because medicine is a science, which has begun to get globalized, and it is based on the same principles regardless of the country of practice. Especially, in an era of extended use of Internet and proliferation of new medical technologies, research-based evidence, innovation and novel treatment approaches spread from one country to another. As a result, since guidelines are becoming part of modern medicine in most Western health systems, those developed in countries with a longer tradition in guideline development and promulgation (e.g. USA and UK) are often translated and used directly by clinicians throughout the world. This promotes an increasing international influence in medical practice.

Regarding the legal framework of medical liability, differences between jurisdictions do exist; both in legal theory and in procedural matters. However, as we mentioned before, nearly all jurisdictions continue to base the attribution of medical liability on the same concept, *fault*- the existence of which is judged by measuring the clinician's conduct

against the required standard of care described either in legislation or in case-law. In other words, despite significantly different legal systems, a doctor's conduct in a medical liability case is evaluated based on the concept of fault. Since guidelines are meant to be a tool for the provision of what is considered to be optimal medical care, fault and the standard of care are exactly the grey areas where guidelines have the potential to provide major solutions. Specifically, they could clarify the theoretical legal approaches to medical error, simplify the legal process and offer important help to the legal and medical communities. Consequently, courts would be assisted to mete out justice more effectively.

As guidelines are gradually becoming an integral part of medical practice in most western health care systems, the legal community (legislators, judges, lawyers etc.) will soon be called to reflect on their place and possible uses in the legal system, to deliberate over their possible advantages and drawbacks and to exchange views with the medical community. In the long term, the conclusions reached and the proposals made during these processes may be incorporated into relevant legislation. The topic (is relatively new and that is the reason why in relation to some of its aspects, we will pose questions, most of which are hypothetical and cannot be answered at the moment.



Nevertheless, it should be mentioned that the development of global guidelines, which ensure the appropriate use of evidence, has become one of the core functions of the World Health Organization; specifically WHO publishes (after the approval of its Guidelines Review Committee) patient safety guidelines on particular health conditions (such as chronic diseases, reproductive health, child health etc.).⁷

The Legal Standard of Care: a “Landscape in the Mist”

Under the fault-based approach, the standards used to determine a physician’s liability are vague. As emphasized earlier, what tort law requires of physicians in the numerous grey areas of medical practice is seldom specified concretely.⁸

Specifically, the notions “fault” and “standard of care”, which lie at the heart of the medical liability regime, are unclear. This vagueness, combined with both the inherent uncertainty/inexactness of the medical science and the human body’s complexity, create an extremely “foggy” landscape, especially when medical liability has to be attributed and these notions need to be specified in a particular case. Both the legal and the medical communities are equipped with ambiguous theoretical tools, which need to be specified based on particular facts, a task which has been proved to be difficult and

with equivocal results as far as fairness is concerned.

Due to the inadequate guidance provided to them and the absence of legislation that clearly defines what society expects of its members,⁹ lawyers and judges are often left scratching their heads over which of the two (or more) medical experts to believe,¹⁰ since they have neither the necessary training nor the relevant technical expertise to make an informed decision. As a result, in most jurisdictions standards for the evaluation of a physician’s conduct (and the examination of the appropriateness of his/her practice) tend to be case specific, as the task of developing and applying the standard of care in professional liability cases has fallen to the courts.⁹

The courts have generally been unwilling to crystallize standards and take advantage of the collective wisdom of the judicial decision-making in similar cases.⁹ Concomitantly, health care professionals and the courts remain at a loss for authoritative guidance as to appropriate health care.⁹ This approach using an uncrystallized standard of care in medical liability cases has many weaknesses⁹ and makes it difficult for all the parties involved to assess the possible existence of fault.

Problems with the Uncrystallized Approach

Firstly, health care professionals may be encouraged to adopt costly, medically unnecessary procedures (i.e., defensive medicine). These procedures could expose patients to additional risks because health care professionals lack clear guidance about what the legal system expects of them.⁹ In other words, the aforementioned uncertainty and ambiguity regarding the legal standard of care might lead to the practice of defensive medicine potentially influencing negatively the health system's economic stability and the patients' health.

Secondly, this approach may encourage the institution of marginal claims by failing to provide lawyers with clear, consistent standards about what is expected of health care professionals.⁹ Ethically, and perhaps financially, lawyers are obliged to be committed advocates of their clients and, thus, inevitably interpret unclear, inconsistent standards of care in favor of the viability of their client's claims.⁹

Thirdly, this approach may increase the risk of both false positive and false negative errors in assessing violations of the standard of care.⁹ In the absence of clear, consistent standards, judges are more likely to be influenced by many extra legal factors that may skew their decisions.⁹ One such factor might be health care rationing, which could have significant

effect on the required standard of care and medical liability in general. In fact, without specific and consistent standards (which would ensure that patients receive healthcare services of an accepted quality level) courts could possibly take into account the under-funding of hospitals when they determine the standard of care owed by the organizations and their staff;¹¹

As a result, due to the lack of clearly formulated standards, judges may be unable to reach fair decisions in such a sensitive area, and justice may not be served effectively. This can prove perilous when a clear assertion or denial of medical liability is needed and crucial interests of both parties are at stake.

