Original article

Medicine, Science and the Law
2024, Vol. 64(2) 96–112

DOI: 10.1177/00258024231182369
journals.sagepub.com/home/msl

How different countries respond to adverse events whilst patients' rights are protected

Eva Gil-Hernández[1,*], Irene Carrillo[2,*], Mary-Elizabeth Tumelty[3], Einav Srulovici[4], Kris Vanhaecht[5], Katharine Ann Wallis[6], Priscila Giraldo[7,8], María Pilar Astier-Peña[9,10], Massimiliano Panella[11], Sofia Guerra-Paiva[12], Sandra Buttigieg[13], Deborah Seys[5], Reinhard Strametz[14], Asier Urruela Mora[15] and José Joaquín Mira[1,2,16]

Abstract

Patient safety is high on the policy agenda internationally. Learning from safety incidents is a core component in achieving the important goal of increasing patient safety. This study explores the legal frameworks in the countries to promote reporting, disclosure, and supporting healthcare professionals (HCPs) involved in safety incidents. A cross-sectional online survey was conducted to ascertain an overview of the legal frameworks at national level, as well as relevant policies. ERNST (The European Researchers' Network Working on Second Victims) group peer-reviewed data collected from countries was performed to validate information. Information from 27 countries was collected and analyzed, giving a response rate of 60%. A reporting system for patient safety incidents was in place in 85.2% (N = 23) of countries surveyed, though few (37%, N = 10) were focused on systems-learning. In about half of the countries (48.1%, N = 13) open disclosure depends on the initiative of HCPs. The tort liability system was common in most countries. No-fault compensation schemes and alternative forms of redress were less common. Support for HCPs involved in patient safety incidents was extremely limited, with just 11.1% (N = 3) of participating countries reporting that supports were available in all healthcare institutions. Despite progress in the patient safety movement worldwide, the findings suggest that there are considerable differences in the approach to the reporting and disclosure of patient safety incidents. Additionally, models of compensation vary limiting patients' access to redress. Finally, the results highlight the need for comprehensive support for HCPs involved in safety incidents.

[1]Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO), Sant Joan d'Alacant, Spain
[2]Health Psychology Department, Miguel Hernández University, Elche, Spain
[3]School of Law, University College Cork, Cork, Ireland
[4]The Cheryl Spencer Department of Nursing, University of Haifa, Haifa, Israel
[5]Department of Public Health, Leuven Institute for Healthcare Policy, KU Leuven-University of Leuven, Leuven, Belgium
[6]General Practice Clinical Unit, Medical School, The University of Queensland, Brisbane, Australia
[7]Head Patient Advocacy, Hospital del Mar, Barcelona, Spain
[8]Pompeu Fabra University, Barcelona, Spain
[9]Primary Care Quality Unit, Territorial Health Authority, Camp de Tarragona. Health Institut of Catalonia, Barcelona, Spain
[10]Patient Safety Group of SemFYC (Spanish Society of Family and Community Medicine) and Quality and Safety Group of Wonca World (Global Family Doctors), Barcelona, Spain
[11]Department of Translational Medicine (DIMET), Università del Piemonte Orientale, Novara, Italy
[12]Public Health Research Centre, National School of Public Health, NOVA University of Lisbon, Lisbon, Portugal
[13]Department of Health Services Management, Faculty of Health Sciences, University of Malta, Msida, Malta
[14]Wiesbaden Business School, RheinMain University of Applied Sciences, Wiesbaden, Germany
[15]Department of Criminal Law, Philosophy of Law and History of Law, University of Zaragoza, Zaragoza, Spain
[16]Alicante-Sant Joan Health District, Alicante, Spain

*Co-first authorship.

Corresponding author:
Irene Carrillo, Health Psychology Department, Miguel Hernández University, Avenida de la Universidad s/n, 03202 Elche, Spain.
Email: icarrillo@umh.es

Keywords
Quality of care, patient safety, disclosure, compensation, legal frameworks, second victims, healthcare professionals

Introduction

Patient safety is one of the global challenges that involve all healthcare institutions and practitioners in all countries. In the last 20 years, there has been an increasing awareness of the frequency with which adverse events occur in health systems across the world. These reports highlighted that patients may suffer injury or harm while receiving healthcare and marked the beginning of a significant change in the conceptual and operational definitions of quality in healthcare institutions. Since then, patient safety has been positioned high on the agendas of healthcare professionals (HCPs) and those responsible for healthcare systems.

