

Review

Medical error disclosure and patient safety: legal aspects

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Significance for public health

The extent of preventable adverse events and the correlative need to improve patient safety are recognized today as a public health issue. In order to lower the toll associated with preventable adverse events, the former culture of professionalism (based on the premise that a good physician doesn't make mistakes) must be replaced by a culture of safety, which requires a multi-pronged approach that includes all the main stakeholders within the health-care system. A number of legal reforms could help in prompting such a change. This contribution stresses the need to include legal aspects when trying to find appropriate responses to public health issues.

Abstract

Reducing the number of preventable adverse events has become a public health issue. The paper discusses in which ways the law can contribute to that goal, especially by encouraging a culture of safety among healthcare professionals. It assesses the need or the usefulness to pass so-called *disclosure laws* and *apology laws*, to adopt mandatory but strictly confidential Critical Incidents Reporting Systems in hospitals, to change the fault-based system of medical liability or to amend the rules on criminal liability. The paper eventually calls for adding the law to the present agenda of patient safety.

Introduction

It is today a widely recognized fact in all Western countries that *adverse events* and *medical errors* frequently occur in hospitals and other health-care institutions.

The notion of *adverse events* encompasses any harm to the patient which is due to the administration of health care. When an adverse event is caused by a medical error, we usually speak of a *preventable adverse event*. Medical error is itself defined as a behaviour which falls below a standard of care.

The term *medical errors*, on the other side, is used here to encompass all errors made by health-care providers, and not only errors made by physicians. However, since claims for damages are brought against hospitals or physicians and very infrequently against other health-care professionals, most legal writings allude only to errors made by medical doctors.

According to several studies made over the last twenty years (starting with the book of Weiler *et al.*),¹ like the famous report from the Institute of Medicine's Committee on Quality of Health Care in America in 1999,² adverse events occur in about 3% of hospitalizations. Approximately 10% of adverse events lead to the patient's death (it is commonly assumed that between 50,000 and 100,000 people die from medical errors each year in the United States). Now it seems that over half of these adverse events result from medical errors and can

therefore be prevented.

As pointed out in the 1999 report, more people die in a given year as a result of medical errors than for instance from motor vehicle accidents or breast cancer.² Such findings mean that medical error should be seen as a public health issue, not only because of the human cost (lives lost, bodily integrity harmed, suffering), but also because of the financial cost associated with it (the cost in the United States was estimated between 17 and 29 billion dollars).² It is no wonder that the World Health Organization adopted in 2002 a Resolution which recognizes the need to promote patient safety as a fundamental principle of all health systems.³ Similarly, a 2006 Recommendation from the Council of Europe states that *patient safety is the underpinning philosophy of quality improvement*.⁴

Society at large should therefore seek to lower that toll. It means that all possible means to prevent adverse events should be explored and, if proved to be efficient, implemented. Almost all specialists in the field join today in asserting that we need a fundamental change in medical culture. The former culture of professionalism (based on the premise that a good physician doesn't make mistakes) should be replaced by a culture of safety. As explained by Katharine Wallis, *developing a culture of safety entails changing the attitudes and behaviour of health care providers: from fear and defensiveness about things that go wrong in health care, to an attitude of openness and a readiness to learn and make changes*.⁵ To reach that goal, every country should develop a multipronged approach that includes all the main stakeholders within the healthcare system. Among the measures that could be part of the package, we would like to mention at least the following ones: i) reorienting the education and training of doctors (and other health professionals) in order to improve their communication skills and to sensitize them to the main issues in clinical risk management; ii) introducing or developing Critical Incidents Reporting Systems in hospitals and other institutions providing health care; iii) developing new tools or refining present tools (M&M reviews, quick alerts, dashboard, safety checklists, guidelines and recommendations, etc.) to improve patient safety; iv) systematically disclosing errors to injured patients and/or their family to increase transparency and build trust; v) giving up the traditional regime of civil liability based on individual fault and setting up a no-fault compensation scheme; vi) banning *ex officio* criminal proceedings against health professionals when patients have been hurt in the course of medical treatment.

The aim of this paper is to explore and discuss very briefly whether (and if the answer is positive, how) the law can contribute to improve patient safety. National legal orders may vary a lot from one country to the other. That is why we shall speak in general terms, without referring to a specific national law.

Is the law a useful tool to improve patient safety?