Finally, the ability of the courts to ascertain and apply the standard of care correctly and consistently is endangered, and concomitantly the public's and the health care professionals' confidence in the judicial system is gradually threatened.⁹

What Could Be the Solution to the "Gordian knot" of Fault-Based Liability?

Assessing the possibility of totally changing the system of medical liability by adopting a no-fault approach is not in the scope of this article. We aim at examining how the fault system can be improved by taking advantage of the evolution of medicine and the latest developments of medical science, the most important of which is the growing

nature of the topic, first we will provide some basic information about clinical guidelines.

Clinical Guidelines: a Very Short

Introduction to their Concept.

Developers

Various efforts to develop guidelines have been pursued by professional societies (for example societies of obstetricians, surgeons etc.), Ministries of Health, health care organizations (Institute of Medicine in the US, NIC in the UK), pharmaceutical companies, insurance companies, patient organizations and various researchers, including private research companies.¹⁵

Ways of Developing

For the health lawyers to have a comprehensive view of clinical guidelines, we should say a few words about the different ways they are developed. A variety of approaches to guidelines development have been described by the Institute of Medicine and the Royal College of General Practitioners.^{16 17} Based upon their potential credibility (which can reasonably be accorded to various development strategies) there has been a suggestion about the hierarchy of development strategies.¹⁸ These strategies are the following: *informal consensus*, *formal consensus* and *evidence-based*.

Informal Consensus

Recognized or self-appointed, national or local experts may produce guidelines after getting together to review the medical and scientific evidence for clinical approaches in particular circumstances.¹⁴ If the authors of such guidelines do not provide specific information about how the evidence was assessed, how it was ensured that relevant scientific data were not unintentionally excluded, how consensus was reached or how disagreements were settled, the guidelines are said to be based upon “informal consensus”.¹⁹

Formal Consensus

According to the formal approach, specifiable methods can be used to achieve consensus.¹⁴ Through the use of multi-step techniques, systematic reviews of available evidence are presented to members of an expert panel who are then asked to formulate clinical recommendations and to modify their recommendations in the light of fellow panelists’ formulations.¹⁴ If criteria of appropriateness have informed this process and the mechanisms for reaching consensus have been made clear, guidelines are said to be based upon “formal consensus”.¹⁴

Evidence-Based

Efforts to formulate techniques of guidelines development have been stimulated by

Thus, after having discussed their role from a medical point-of-view, their possible uses from a legal point-of-view should be identified. Rossoff, in his important article, made a first attempt to show how the legal community could take advantage of the information provided by clinical guidelines. Clinical guidelines could be used in different ways: as evidence of a *respectable minority approach*, as evidence of *reasonable prudence* or as evidence of *acceptable practice*.¹⁰

Nevertheless, we will focus on the most straightforward and complete acceptance of clinical guidelines in the field of medical liability. According to this approach guidelines could be directly applied *as the legal standard of care* and the legal community could simply treat them as setting the applicable legal standard without going through any intermediate steps (examining for example whether the guideline is professionally accepted or whether it is in line with customary practice).¹⁰

Although this seems to be a simple route theoretically, it would be a major step politically, since detaching standard setting from professional consensus would have far-reaching implications.¹⁰ Specifically, if practice guidelines are developed to describe what has been found to be the most appropriate treatment and care in the clinical situations they address, it seems logical that they should constitute the standard of care a

treating physician should be held to in the given clinical situation.²⁴ Despite this “appealing simplicity and logic”,²⁴ things (as it will be shown below) are not so simple. This is probably the reason why most legislative proposals, which include the use of clinical guidelines in medical liability (especially in the U.S.A.), do not make them the predetermined standards of care for all purposes in medical negligence cases.¹⁵

At this point, it should be noted that the following assessment of the possible advantages and disadvantages of using clinical guidelines to establish fault in medical liability is made to the hypothetical basis of their direct application.

Advantages

Establishing clinical guidelines as the fundamental criterion (so as to clarify the vague notions of tort law and medical liability in specific cases) could have significant merits; merits for the quality of the health services provided across a health system, for health care professionals and for the legal community, for the legal professionals (who are called to handle demanding cases in a very sensitive field) and for the legal process.

Quality of Care

Clinical practice guidelines, like tort litigation, aim at condemning substandard care.²⁵ In this regard, guidelines relate to medical liability litigation, which, like other areas of



tort law, is intended to bring about better care by visiting sanctions on those who injure patients while using substandard techniques.²⁶

Good guidelines are properly formulated and consolidate good, evidence-based practice.²⁷

If physicians are motivated (or obliged, due to the threat of litigation) to comply with clinical guidelines, quality of the services provided will be improved and overuse of certain procedures will be reduced.²⁸ Thus, clinical guidelines have the potential to enhance patient safety, reduce the number of adverse events and, finally, achieve the public policy of deterring substandard medicine.²⁷ Their promulgation (via the use of new technologies, telemedicine, computerized databases and online consultations) could establish a national standard of care²⁹ and patients could be able to receive high quality healthcare without regional variations.