Studies on the frequency of safety incidents in healthcare facilities at all levels of care[1] have been followed by research on the implementation of safe practices[2] and analysis of the costs caused by adverse events in terms of economic, physical, and emotional suffering, sick leave, loss of workforce, loss of annual disability-adjusted life years, and deaths.[3–6]

There are clear advances in patient safety, but difficulties and barriers also persist.[7] Learning from errors has helped in improving safety[8] but more progress is needed to cultivate a blame-free environment within the walls of the healthcare institutions, as well as society at large. Risk management mechanisms have been introduced that promote the psychological safety of speaking-up about near misses and safety incidents, while steering away from a blame culture.[9] Nevertheless, some barriers still exist that impede achievement of patient safety targets at the individual, organizational, and socio-cultural levels. For example, the legal framework of individual jurisdictions can help facilitate better understanding of the context in which adverse events occur, increase transparency towards patients and their families following adverse events, and recognize the impact that safety incidents also have on HCPs.[10–13]

This study explores the legal frameworks adopted by countries around the world that enable HCPs to learn from adverse events, whilst ensuring the protection of patients' rights. In doing so, the research provides an overview of the national approaches to the disclosure of patient safety incidents, compensation mechanisms, and supports for HCPs.

Methods

We conducted an international, cross-sectional study based on the opinion of key informants on the legal frameworks and the mechanisms and action plans implemented at national level to respond to safety incidents ensuring the protection of patients' rights. This study is reported according to STROBE guidelines.[14]

The Research Commission of the Department of Health of Alicante-Sant Joan (Spain) considered this study, concluding that the object of the study and the methodology applied was exempt from ethical review according to the Spanish regulation.

Participants

Members of the COST Action 19113 funded by COST Association and lead by the ERNST (The European Researchers' Network Working on Second Victims) Consortium were invited to participate. In accordance with COST regulations, this network includes the participation of pan-European countries and the collaboration of non-European partners, including countries from the American and Asian continents. These Consortium members were invited as 'information-rich' participants with recognized expertise in the field of patient safety, from a variety of disciplines including medicine, nursing, and law. ERNST members are working mitigating the impact of adverse events in their countries. In turn, they were allowed to ask other colleagues for information to ensure that all answers were completed properly. Additionally, researchers from countries that have initiated legal reforms with the goal of increasing patient safety, identified through the specialized literature were also invited. The inclusion criteria for these participants were those who work in patient safety and/or have published studies related to legal and ethical issues surrounding patient safety (e.g., no-fault compensation systems, apology laws, confidentiality and transparency, legal frameworks relating to open disclosure, reporting systems and analysis of patient safety incident reports, etc.). In total, 113 people corresponding to 45 different countries were invited.

At that time, ERNST was composed of 26 countries (Belgium, Bosnia and Herzegovina, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Iceland, Ireland, Italy, Lithuania, Malta, Moldova, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Spain, Sweden, Switzerland, and Turkey), one co-operating member (Israel), and one neighboring country (Azerbaijan). As non-European partner countries of the ERNST network, we invited researchers from Argentina, Brazil, Chile, Colombia, Ecuador, Mexico, Peru, Japan, and the USA. Likewise, participants from

Australia, Bulgaria, Canada, China, Korea, New Zealand, South Africa, and the United Kingdom were identified and invited.

The most common scientific fields among the participants were public health, health sciences, health policy, clinical medicine, and psychology. However, areas such as communication, economics, law, nursing pedagogy, pharmacy, and sociology, among others, were also represented.

Participation was voluntary and informed consent was obtained from all participants. Participants were also advised about their right to withdraw from the study.

Instrument

We developed an ad-hoc online survey of 25 questions to explore three core topics relating to the management of adverse events (Annex 1). First, legislation and policies relating to safety culture for learning from safety incidents, including reporting systems, adverse events analysis, and patient safety strategy were explored. Secondly, issues relating to patients' rights including access to safety incidents information in the medical record, open disclosure, apology, mediation mechanisms, and compensation mechanisms were analyzed. Thirdly, questions surrounding support for the HCPs involved in the event (second victims), the legal framework (e.g., no-fault schemes), legal privileges in notification, and apology were posed. In addition, five open fields were included so that participants could make any comments considered necessary regarding these issues. The survey was developed by IC and JJM informed by the specialized literature. PG, MPA, KV, and KAW review the first draft of the instrument. The legibility of the questions and the length of the survey were assessed. The country of the participants was identified to determine the degree of legal framework development.

Procedure

Participants were invited to participate in the study individually via email, where the study's objective, the characteristics of the survey (topic, length, time consumption, etc.), and the voluntary and confidential nature of participation in the study was also outlined. The study period was from April 2019 to October 2022.