First of all, one should recall that law has become today the primary

tool a society can use to pursue its goals and to influence personal and professional behaviour. Recommendation no. 7 of 2006 (appendix J1) of the Council of Europe on management of patient safety and prevention of adverse events in health care stressed the fact that *legislation constitutes one of the most important regulatory mechanisms in health care*.⁴ In other words, laws can contribute to a change in professional cultures.

Now health professionals frequently express the view that legal provisions are burdensome and should, therefore, be substituted by professional guidelines or other means of self-regulation. It is a known fact that a wide range of medical activities that were formerly ruled by professional and ethical rules are nowadays governed by legal norms. Such an evolution has been prompted by the emergence and quick development of individual rights as well as by the widely shared feeling that self-regulation was too unilateral and consisted in a professional privilege that is hard to reconcile with patients' rights. In other words, it is usually accepted today that once a society has decided to do something in order to improve patient safety, it should pass laws that are consistent with that general goal and that take into account the legitimate interest of all stakeholders.

Laws are not necessarily coercive or burdensome for doctors and other health professionals but on the contrary can be fine-tuned to try and reach their goal in the most efficient and less damageable way. Indeed, legal provisions may coerce, for instance if the law requires health professionals to report adverse events happening in the course of health-care delivery. But they may also promote specific professional behaviours, for instance when a legal provision conditions State subsidies to hospitals to the implementation of a critical incident reporting system. In-between, other legal provisions may simply be neutral or may try to deter or even to prohibit professional behaviours that are deemed inappropriate.

Laws are often criticized because they have supposedly not reached their goal, for instance because they did not succeed in altering personal behaviour. But when we deal with changes in professional culture, it is unrealistic to expect a new law to have an immediate impact. Laws can accompany or facilitate societal or professional changes thanks to the symbolic value of the law. It has been shown on many counts that in the long run, a legal change may indeed make medical customs evolve. One of the best examples is the development of the legal doctrine of informed consent in the seventies that has deeply changed the patient-doctor relationship over a few decades.

Setting a goal is not enough when proposing a new law. Lawmakers must also spell out in a clear way the core values on which the law is built. In the field of patient safety, the law must refer to values such as transparency, verity, trust and justice (by the way, it was quite appropriate to hold the COME conference on medical error disclosure in Monte Verità!). It is a way to gain wide societal (and professional) acceptance, itself a prerequisite for an efficient implementation of the law.

Finally, since laws mandate, promote, deter or prohibit specific human behaviours, they should be based on at least some empirical evidence that they will work. Now, when lawmakers from continental European countries deal with medical error disclosure and patient safety, they very often do not possess enough empirical evidence to fully support their proposal. We clearly need more studies in many European countries, for instance, on the results obtained through a mandatory or voluntary critical incident reporting system or on the positive and negative effects of medical error disclosure laws. See for example the study by Wallis in New Zealand,⁵ who tried to assess in her thesis the influence of New Zealand's medical regulatory system on the development of a culture of safety. She firstly measured the *punitiveness* of the regulatory system, and then the openness about medical error and the opportunities for learning to improve patient safety.

In that respect, Recommendation no. 7 of 2006 clearly asserts that *the development and implementation of an effective patient-safety poli-*

*cy requires sound evidence (as opposed to mere opinion). Therefore, applied research on patient safety is a vital component of a comprehensive strategy to address this problem.*⁴

Possible contributions of the law to improve patient safety

In most jurisdictions, the traditional legal answer to the issue of patient safety has been brought by the tort system, *i.e.* the regime of professional liability.⁶ Indeed, the legal rules on professional liability are supposed to fulfil two different functions: on the one hand, they must fairly compensate the victim of negligent care; on the other hand, they must play a preventive role by giving health care providers (both individuals and hospitals) incentives to improve care in order to prevent damage (*Faure: if law is analysed from the economic point of view, damage is defined as an externality. The central question is, therefore, to assess which legal rules can provide the best incentives to health professionals for delivering optimal care. In other words, the law must internalise the risk of damage*).⁶ In a law and economics perspective however, to be efficient, legal rules *should not give incentive to avoid every possible accident that could occur, but only damage that could be avoided by investments in care of which the marginal costs are lower than or equal to the marginal benefits in accident reduction*.⁶

Virtually, no one today criticizes the principle that a patient who has been harmed by his medical treatment should have the possibility of receiving equitable financial compensation. Civil liability of health professionals is based on individual fault or negligence in most European and North American countries. Such a regime is, it is submitted, inapt to fulfil its two main functions (compensating the victim and preventing similar harm in the future). For various reasons that cannot be developed here, courts don't seem to be very effective in reaching a verdict that really reflects what happened.