Consequently, it is obvious that setting the parameters of legally safe medical care (i.e. the threat of liability because of non-compliance) could be proved to be the most valuable tool to ensure that clinical guidelines are effective in modifying clinical practice.³⁰ This would be the case, especially if clinical guidelines and their proliferation are seen "as part of a significant cultural shift, a move away from unexamined reliance on professional judgment toward more

structured support and accountability for such judgment."¹³

Health Care Professionals

In general, every professional would be excited about the prospect of developing better tools that will enable him or her to do their jobs more efficiently.¹⁰ Since all clinical approaches are not equally effective for particular medical situations and guidelines are usually based on scientific studies comparing the effectiveness of various clinical approaches, practitioners could be informed about what works best and what does not.³¹ Therefore, guidelines could ideally add structure to the medical decision-making process.¹² Moreover, physicians would be motivated to keep up to date with developments in their field and get knowledge of new and existing guidelines.²⁷ Consequently, the direct application of clinical guidelines to determine the legal standard of care could result in not only more effective medical practice, but also more informed and more efficient health professionals.

Taking into account that representatives of the medical community would certainly participate in the development and formulation of guidelines, health care professionals would have the opportunity to play a greater role in setting the standards of care based on which their conduct will be evaluated in the context of medical liability.⁹ Like any other professional, physicians

obviously prefer setting their own standards of practice than relying on the current ambiguous standards created by the legal community.³² More specific and professionally imposed standards⁹ would not only articulate appropriate practice, but they would also inform physicians (in terms familiar to them and not in the vague legal terminology of which are unaware) which conduct is subject to tort law's sanctions.⁹

Finally, with health care professionals being better informed as to which treatments are more efficient and as to what the law requires from them, the risk of a lawsuit for medical malpractice would logically decrease (due to their compliance with the guidelines) and the same would probably happen concerning the number of claims brought (because improved quality of care would reduce the need for suits in the first place).³³ Practicing medicine free from the constant threat of litigation³⁴ could have a positive impact on physicians, patients and the health system.

Legal Professions, the Legal Process and the Tort System

The procedures of medicine often seem too complex and too technical to lawyers and judges, who certainly lack the necessary knowledge and training. Nevertheless, both representatives of the legal profession are not exempt from their obligation to be involved in the evaluation of the physician conduct and

the analysis of his/her clinical decision-making process in order to decide whether that conduct was faulty and, thus, whether medical liability should be attributed in a particular case. These tasks become even more demanding given the vague, unpredictable and case-specific standards of tort law.⁸

In this challenging process, guidelines may help judges and lawyers demystify clinical decision-making.³⁰ If clinical decision-making can be reduced to a series of steps outlined in a published guideline, it could be susceptible of similar clarification in court and, therefore, the judiciary could be more willing and informationally equipped to assess the reasonableness of clinical practice (instead of simply following medical experts).³⁰ In other words, courts could adopt a more proactive role in the related cases,²⁷ abandon the hesitant (and criticized of deference to the medical profession) approach of the past years and, finally, reach more accurate decisions in a difficult technical area.¹⁰

In addition, courts always face significant difficulties to find out what the existing medical practice is in the particular medical field (so that they can evaluate the defendant's conduct in comparison to it). If clinical guidelines are incorporated in everyday medical practice and are followed by the majority of clinicians, they could shed light on existing practice-which has always



been a hard task for the legal community, since medicine is a science where different schools of thought and practice exist.⁹ Furthermore, in the case of promulgation of nationally accepted guidelines, the judicial process could be significantly *crystallized*, as courts would be provided with clear standards against which to measure a clinician's behavior in practicing medicine.¹²

Trials could be simplified, their outcomes could become more predictable and accurate and, therefore, settlements could be easier than ever.⁸ Lawyers would have clear, consistent standards and better guidance in order to be able to identify marginal claims and serve their clients' interests more effectively. In addition, rather than spending time to establish the standard of care, the legal process would focus on whether *extenuating circumstances* mitigated the application of the standard in the particular case.³⁵ (such as lack of the necessary equipment, organizational failures, lack of resources, etc.)

In general, the tort system could be improved and achieve its goals more efficiently. As we know, in all countries the tort regime aims at reducing the level of injury and disability in society, by deterring unsafe conduct and compensating people injured by that unsafe conduct.³⁶ Moreover, it aims at operating as a vehicle to determine liability and clearly communicate what society regards as

reasonable/ proper behavior in similar situations.⁹ Should courts compel compliance with what is –based on either professional consensus or objective research- considered to be best medical practice (instead of trying to define vague legal notions on a case-specific basis without possessing the necessary background knowledge) the aforementioned aims of tort law would be better served. Particularly, unsafe conduct would be deterred, “good”, evidence-based science would be promoted and encouraged and what society regards as an appropriate behavior in similar situations would be communicated clearly.