Data analysis

Frequency analyses were performed for questions with closed answers. The open-text questions on previous experiences and interests were analyzed qualitatively by grouping the responses into thematic categories with the identification of the origin country of each participant. For those countries where there was more than one informant, the responses were integrated to avoid the overrepresentation of one informant over another. Data analyses were performed with IBM SPSS Statistics 28.0.0. For the open-text questions, EG, IC, and JJM independently analyzed the responses, identified relevant information, and assessed possible consistency across countries. Information provided by informants on the particularities of their country or alternative mechanisms in place, but not covered by the survey, was qualitatively incorporated into the study results. The answers to question 25, about specific rules and legislation applied in each country regarding patient safety, were subsequently supplemented with the information available in the WHO MiNDbank database.[15]

Results

In total, 31 informants participated providing information from 27 countries (19 European countries and 6 Latin American countries belonging to ERNST and 2 non-ERNST countries) (Table 1). This represents a 60% participation rate of countries invited. Nine informants (29.0%) were managers of health institutions and 22 (71.0%) researched in patient safety, all who had more than 3 years of experience in patient safety. 18 (58.1%) worked in a university, 7 (22.6%) worked in a hospital, and 6 (19.4%) worked in a healthcare organization. Those countries for which there was more than one respondent were Chile (3), Peru (2), and Spain (2).

Table 1. Countries from which respondents answered the survey (N = 27).

Non-ERNST members	Europe ERNST members	Latin America ERNST members
Canada	Belgium	Argentina
New Zealand	Bosnia and Herzegovina	Brazil
	Croatia	Chile
	Denmark	Colombia
	Estonia	Mexico
	Finland	Peru
	Germany	
	Ireland	
	Israel	
	Italy	
	Lithuania	
	Malta	
	Norway	
	Poland	
	Portugal	
	Romania	
	Slovakia	
	Spain	
	Turkey	

The results of the first 24 questions of the questionnaire, which correspond to closed questions, are shown in Table 2.

Patient safety culture: proactive and reactive approaches to clinical risk management

The existence of a national agency or similar entity responsible for leading the patient safety strategy was reported by less than half of the respondents for each country (N = 13, 48.1%). Only participants from 6 of 17 countries (35.3%) noted the existence of reports assessing the impact of patient safety policies and standards in pursuit of continuous improvement of quality care. Despite the weight of legal issues in addressing adverse events, in most participating countries (N = 15, 55.6%), activities on patient safety policies aimed at lawyers and jurists were either unknown or did not exist.

Regarding the reactive management of patient safety incidents, 85.2% (N = 23) of the participating countries had a reporting system at the institutional or national level. Interestingly, in Denmark patients can also report adverse events in the same system as the professionals do. In the remaining 14.8% (N = 4), a reporting mechanism was not usually available. In line with this data, 63.0% (N = 17) of the respondents indicated that, in their country, this tool for reporting incidents in practice is more of a formal system than a realistic one focused on learning from experience and avoiding similar incidents in the future. Regarding the type of incidents reported, 92.6% (N = 25) of respondents indicated all kinds of incidents (with and without harm), despite their possible legal implications. The participants from Germany and Turkey were the only ones who indicated that exclusively near-misses were reported.

In 55.6% (N = 15) of the participating countries, it was customary for the HCP involved in the adverse event to take part in its analysis, regardless of the inter-institutional variability at the national level. However, the participation of the involved professional in the incident analysis was a generalized practice in only 33.3% (N = 9) of the countries. Specifically, in Denmark, Finland, Ireland, Italy, Malta, Romania, and Slovakia, the involvement of the professional in the adverse event analysis was mandatory. These participation figures decreased (N = 12, 44.4%) when asked about the participation of the professional in a root cause analysis to identify new barriers to help prevent the recurrence of similar adverse events in the future.

Protection and respect for patients' rights

Access to medical record information (including patient safety issues), open disclosure of adverse events, and fair compensation for harm associated with severe adverse events were explored in the context of ensuring patient's rights.

In 81.5% (N = 22) of the participating countries, patients had access, by law, to all clinical information on diagnoses and treatments included in their medical records. However, in only 9 of these, patients could also obtain information on possible safety incidents that occurred during their care. Furthermore, in 76.0% (N = 21) of the participating countries, health centers are legally obliged to provide complete medical records to the patient or relatives (in the event of the patient's death).

Regarding the open disclosure of serious adverse events to patients, participants from 44.4% (N = 12) of the participating countries indicated that this was an internally protocolized practice in healthcare institutions. However, the same percentage of countries had no known policy (either national or local) that mandated disclosure of an adverse event. Consequently, in most countries (N = 13, 48.1%), the practice of open disclosure after an adverse event was voluntary and largely dependent on the initiative of the HCP or the team involved. 22.2% (N = 6) of the countries reported the practice as being very infrequent. Only participants from Chile, Ireland, Italy, and Norway reported that their countries had precise legislation regulating the professional's duty to report adverse events to the patients who suffer from them.

Mechanisms for redress after an adverse event, including alternative forms of dispute resolution, were also explored with participants. Six out of ten (N = 16, 59.3%) countries did not have a known mediation system. In 60% of the countries where such a system existed, patients were also entitled to litigate a claim.