The issue has been known for some time (see for instance Weiler *et al.*).¹ It has mainly to do with the law on evidence and the difficulty to reconstruct *ex post* what happened to the patient, in other words, to prove medical negligence as well as causation. This might be one of the reasons why most medical malpractice claims are settled out of court (*e.g.* Rubin *et al.*)⁷

In other words, judges not infrequently hold liable physicians who were not negligent or they deny compensation where the physician actually erred. As to the preventive function, liability based on personal fault encourages a culture of secrecy instead of a culture of openness; it makes it more difficult to know which errors have been made and, therefore, to prevent them in the future.

Since the law has mainly focused on redressing what went wrong for the patient, it has so far shown little interest in the disclosure of adverse events and medical errors, especially when the latter did not harm the patient. In many countries, the legal advice traditionally given to physicians has been neither to disclose errors which did not affect the patient nor to apologize for errors which resulted in patient injury. This kind of legal advice has contributed to strengthen, or at least to keep alive, the traditional medical customs of secrecy and denial.

The traditional medical culture as well as the traditional stance of the law is, it is submitted, short-sighted. Physicians do not disclose errors because they are afraid of being held liable. They fear that an apology be taken as an admission of guilt or liability. But it is well known today that most injured patients mainly seek an explanation and hope for an apology rather than strive for financial compensation.⁸ Keeping silent when something went wrong is a flawed strategy since many legal claims are due to deficits in the physician-patient communication.⁹

In several European countries, a duty to disclose medical errors can be derived from the general legal norms on contract. Under Swiss law for instance, the physician-patient relationship is governed by the legal provisions on the contract of agency.¹⁰ An agency contract is a contract whereby the agent undertakes to provide certain services in accordance with the terms of the contract. According to art. 398 par. 2 of the Swiss Code of Obligations [CO], *the agent is liable to the principal for the diligent and faithful performance of the business entrusted to him*. In addition, the agent is obliged to *give an account of his agency activities* (art. 400 par. 1 CO), an expression which should be understood as covering possible mistakes made by the agent in the completion of his tasks.^{11,12} However, in the real world, such general legal provisions have usually been ignored by physicians and, therefore, have had no impact.

In order to encourage open disclosure more specifically by physicians, a number of countries have enacted *disclosure laws* mandating disclosure of medical errors under specific circumstances (McLennan *et al.*, for example, mention Sweden, Canada, Australia, New Zealand, the United Kingdom and the United States as countries having such laws).¹³ Several countries have also enacted so-called *apology laws*, *i.e.* laws providing that an apology given after an adverse event cannot be used in ulterior legal proceedings (Australia for instance has enacted such a law). The actual effect of those laws on professional behaviour is debatable. Indeed, there seems to be little evidence that such laws have significantly encouraged open disclosure of medical errors. Apology laws have also been criticized as ill-conceived because in virtually all countries, a court of law would never consider a mere apology as evidence of negligent behaviour.⁸

But here again, one should not underestimate the symbolic value of the law. If disclosure laws or even apology laws are enacted along with other norms on patient safety, they may indeed be helpful in making medical customs evolve. But to become really effective, they must be part of a more global policy involving also a reorientation of professional training, various institutional incentives to openly disclose medical errors and the development of well-conceived Critical Incident Reporting System ensuring confidentiality.

In order to convince all stakeholders to encourage medical error disclosure, we probably need some further evidence pointing in the same direction as the famous study conducted in the University of Michigan Health System (UMHS),¹⁴ which involved inpatients as well as outpatients treated in UMHS. The authors of that study compared liability claims and costs over a twelve-year period (from 1995 to 2007) during which (in 2001) UMHS shifted from a *traditional* policy of keeping silent or denying any error to a *disclosure-with-offer program*, *i.e.* a systematic reporting of medical errors and a spontaneous offer of compensation addressed to the patient or their family. The main findings of that study can be summarized as follows: the average monthly rate of new claims, the average monthly rate of lawsuits as well as the median time from claim reporting to resolution decreased after implementation of the disclosure-with-offer program. In addition, the average monthly cost rates also decreased for total liability, patient compensation and claims-related costs (The authors of the study warn that their findings cannot establish causality, in part because of the peculiarities of UMHS). If hospital managers, doctors and politicians were convinced that a *disclosure-with-offer program* was cost-effective (of course, lawyers might not like such programs, since they reduce legal costs...) and did not entail undesirable legal consequences for doctors, it would greatly help moving towards a culture of safety.