Issues or areas of concern

Despite these advantages, the potential of making clinical guidelines the fundamental criterion for the formulation of the legal standard of care and, thus, for the establishment of fault in specific medical liability cases is not fully supported. In the following section of the article, the possible obstacles to the complete incorporation of guidelines in medical liability and the problems that could arise from it will be presented. They will be presented in three pillars: the medical profession, the development and the content of clinical guidelines and the legal profession /legal procedure in general.

Health Care Professionals

The most serious concern of the medical community regarding the direct application of clinical guidelines as the legal standard of care is associated with the clinicians' desire to protect their professional autonomy and discretion.

When more is known about the "right" way to treat a particular condition, there is less latitude for individual judgment.¹⁰ Even though in the past, clinicians have been given wide latitude to exercise personal discretion in choosing treatments for their patients (i.e. "medical paternalism"), nowadays they feel increasing pressure to conform to established norms of treatment.¹⁰ As it has been said, for physicians, mandatory (so as to avoid being found liable in case of non-compliance) compliance with specific standards of practice would mean "an end to business as usual".⁹

According to physicians, having to follow guidelines in order to avoid the risk of malpractice exposure⁹ would be both an insult to their autonomy and an intrusion into their freedom to practice medicine based on their best judgment.¹⁵ Clinical guidelines (especially those not systematically updated) could constitute inflexible standards of care and, consequently, may adversely implicate physicians who appropriately invoked experience and intelligence and who meticulously considered the facts of an individual patient's case, in making difficult

clinical decisions.¹² That could be devastating for independent medical innovation, which has been one of the most important tools for the evolution of medicine throughout the years. In this case, pluralism and competition, which are intrinsic to medical practice, would be ruined, "cookbook medicine" would increase and, inescapably, quality of the health care services provided would deteriorate.¹⁰

Another source of concern for health care professionals is that guidelines, instead of protecting them from the threat of litigation, could, in some cases, increase the possibility of being found liable. Specifically, in an environment, which supports clinical guidelines, a clinician might more readily be held accountable for an adverse event or a poor outcome of treatment, if these can be attributed to deviation from a guideline-based prescribed treatment approach.¹⁰ Apparently, the more specific the standard of care is (and this will be the case if guidelines become the legal standard of care), the more probable is for the physician to be found liable if he/she violates that standard.⁹ Thus, it is apparent that despite health care professionals' interest in setting standards of practice to stave off judicial intrusion, when intrusion appears less imminent, interest in setting or complying with specific, professionally set standards of practice disappears.³⁷

would probably include numerous options and alternative recommendations and, thus, may be more difficult to apply as a standard.

²⁴ Such detailed guidelines could be both confusing and useless to physicians, as the latter would spend more time trying to find which is the most suitable guideline rather than focusing on making a diagnosis ³⁴ based on the health needs and the best medical interests of the particular patient.

Clinical Guidelines: Development and Content

In order for clinical guidelines to become the basic criterion for the assertion fault and the attribution of medical liability, it is essential that all the problems related to their development and content be resolved. Currently, representatives from both the medical and the legal community have expressed concerns about the appropriateness of guidelines to constitute the standard of due care. There are still many issues to be resolved before guidelines can be used as conclusive evidence. We should not forget that evidence-based medicine and clinical guidelines are quite new in clinical practice and, consequently, they are undergoing constant evolution and continuous major improvements.

Development

An important issue could arise concerning the prestige of the organizations developing clinical guidelines. ¹⁵ As it was previously

mentioned, guidelines are currently developed and published by various organizations, public and private. Public bodies -such as the English NICE or the American Institute of Medicine (IOM)-, medical societies, insurance companies are some of them. Obviously, not all of them have neither the same level of technical expertise to develop efficient guidelines nor the same prestige. This pluralism, even though it could be positive from a scientific point-of-view and could promote good science (by providing physicians with multiple choices and by leaving them make the final treatment decision based on their judgment), it could also create problems, if guidelines were considered to be conclusive evidence of the standard of care.

First of all, without clear, consistent and strict rules (preferably incorporated in legislation) governing the procedures of their development, serious objections could arise regarding the assessment of guidelines' authoritativeness.

Secondly, there would certainly be contradictory guidelines developed by different bodies (in fact, contradictory guidelines already exist). The plethora of contradictory guidelines for the same area of medical practice raises serious questions about their use as legal standards. ⁴¹ The profusion of -seemingly or actually-

Hence, clinical guidelines can only give *tentative* indications of what might be considered reasonable practice under the most standard conditions, and very few situations fall into that category.³⁴ Often developed for specific situations in controlled experimental environments,¹² they are created for “average patients” and cannot cover the huge variation patients present.⁴¹ Even those, who are strongly in favor of evidence -based medical practice, have recognized that it would be preferable to avoid a “one size fits all” approach,⁴¹ as only a physician's trained eyes, ears, and mind can reconcile the large number of factors that interact in a specific clinical situation.¹² Besides, we should not forget the trends towards more personalized approaches (i.e. personalized medicine), which are beginning to affect both the research and the practice of medicine.