To the best of the knowledge of the study informants, most participating countries did not have legislation specifically designed to provide compensation in case of an adverse event (N = 21, 77.8%), nor did they have a specific compensation scale for these cases (N = 22, 81.5%).

No-fault compensation systems were less common. Informants from Belgium, Denmark, Lithuania, New Zealand, and Norway reported that a no-fault compensation system existed in their countries. In all the other jurisdictions analyzed, the most common form of redress for patient safety incidents was litigation, with the tort liability system common in most of the countries. In some cases, this system co-exists with a mediation system. For example, in Chile patients can go to the Superintendence of Health to file a complaint and a mediation process begins. In Poland, individual mediation between the hospital insurer and patient also occurs. In Mexico, they have the National Commission of Medical Arbitration (CONAMED), whose purpose is to contribute to the resolution of conflicts between users of medical services and the providers of such services, through conciliation agreements including financial compensation, medical care, etc. In some countries (e.g., Spain) there is

Table 2. Questions and answers, with their corresponding percentages, to the first 24 items of the survey (data correspond to countries, as data from different participants with the same country of origin have been integrated).

Question	Answers, N (%)				Comments
1. Is there a Report System?	Yes, common at national level 15 (55.6%)	Yes, in several healthcare institutions 8 (29.6%)	Usually not available 4 (14.8%)		In 12 (52.2%) of the affirmative cases it is voluntary.
2. What kind of incidents are reported (with and without harm)?	All kind of incidents 25 (92.6%)		Only near misses 2 (7.4%)		
3. Is it a realistic one - focused on avoiding the same AE (learn from experience), may happen again- or a formal system?	Realistic-focused on promoting learning 10 (37.0%)		Formal system 17 (63.0%)		
4. Is there any regulation to protect professionals who report to the system?	None 12 (44.4%)	Anonymization of data after some days from reporting 12 (44.4%)	Regulation having the force of Law 3 (11.1%)		
5. What is the protection of professionals analyzing the notified incidents?	None 15 (55.6%)	Anonymization of data after some days from reporting 7 (25.9%)	Regulation having the force of Law 5 (18.5%)		
6. To what type of information of their medical record can the patients access?	All information included in the medical record, including information about safety incidents 9 (33.3%)	All clinical information about diagnosis and treatments 13 (48.1%)	Limited information available 3 (11.1%)	They have no access to information 2 (7.4%)	

(continued)

Table 2. Continued.

7. Do the health centers have a legal duty to provide full medical record information to the patients or their relatives (when the patient has died)?	Yes			No		
	21 (77.8%)			6 (22.2%)		
8. In case of an adverse event, are patients systematically informed and/or apologized for?	There is a legislation and professionals have the duty to inform patients	There is usually a national or local policy		Open disclosure depends on the initiative of healthcare professionals	It is rare cases of open disclosure	
	4 (14.8%)	4 (14.8%)		13 (48.1%)	6 (22.2%)	
9. In case of a severe adverse event, how about open disclosure approaches?	There is Sorry Works/Law or similar	There is a national Open Disclosure policy		There are usually Open Disclosure protocols or internal procedures in healthcare institutions	There is not Open Disclosure policy	
	1 (3.7%)	2 (7.4%)		12 (44.4%)	12 (44.4%)	
10. In case of an adverse event, are HCPs systematically involved in an adverse event analysis?	Yes, it is mandatory	In more than 75% of institutions	Around 50% of institutions	25-35% of institutions	Less than 25% of institutions	Never
	7 (25.9%)	2 (7.4%)	6 (22.2%)	3 (11.1%)	8 (29.6%)	1 (3.7%)
11. In case of an adverse event, do the HCPs involved participate in a root-cause analysis to identify new barriers to prevent the recurrence of similar adverse events?	Yes, it is mandatory	In more than 75% of institutions	Around 50% of institutions	25-35% of institutions	Less than 25% of institutions	Never
	4 (14.8%)	3 (11.1%)	5 (18.5%)	3 (11.1%)	11 (40.7%)	1 (3.7%)

(continued)

Table 2. Continued.

12. In case of an adverse event, are HCPs involved in an adverse event (second victims) receiving support to cope with the emotional impact that supposed the safety incident occurred?	Yes, in all healthcare institutions 3 (11.1%)	In more than 75% of institutions 1 (3.7%)	Around 50% of institutions 2 (7.4%)	25-35% of institutions 1 (3.7%)	Less than 25% of institutions 8 (29.6%)	No, this intervention is not included yet 12 (44.4%)
13. What type of protection do HCPs has when they ask forgiveness or when they apologize for what happened?	Sorry Law or Sorry Works policy 1 (3.7%)	Regulation having the force of Law 5 (18.5%)	Institutional support 12 (44.4%)	None 9 (33.3%)		
14. Do Apology Law include protection for a full apology (including the admission of fault or liability)?	Yes 2 (7.4%)	No 25 (92.6%)				
15. Can patients claim compensation and at the same time file a lawsuit?	Yes 16 (59.3%)	No 11 (40.7%)				
16. Is there a mediation system?	Yes 11 (40.7%)	No 16 (59.3%)	In 6 (60.0%) of the affirmative cases patients can ask for mediation or alternative dispute resolution and at the same time file a lawsuit.			