Disclosing medical error could be made easier by changing the rules on criminal liability. In many national legal systems, serious offences (for instance serious assault or homicide through negligence), are prosecuted *ex officio*, *i.e.* without requiring that a complaint be filed by the victim. It might be more appropriate to leave it in the hands of the victim or their family, in order to encourage a peaceful settlement and

avoid generally unneeded criminal sanctions.

States should also envision enacting laws that either mandate or encourage hospitals to set up a Critical Incident Reporting System (CIRS). Such systems are useful especially to gain more knowledge about adverse events (due either to a medical error or to organizational factors) which have happened without hurting any patient (what is called a *near-miss* in aviation safety, *i.e.* a situation that did not actually cause any harm but that could have brought a catastrophic result). They must of course ensure that an appropriate feedback is given to the health professionals involved in the critical incident. It is also important that other professionals who could learn from the incident be informed of the recommendation made following the critical incident. In order to encourage reporting, clear rules on the confidentiality of the reports as well as of the ensuing interviews must be adopted.

The introduction of CIRS has been advocated at the European level for quite some time, especially in two legal instruments.

The first is Recommendation no. 7 of 2006 by the Committee of Ministers of the Council of Europe to Member States on management of patient safety and prevention of adverse events in health care (adopted by the Committee of Ministers on 24 May 2006). In its preamble, that Recommendation asserts that *although error is inherent in all fields of human activity, it is however possible to learn from mistakes and to prevent their reoccurrence and that health-care providers and organisations that have achieved a high level of safety have the capacity to acknowledge errors and learn from them*. The text then recommends that all 48 Member States *promote the development of a reporting system for patient-safety incidents in order to enhance patient safety by learning from such incidents*. The above-mentioned Recommendation also spells out the main features of such a system, which should be, *inter alia*, non-punitive in purpose, voluntary, anonymous and confidential wherever possible. The same document asks Member States to *ensure that a health-care professional reporting to the system shall not, as a sole result of such reporting, be subjected to disciplinary investigation or measures by the employing authority, or reprisals such as supervision or criminal sanctions by the courts*. At the same time, it states that *the appropriate response to a problem must not exclude individual responsibility, but should focus on improving organisational performance rather than on individual blame*.⁴ The Recommendation further calls Member States to pass laws that would *ensure that patients are immediately informed of an adverse event*.⁴

The Recommendation itself is very cautious as to the need for making reporting and analysis of patient-safety incidents a legal obligation, stating that experiences vary a lot from one country to the next. However, its appendix recommends to Member States to *oblige all providers of health-care services – both public and private – to receive, record and analyse reports on patient-safety incidents for use in the improvement of patient safety and treatment*.

Another part of the Recommendation requires that *health professionals should be given the opportunity to learn how to handle guilt and be supported to avoid becoming the second victim of the safety incident*. It stresses the fact that *support from the organisation to the health professionals is crucial to make disclosure of the incident possible and to enable continuation of work in health care*. Finally, the Recommendation states that *education and training curricula for all health professions should include basic knowledge on: the principles of clinical decision making, risk awareness, risk communication, risk prevention, individual and collective attitudes and behaviour in the case of adverse events (medical, legal, financial and ethical aspects)*.

The second legal instrument at the European level emanated by the European Union, which advocates to set up CIRSs, is the Council Recommendation of 9 June 2009 on patient safety.¹⁵ It repeats a number of considerations already found in the Council of Europe Recommendation of 2006 and, for instance, asks countries to *support the establishment or strengthen blame-free reporting and learning sys-*

tems on adverse events that: provide information on the extent, types and causes of errors, adverse events and near misses; encourage health-care workers to actively report through the establishment of a reporting environment which is open, fair and non-punitive.

As to the role of the law, the 2009 Council Recommendation on patient safety cautiously declares that *where necessary, the legal issues surrounding the healthcare workers' liability should be clarified!*

Adding the law to the agenda of patient safety

To sum up, law probably can have an impact on patient safety, even though the latter probably remains limited as long as the professional and institutional culture does not evolve. Combined efforts should therefore be made at the political-legal, educational and institutional levels. In the words of the Australian Commission on Safety and Quality in Health Care, *health service organisations should create an environment in which all staff are: encouraged and able to recognise and report adverse events; prepared through training and education to participate in open disclosure; supported through the open disclosure process* (Australian Open Disclosure Framework consultation draft, quoted by McLennan and Truog)⁸

Laws promoting patient safety will have to strike a delicate balance between competing interests in order to create the right incentives while safeguarding the legal protection of patients.

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