Furthermore, another serious issue of clinical guidelines is that, even regarding the “average patient”, they usually set only minimal standards.³⁴ Therefore, setting clinical guidelines as the standard based on which physicians’ conduct would be evaluated in each and every occasion, would mean that the minimal standard is always good enough;³⁴ even if health care professionals could have done better on a specific occasion, what they did was acceptable because it met this lowest level of care.³⁴ That would definitely

constitute an unwise public policy,⁴³ which would not enhance patient safety. Instead, it could cause harm by forcing professionals to follow specific treatment methods, when it might be better for a particular patient to follow an alternative approach.⁴³

Finally, if we take steps to compel health care professionals to comply with clinical guidelines, an additional problem would be the non-recognition of the inevitability of regional variation in the provision of health care services.⁹ Regional variations are actually observed even in the most prosperous health care systems and are considered medically legitimate by well-respected members of the medical community.⁹ For instance, small hospitals in remote areas have limited resources and cannot utilize the most expensive equipment or technology.⁹ Would it be reasonable and fair to “condemn” those hospitals and their physicians by officially making their practices legally unsafe and, thus, by exposing them to the constant threat of litigation, when at the same time they are not given the necessary resources to meet the standards of care set?

The Legal Profession and the Legal Process

From a legal point of view, albeit appealing and straightforward on the surface, making guidelines the prescriptive standard of care in medical liability is not free from difficulties.



If clinical guidelines are officially deemed the fundamental criterion to determine fault in medical liability, the role of legal professions (judges, lawyers etc.) in this area would probably be limited to merely assessing whether the standards set by others (outsiders to the legal community such as technocrats, physicians etc.) have been followed in particular cases. Therefore, judges and lawyers might be relegated to a secondary role in medical liability lawsuits, even though both society and the law clearly require them to be the ultimate guardians of justice in the particular field. That is the reason why courts fear that absolute deference to professionally imposed standards risks abrogating their responsibility in the medical negligence trials.⁹

However, even if legal professionals became eager to defer to clinical guidelines to establish culpability, their task would not be simple. Their use in actual cases would be quite difficult because the structure of legal reasoning focuses on the particular facts of the case at hand rather than appealing to abstract decision procedures.⁴⁴ The courts would have to learn new principles and develop new rules to apply guidelines in litigation.¹⁰ The creation of new principles and rules (concerning both the legal theory and the legal procedure) would be necessary, as some of the current rules might be

incompatible with a guideline-based reality in medical practice.

In most jurisdictions, the law sets objective criteria to evaluate the physician conduct in specific cases. Specifically, despite minor differences in wording, some form of “customary practice” (or acceptance from the professional community) criterion has been adopted to set the legal standard of care. Thus, in most jurisdictions, under most circumstances, adherence to prevalent professional standards is an adequate defense to a claim of medical negligence.¹⁰ However, if the courts treat clinical guidelines as evidence of what is customary practice in the medical profession,¹⁰ issues could arise in the case of a newly developed guideline, because the treatment approach it calls for may differ (perhaps substantially) from prevailing practice in the profession.¹⁰ What would the courts do in this case? Would they condemn all the physicians who –probably justifiably– did not totally change their practice from one day to another and preferred to continue using currently accepted methods instead of “sailing in uncharted waters”?

As a result, while the potential of taking advantage of the information provided by guidelines might at first fascinate the legal community, it could also be proved confusing.¹⁰ It is clear that the court's job in medical liability lawsuits may be significantly more complex in the face of the better knowledge

and evidence made possible by guidelines, than it was previously, in "less enlightened" times.¹⁰ The analysis in the following paragraphs certainly confirms these views.

Demanding questions arise regarding the way courts and lawyers would handle conflicting guidelines or guidelines developed with different strategies or published from different organizations. Some of the questions (more would certainly emerge in practice) can be summarized below:

What would the court do if there are multiple –and contradictory- guidelines for the same clinical condition?¹⁰ Could the court, which lacks the necessary technical knowledge, treat one of them as more or less authoritative and reliable in the process of reaching an accurate decision?¹⁰ What would the court do in case equally respected professional groups or organizations developed these guidelines and, thus, their guidelines were of equal importance?¹⁰ Could a court allow evidence and/or arguments to the point that one guideline developer was entitled to more respect than the other or that one set of guidelines was more credible because it was better supported by the underlying data or by a more robust methodology for outcomes research, possibly including cost-effectiveness analysis?¹⁰ Might the court allow the parties to present the mechanics of guideline development?¹⁰ Might one party try to show that, whereas its guideline was based on solid,

up-to-date empirical data, its opponent's older guideline was developed through a more subjective, consensus-based process and, thus, was less valid?¹⁰

The legal community would certainly find the task of answering these questions daunting, as it would require thorough analysis of the special characteristics and development processes of guidelines; this analysis presupposes the relevant technical knowledge as well as the use of the –already criticized for its objectivity drawbacks- expert testimony. Therefore, it is apparent that instead of making their life easier, guidelines in medical liability cases could puzzle courts by creating a labyrinth of questions and dilemmas.