(continued)

Table 2. Continued.

17. Are there informative actions, workshops, meetings, interchange channels, or anything else to disseminate patient safety policies and targets (for example to discriminate malpractice from adverse events) among lawyers and jurors?	Yes 12 (44.4%)	No 15 (55.6%)
18. Is there a Compensation Act applicable in case of an adverse event?	Yes 6 (22.2%)	No 21 (77.8%)
19. Is there a national scale of compensation applicable when patients suffer from harm as a consequence of care?	Yes 5 (18.5%)	None 22 (81.5%)
20. Are there any alternative compensation schemes?	Yes 7 (25.9%)	No 20 (74.1%)
21. Is there no-fault compensation legislation or policy for patients harmed after an adverse event?	Yes 5 (18.5%)	No 22 (81.5%)
22. Is there fair compensation legislation or policy for patients harmed after an adverse event?	Yes 6 (22.2%)	No 21 (77.8%)

(continued)

Table 2. Continued.

23. Is there a National Patient Safety Agency or similar institution leading a national strategy on patient safety in your country?	Yes 13 (48.1%)	No 14 (51.9%)	In 8 (61.5%) of the affirmative cases this strategy includes an open disclosure policy, and in 4 (30.8%) includes a no-fault compensation policy.
24. Are there national/local reports assessing the impact of policies, rules, or legislation and do they enable learning to enhance patient safety?	Yes 6 (35.3%)	No 11 (64.7%)	Only 17 countries answered this question, so percentages are based on this total.

the possibility of opening an asset file, and the insurance company can mediate between the patient and the family, and in Argentina there are alternative compensation schemes.

Legal privilege and emotional support for HCPs involved in the occurrence or management of an adverse event

As regards reporting patient safety incidents, in most participating countries (N = 24, 88.9%), there was no specific regulation in place or known that offered legal privilege to the professional using the reporting systems. The most common practice was data anonymization a few days after the analysis. A similar situation was observed concerning the professionals or safety committee involved in analyzing the reported incidents.

Regarding open disclosure, there were no legal mechanisms to protect expressions of apology by the professional to the patient victim of an adverse event from being used in a malpractice lawsuit in 21 (77.7%) of the participating countries. However, other informal supports were reported, for example, 44.4% (N = 12) of participants reported the institution's provision of support to address this difficult conversation with the patient or their relatives. The participant from Canada noted the existence of Sorry Laws, whilst Ireland has legislation (Civil Liability (Amendment) Act 2017) that protects disclosure and apologies from being admissible in litigation and/or disciplinary matters.

Regarding the impact of adverse events on HCPs, in more than a quarter of the countries involved (N = 12, 44.4%), informants were unaware of specific interventions to support HCPs involved in an adverse event (second victims). Only in two out of 10 countries was the provision of support for second victims a generalized practice.

The last question of the survey asked about the rules and legislation applied in each own country regarding patient safety. 19 (70.4%) responses were received, which are represented in Table 3 along with the information extracted from the WHO MiNDbank database.

Discussion

An analysis of the data suggests that although there is vast variability between represented countries, all of them have enacted rules, legislation and/or policies in relation to some or all the following: learning from safety incidents to increase quality assurance and patient safety (e.g., using the information included in report systems), patients' rights (access to medical records, open disclosure, apologies, and forms of redress), and support for HCPs involved in adverse events (e.g., established targets in national patient safety strategies to support HCPs when they become into second victims). This study highlights the disparity which exists among countries in the context of the provision and promotion of patient safety. Given the variability across jurisdictions, the research provides a platform from which benchmarking studies may be undertaken.

Patient safety culture

Part of the variability observed is since less than half of the participating countries had a specific agency or institution responsible for leading a national patient safety strategy. Although possession of such a strategy does not guarantee its implementation, much less its desired impact, it is arguably the starting point for progress in patient safety at the national level and for unifying efforts internationally. It also is indicative of a commitment to a culture of patient safety. In the case of the countries where such an agency and strategy exist, the low degree of implementation of the other initiatives and guidelines addressed in this study suggests that the strategy is sometimes a declaration of intent that encounters difficulties in translating into resources and local and institutional policies. Moreover, the fact that there is no performance evaluation reinforces this point.

Patient safety improvements require two main considerations.[11] First, a change of culture in healthcare organizations and their environment, seeking a positive, non-punitive, and learning attitude on the part of managers is required. This includes the commitment and involvement of professionals in the analysis and management of health risks. Secondly, a legal framework that balances patients' rights with conditions that favor a safety environment in the exercise of clinical work is also needed. WHO is aware of that and urges countries to introduce regulations to ease patient safety culture among healthcare organizations in their countries, as it is defined by the strategic objective 1 of the Global Patient Safety Action Plan: Policies to eliminate avoidable harm in health.[16]

Commitment and involvement of professionals in patient safety

The involvement of both professionals and patients in patient safety has been recognized as one of the key factors in achieving a safer environment.[17] As regards reactive risk management, the existence of safety incident report systems is a widespread reality among the participating countries, but only in a few cases it is a realistic approach to promoting learning.[18,19] In the remaining two-thirds, a gap exists between identifying the remote and recent causes of safety incidents and introducing interventions to prevent recurrent adverse events. However, this is in contrast with one of the main functions of a reporting system, which should be to analyze what has happened and learn from it to prevent future mistakes.[20] It is relevant to

differentiate between exploring how an adverse event arose and learning from it. Counting how many adverse events have occurred or how often they occur does not mean learning. For learning to take place, the causes must be analyzed, and the source of the problem must be established. Therefore, it is not enough just to have a report, but analysis of what happened is essential. Nevertheless, this learning process can be hindered by feelings of guilt and shame that prevent a HCP from telling what happened. In voluntary systems, one issue that may influence the willingness of HCPs to participate in incident reporting and analysis is the fear of being identified and sanctioned,[21,22] or what is more, that he or she may be sued or taken to court for conflict of interest.

According to the participants in our study, in most countries surveyed, HCPs involved in the adverse event are not systematically involved in analyzing what happened and its causes. Regardless of the fact that preconceived ideas about the event, biases, or a natural wish to avoid criticism could lead to the HCP's involvement in the subsequent investigation limiting exploration of the issues, his/her participation in the event analysis is crucial as an information source and can help to his/her recovery and to avoid the second victim syndrome. Likewise, it sends a message in favor of the community of professionals. In this study, most countries lacked regulations that contribute to engagement of professionals during these processes, and most protective measures relied on post-analysis anonymization of data. This is even though international guidelines highlight the importance of the right to protection of the reporter's identity when reporting a patient safety incident.[20,23]

Safety incident reporting systems and procedures for analyzing their causes are some primary means by which the institution expresses its commitment to risk management. These practices are a prerequisite for and, at the same time, contribute to promoting a culture of patient safety.[24–26] It is, therefore, a foundation for moving toward more challenging patient safety practices as those that specifically target patients who suffer an adverse event and their families.

However, to achieve these targets some cultural changes are needed. A blame culture shares the idea that the cause of avoidable adverse events lies primarily in the occurrence of human error when most often it is the result of the combination of system failures and errors.[27] Blame culture adopts a person-centered view of the avoidable adverse event with the consequence that disciplinary action, guilt, and shame are expected. Nevertheless, it is proven that most adverse events have a systematic origin. In contrast, by adopting a systemic vision, the immediate causes as well as the remote ones are analyzed.[28] Indeed, different profiles of HCPs (including managers) should be involved in the analysis to ensure different points of view and encourage that recommendations are applied.[18] Rather than simply using the term 'error', it is better to consider incidents that cause or can cause harm to the patient, in which case, organizational and procedural changes are more likely to be required.

Moreover, a proactive safety culture and a clear understanding of what patient safety incidents represent and how to prevent them have proven effective in creating an enabling environment to prevent patients from suffering avoidable harm during the care they receive.[29] In this regard, it is important to consider that HCPs can be psychologically affected after an adverse event, which is known as the second victim phenomenon.[30] This, in turn, increases the risk of new adverse events in a circle that perpetuates itself over time.[31,32] This fact has shifted the traditional blame paradigm even more to emphasize the systemic vision approach within a learning environment.

Protecting patients' rights and supporting HCPs

When an adverse event occurs, the patient (and/or his/her family) should be informed, and where appropriate, compensated in an adequate and fair manner. A body of international research has highlighted the importance of communication with a patient who suffers an adverse event.[10] Open disclosure is essential for the delivery of high-quality patient care.[10] This consists of informing patients or their families that a patient safety incident has occurred, providing an apology or expression of regret, explaining what happened, indicating potential consequences for the patient, and discussing the changes being made to prevent recurrences.[33] The non-disclosure of patient safety incidents to those affected by them is unethical. Despite this, only three out of 10 patients, according to some studies, are informed in OECD countries,[10,34] In this study, informants from more than 70% of the participating countries indicated the absence of a specific policy or legislation regulating the systematic duty to openly disclose adverse events to patients. In four out of 10 cases, there was an internal institutional protocol for this communication, while in one-fifth of the countries, it was an uncommon practice.