The particular problems would not vanish, even if a single guideline existed and the courts could simply apply it as the standard of care.¹⁰ There would still be challenging questions to be answered by lawyers and judges. For instance, there could be factual questions like the following: was the particular guideline the appropriate to the case being litigated;¹⁰ (b) if so, did the defendant comply adequately with the clinical guideline?¹⁰ (c) If he did not, did the plaintiff's harm result from that non-compliance?¹⁰ Answering questions like these convincingly would be too difficult a task for the legal community with clearly doubtful (as far as fairness and justice are concerned) results. It is also obvious that, even when



things seem straightforward, the known deficiencies of the current fault-based approach in medical liability remain.

Finally, another source of concern could be the lack of sufficient scientific research or clinical experience on which to base a practice guideline regarding a particular medical condition.²⁴ Medicine is a constantly evolving science and treatments for newly discovered medical conditions come into light every year. Consequently, there will certainly be liability cases concerning medical conditions, which have not been fully explored yet. However, if clinical guidelines were given independent legal standing, how would the legal community handle cases where relevant guidelines do not exist? Would these cases be treated differently, by returning to the traditional battle of experts and the inadequacies of the present system? And if this distinction were adopted, would it be just to employ double standards when dealing with medical negligence cases?

Proposals

From the above, it is obvious that guidelines are currently far from being suitable to constitute the fundamental criterion to establish fault and attribute medical liability; and this applies equally to health systems (such as the British or and the American) where guidelines are being developed and used for many years. In order for guidelines to

play a greater role in medical liability, it is essential that most of the problems related to their development, their content and their legal use be resolved.

In this chapter we will discuss the changes, which must take place so that guidelines can become a useful, authoritative and credible tool to make the notion of the legal standard of care more comprehensible and to clearly set the boundaries of legally safe conduct of physicians.

It should be underlined that clinical guidelines are primarily developed to offer assistance to health care professionals by informing them about the effectiveness of different treatments. Consequently, fixing the inherent issues of guidelines ought to be an absolute priority before any piece of legislation concerning their legal use is drafted. That is the reason why the proposals regarding the guidelines themselves precede the recommendations related to their use in medical liability cases.

Guidelines: Development and Content

The proposals inevitably focus on the sources of concern expressed in previous chapters, which hinder the absolute deference of both the legal and the medical professionals to guidelines.

First of all, it is essential that more experience be gained, so that the most appropriate developers of guidelines and the most

appropriate processes for their research and development can be identified.¹⁵ This is probably the most fundamental change needed. In order for their use to be facilitated, it is important to have commonly understood and consistent processes for their development, formats for drafting and presenting them, and vocabularies for describing their characteristics.²⁴

After experience has been gained (through research and rigorous screening) in these fields, the next step would be to promulgate guidelines in the most formal way; by incorporating them in legislation. The legislation should clearly state the minimum criteria (in relation to staff, funding, objectives etc.) a potential developer must fulfill so as to have the right to disseminate clinical guidelines, the process of applying to get the necessary authorization and the rules, which govern the procedures for the research, development and dissemination of guidelines (for example to ensure objectivity and resolve issues of drafting, presentation and vocabulary etc.). Moreover, the measures of their authority, validity and credibility should be comprehensibly stated. In addition, equally necessary is the inauguration of an organization responsible for monitoring the implementation of the aforementioned legislation.

Even though it is important, for reasons of pluralism and competition, to have more than

one organization, which develops guidelines, the task of enforcing the law must be assigned to a governmental organization. In the author's opinion, this is the only way to ensure objectivity, transparency and freedom of conflicts. Individual specialty groups or private organizations may sometimes be concerned with advancing their own interests.

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Consequently, for these reasons (and for unanimity to be achieved in a field like medicine, where different opinions exist even for the most core issues), it is necessary to designate a public body (a governmental agency) as the sole arbiter of guidelines' authority and, thus, of what is acceptable medical practice.¹⁰ The agency (similar to the British NICE for example) staffed with professionals with the necessary experience and technical expertise (health care professionals, lawyers and technocrats) will monitor the application of the aforementioned rules, especially those related to the research and development of guidelines. In addition, the agency should have the legal authority to impose administrative sanctions to those organizations, which violate these rules. Moreover, under the auspices of the public agency, a governmental certification program¹⁰ could be launched to rank the guidelines developed by credibility. The criteria by which the guidelines will be evaluated must

physicians and patients decide which avenue to take.¹⁵ It is common ground that formal scientific research is not always enough to ascertain what is in a patient's best medical interests and, as a result, expert opinion and first-hand experience play an important role in filling the gap between what a guideline covers and what needs independent medical judgment.⁴⁶

Medical Liability and Guidelines

If the above proposals are adopted, clinical guidelines will gradually overcome their contemporary problems and become, at first place, a more useful tool for clinicians in everyday medical practice. In the medium to the long term, benefits could flow to the legal system as well, by making more accurate, efficient, and affordable resolution of disputes about the quality and appropriateness of health care provided, possible.¹⁰

However, in order for the courts around the world to be able to solve medical liability disputes with either absolute or relative recourse to clinical guidelines, it is crucial that major changes in the legal context of medical liability take place. As guidelines are a relatively new source of medical knowledge and a novel “phenomenon” in medicine, it is time for the legal science to reflect on their incorporation in both the legal theory and the judicial procedure of professional negligence of clinicians.

At the next stage, legislators must formulate policies and introduce laws in order for guidelines to acquire independent legal standing and play an upgraded role in establishing the legal standard of care. In any case, it is necessary that the guidelines have a more distinct role in the legal system.

For these purposes several law reforms (including tort reforms)²⁹ need to take place. The reforms must focus on the following fields:

- i. The incorporation of the notion of guidelines in the core of the legal theory of medical liability as an integral part of the concepts of “fault” and “standard of care”
- ii. The way courts will use clinical guidelines in the process of forming the legal standard of care and of establishing “fault” in specific cases (i.e. reform of the rules of civil procedure for the admission of guidelines in negligence trials)
- iii. The guidance legal professions (especially judges) need to receive during the aforementioned process
- iv. Introducing the necessary training of legal professionals (judges, attorneys etc.) in order for them to get familiarized with the concepts of clinical guidelines and evidence-based medicine in general (so as to understand the different types of



guidelines, the various procedures of their development, the criteria for the assessment of their credibility),

- v. Establishing training programs for both medical students (as part of their medical education) and practicing physicians (as part of their continuous professional development), so as to get informed about the most efficient ways of using clinical guidelines in everyday medical practice.

The major step would certainly be the unification of the medical and the legal standards of care.²⁹ This obviously presupposes that public officials and representatives from the medical, legal and lay public communities totally approve and adopt clinical guidelines.²⁹ However, even if guidelines were adopted as the legal standard, questions would remain regarding their application.¹⁰

Concerning the weight to be given to a guideline, the most extreme approach would be to treat it as a per se standard.¹⁰ If a health professional did not comply with guidelines, that would lead to a conclusive or irrebuttable presumption that the physician was negligent.¹⁰ On the other hand, if the physician did comply with the guidelines, the care provided would be considered due and reasonable.¹⁰ Nevertheless, this direct application of clinical guidelines as the legal standard for medical care could be described as extreme, as it

seems inappropriate and unlikely (both at this relatively early stage of their development¹⁰ and at a later stage when processes of guideline development will be improved).

The most correct approach would be a less prescriptive one, according to which compliance with relevant guidelines would raise a rebuttable presumption that the physician's conduct was appropriate;¹⁰ non-compliance would raise a rebuttable presumption that the physician was negligent.

¹⁰ Whichever party asserted the guidelines, the opposing party would try to parry this presumption by proper evidence.¹⁰ Thus, according to this approach clinical guidelines could help define the standard of care, but only as part of a "larger armamentarium".²⁹

Furthermore, after determining the basic principles on which the legal use of guidelines will be based, some mechanism should be created to introduce them more prominently into the legal process and to help courts decide which guidelines should be regarded as authoritative.¹⁰ The aforementioned (see previous section) assessment of the guidelines' credibility by a governmental agency coupled with some guidance to judges as to how to handle both reliable and less reliable guidelines¹⁰ could help courts reach more accurate decisions.

Specifically, courts would need guidance in two main directions: firstly, in distinguishing guidelines with full credibility and weight

from those not as deserving and, secondly, in deciding what evidentiary weight to accord guidelines falling into each of these categories.

¹⁰ The guidance by the agency would significantly help courts solve the issue of multiple, competing guidelines for particular medical conditions. ¹⁰ It should be noted, however, that the dilemmas created by competing guidelines will not entirely cease to exist, as they reflect the inherent diversity and pluralism of medical science. In medicine nearly nothing is black and white and there are different professional opinions for the same clinical situations.

Legislating the training of health care and legal professionals is equally significant and essential for the success of the aforementioned proposals. Judges and lawyers, who do not have the necessary technical expertise, must receive special training in order to become familiar with the concept of clinical guidelines, the processes of their development, the criteria based on which their authority is assessed etc. Generally, it is of great importance for the legal community to acquire the relevant background knowledge in order to be able to understand and enforce the legislation related to clinical guidelines and to take advantage of the guidance from the governmental agency. In this way, both judges and lawyers will not heavily depend on expert testimony, which has been proved a relatively inefficient (and

surely controversial) tool for the settlement of medical liability trials.