Whilst policies vary, it is maintained that the relevant HCPs should be involved in this discussion. Although patients may gain insights as to what has happened in circumstances where they can access their medical records, the presence of a HCP who can explain and discuss the adverse event is necessary, since the patient does not always have the prior knowledge to do so.[35]

Patients and professionals agree that open disclosure is the correct practice after an adverse event. However, the findings of this research suggest there is a gap between theory and practice.[36] Two of the most common barriers cited in the literature to disclosure are fear of malpractice litigation and lack of skills or training to perform the disclosure conversation appropriately.[37,38]

Accompanying the information about the adverse event with an apology is essential to meet the emotional needs of

Table 3. Rules and legislation of each country regarding patient safety.

Country	Rules or legislation regarding patient safety
Argentina*	Actions for patient safety in the healthcare setting
	Tool for the Assessment and Improvement of Patient Safety in the Healthcare Setting (RM 2801/2020)
	National Advisory Committee for Patient Safety (RM 1616/2017)
Belgium*	Strategy Note on Patient Safety (2008)
Bosnia and Herzegovina	Law on Health Care (Republika Srpska Official Gazette no. 18/99)
	Law on the System for the Improvement of Quality, Safety, and for Accreditation in Healthcare (Official Gazette of the FBIH, nos. 59/05, 52/11 and 6/17)
Brazil	Order No. 1660 of July 22, 2009: Reporting and Research System in Health Surveillance (VIGIPOS)
	Resolution - RDC No. 36, of July 25, 2013, institutes actions for patient safety in health services and makes other provisions
	Order MS/GM No. 529 of April 1, 2013: National Patient Safety Program (PNSP)
	National Program for the Prevention and Control of Healthcare Associated Infections (2016–2020)
Canada*	Canadian Patient Safety Institute strategy (Patient Safety Right Now, 2018–2023)
	Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals (2019)
Chile	Law No. 20584 on Patient's Rights and Duties
	Patients Safety Standards (Res. Ex. 1031 (17/10/12))
Colombia*	Single Accreditation System
	Mandatory Quality Assurance System
	National Patient Safety Policy
	Technical Guide of Good Practices
	Patient Safety Program
Croatia	Act of 14 December 2018 on Quality of Health Care (Text No. 2339)
	Ordinance on Healthcare Quality Standards and the Method of their Application (Text No. 1693)
	Law on the Quality of Health Care and Social Welfare (Text No. 2472)
	Law on Health Care (Text No. 4097)
	Law on the Protection of Patients' Rights (Text No. 2953)
Denmark*	Promulgation of the Health Act (LBK no. 913 of 13/07/2010)
	Danish Patient Safety Act 2003
Estonia	- - - *(There are no specific regulations yet, it will come into force in 2024)*
Finland	Health Care Act 1326/2010
	Plan for implementation of quality management and patient safety Act 341/2011
	Act on the Status and Rights of Patients (No. 785/1992)
Germany	Law on Patient Safety Rights (Patientenrechtegesetz §630a-h BGB)
	National Health Objective on Patient Safety (2022)
Ireland	Civil Liability (Amendment) Act 2017
	Health Act 2007
Israel	Adverse Event Procedure (2009)
	Availability of Information Act (1998)
	Patient's Rights Act (1996)
Italy*	Law No. 24 of May 8, 2017: Provisions on the safety of care and the assisted person, as well as on the professional responsibility of health professionals
Lithuania	Law on the Rights of Patients and Compensation of the Damage to their Health (I-1562)
	Order No. V-401 of May 6, 2010: Approval of Adverse Events Monitoring and Management Record
Malta	Health Act of October 25, 2013, to regulate the entitlement to, and the quality of, healthcare services in Malta, to consolidate and reform the Government structures and entities responsible for Health and to provide for the rights of patients
	Ombudsman
Mexico	General Health Act (Diario Oficial de la Federación, February 7, 1984)
	Quality and Patient Safety Committee (COCASEP)
	Agreement declaring the mandatory implementation, for all members of the National Health System, of the document called Essential Actions for Patient Safety (DOF, 08/09/2017)
New Zealand*	New Zealand Health Strategy 2016
	Health Practitioners Competence Assurance Act 2003
	Health and Disability Services (Safety) Act 2001

(continued)

Table 3. Continued.