Concerning the training of health care professionals, it could be organized by medical schools regarding medical students and by medical associations and societies regarding practicing clinicians. During the training, emphasis must be given on the way physicians can exploit the evidence-based data of guidelines without suppressing their professional judgment. It must be made clear to them that only the combination of information included in guidelines and independent judgment can lead to the most successful outcomes.

Although the idea of introducing training programs for physicians might seem unnecessary, the particular proposal is crucial to the effective use of clinical guidelines in the legal context. In point of fact, the high level of *acceptance* and use of guidelines within the medical community is a prerequisite in order for them to play a major role in the formulation of a national health policy, in the articulation of the legal standard of care and, finally, in the assertion of fault in medical liability. In other words, only if they are fully embodied in medical practice and their use by health care professionals becomes the norm rather than the exemption, the courts will begin considering them as the standard against which the conduct of physicians will be measured.



In order for the acceptance of clinical guidelines by the medical community to be enhanced, the professional responsibility of physicians to have knowledge of existing and new guidelines (particularly those deemed by the governmental agency as authoritative) should be clearly included in codes of medical ethics as part of the clinicians' general duty to keep up to date with the latest developments in their scientific field. A possible wording could be: "Clinicians are responsible for keeping up to date with the all latest developments in their specialty. In the context of the aforementioned duty, particular attention must be given to clinical guidelines, especially those deemed to be authoritative by the responsible governmental agency."

In spite of the fact that in most countries codes of medical ethics do not constitute enforceable legal rules and the breach of them can only result in disciplinary sanctions, the incorporation of a duty of knowledge of guidelines in the codes will certainly encourage and inspire clinicians to adopt both a guideline-friendly mentality and guideline-informed treatment approaches.

As far as European Union is concerned, in an era of emphasis on patient safety⁴⁷ and cross-border health⁴⁸ clinical guidelines could offer invaluable help to Member States regarding both fields. In fact, the recommendations to adopt common patient safety policies and the need to facilitate (and organize) cross-border

provision of health services can be proved the perfect occasions for the exchange of knowledge, medical innovation and evidence/research-based data between European Health Care Systems. One step further could be the harmonization of the quality of health care services through the development of European guidelines (with contribution and cooperation of several health organizations and health professionals).

In this way, "good science" would be promoted and in the long term the medical standards of care provided within the European Union could be unified. These common medical standards would not only benefit European patients, but in the long term-they could also lead to the harmonization of the legal standards of care. National courts, without being bound by the European standards of care, could at first place take advantage of the aforementioned standards to reach more accurate decisions. If this was proved to be an efficient system, European guidelines could be incorporated into national legislation of Member States and, thus, acquire independent legal standing. Despite minor differences among European jurisdictions regarding the legal standard of care (in England is the responsible body of medical opinion, in Greece is the average prudent doctor, etc.), most of them still use fault as the main criterion for the attribution

of medical liability. Hence, if a common standard of care is adopted, one of the most challenging issues of medical liability will probably be solved. (however, problems will definitely continue to exist in all fault-based jurisdictions, especially concerning *causation*, which is an equally problematic area).

Conclusion

Despite proposals towards the adoption of a no-fault system in various countries, the idea of liability for fault remains central to the law of medical liability in most jurisdictions.¹ However, the vague, uncrystallized and case-specific standards to determine fault have confused both the legal and the health care professionals.

This, combined with the inherent uncertainty of medical science and the complexity of modern medicine, has made the resolution of medical liability cases too demanding a task. In fact, many of the adverse events in health care are no more than inevitable concomitants of this uncertainty and complexity.⁴⁹ Most cases end up as battles of experts and judges try to find the right balance between the opposing views, to reflect on the possibilities and to make hypotheses in order to reach as accurate and just decisions as possible. The fault-based system has many inefficiencies and it is beyond doubt that changes need to take place. Since the possibility of no-fault systems has

been rejected, the solution must be founded within liability for fault and particularly by taking advantage of the evolution of medicine. As evidenced-based medicine and its most important manifestation (e.g. clinical guidelines) become increasingly important and acquire an enhanced role in medical practice, medicine starts becoming a more exact science. Although medicine will probably never (at least in the near future) become a totally exact science, clinical guidelines could offer more objective and crystallized standards of care and, consequently, make the legal process of medical liability simpler, clearer and more specific. Clinical guidelines, especially those based on research evidence, include objective piece of information. If guidelines are incorporated in the legal standard of care, they could make it possible for the ambiguous concepts of tort law (fault, standard of care) to be expressed in a concrete form. Thus, the more exact medical science becomes, the more specific the standards of due care will be and the more certain courts will be regarding whether a physician's conduct is faulty or not. In other words, the more specific the norms of medical science become, the more straightforward the ascertainment of its breach will be.

Nevertheless, as mentioned in previous chapters, despite guidelines' advantages and appealing simplicity, experience and research

essential tools to resolve the relevant cases as fairly and accurately as possible.

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