Country	Rules or legislation regarding patient safety
Norway*	Patient and User Rights Act (LOV-1999-07-02-63)
	National Action Plan for Patient Safety and Quality Improvement (2019–2023)
Peru*	Ministerial Resolution No. 163-2020/MINSA of 2 April, 2020
Poland*	Act of November 6, 2008, on Patient Rights and the Patient Rights Ombudsman
Portugal*	Basic Health Law No. 95/2019 September, 4
	National Patient Safety Plan 2021-2026 (No. 9390/2021, September 24)
	Norm No. 015/2014 – National System of Incident Reporting - NOTIFICA
Romania	Order No. 639/2016 for the approval of the Methodology for monitoring the accredited health units
	Order No. 261/ 2018 regarding the approval of the Stages for the implementation of the National Program for ensuring and improving the quality of health services and patient safety within the outpatient health units
	Order No. 446/2017 regarding the approval of the Standards, Procedure and methodology for the evaluation and accreditation of hospitals
Slovakia*	Law 567/2004 Health Care Act
Spain	Law 16/2003, of May 28, on Cohesion and Quality of the National Health System
	Law 41/2002, of November 14, 2002, Basic Law Regulating Patient Autonomy and the Rights and Obligations Regarding Clinical Information and Documentation
Turkey*	Quality Standards in Health
	Communication on the Procedures and Principles for the Provision and Protection of Patient and Employee Safety in Health Institutions and Organizations" (R.G. No. 27214) of April 29, 2009
	Regulation on Ensuring Patient and Employee Safety, of April 6, 2011
	Patient Safety Association, 2006
	Patient Rights Regulation (Official Gazette Date: 01.08.1998, Number of Official Gazette: 23420)

*This information has been completed according to the WHO MiNDbank database.

patients. Despite the fear it may arouse among HCPs, for many, it is the best way to alleviate their feelings of guilt and distress about what happened.[39] Furthermore, an expression of sympathy or an apology can relieve anger and frustration, thus allowing an easier agreement instead of a more expensive and longer lawsuit, partly because most of the time, the reason for the lawsuit is to find out what went wrong, to seek acknowledgment of the error, and to prevent recurrence.[12,40,41] At present, guidelines,[42] professional regulations, and a legal framework co-exist. However, these are sometimes contradictory or, at least, difficult for HCPs to understand, which jeopardizes the objective of achieving a higher quality of care.

After the occurrence of an adverse event, patients or their relatives may decide to pursue redress. In three-quarters of the countries surveyed, there is no Compensation Act applicable in case of an adverse event or any alternative compensation schemes. As a result, redress is mainly pursued through the courts. Some countries have chosen to implement communication-and-resolution programs (CRPs) to bring together open communication, reporting and analysis of adverse events, apology, and compensation to patients who are victims of an adverse event or their families.[43] Most of these initiatives have been carried out in the United States, encouraged by AHRQ's CANDOR toolkit.[44] Some of these experiences have shown evidence of a reduction in the volume and costs of malpractice claims, but the effect of these programs on patient safety is still unknown.[43] The variability in the implementation and success of CRPs is high, and it seems to depend on the support of organizational leaders, the training of professionals in the program, the relationship between facility risk managers and liability insurance representatives, decision-making protocols, supervision, and the size of the institution.[45]

In addition to these alternative programs, mediation, and arbitration can also play a role in successful medical dispute resolution. These mechanisms as well as no-fault systems aim to realize the principles of just culture and are better accepted by patients and professionals as they reduce costs, stress, and uncertainty. They are closer to the idea of harnessing as much information as possible to create an increasingly safe environment than the adversarial (litigation) system and facilitate compensation to the patient who suffered an adverse event in the more common case of systemic causes. In this study, only four out of ten nations have a mediation system available to claimants or victims. However, some studies suggest that, under certain conditions, alternative dispute resolution may be a good option. In China, the People's Mediation Law allows mediation of disputes by the People's Mediation Committee free of charge. Upon request by the patient or the medical institution, the process is conducted in four steps: declaration by both parties; analysis of the case by medical and legal experts; the invitation to specialists or other professionals related to the case; and negotiation by the mediator with both parties. The agreement after

mediation has legal effect, but for it to be legally binding, the patients or health institutions must request judicial confirmation. In an analysis of 4902 mediation records conducted between 2013 and 2015, 41% of cases reached a mediation agreement, 21% resulted in reconciliations between hospitals and patients, 11% proceeded to litigation, and 21% withdrew.[46] A similar system has been operating in Mexico (CONAMED) since 1996 and France since 2002. In the latter, the National Office for Compensation for Medical Accidents, Iatrogenic Disorders, and Nosocomial Infections (ONIAM, acronym in French) is a public institution whose mission is to organize a friendly, fast, and free-of-charge compensation system for victims of medical accidents. ONIAM and the Commission de Conciliation et de Compensation, although independent institutions, work in collaboration so that victims of serious adverse events can receive fair compensation. The victims can access ONIAM and be quickly compensated by an alternative dispute resolution system, knowing that they can always, if they prefer, go to court room.[47]

The predominant fault-based model of redress and accountability for patient safety incidents contributes to concerns about the liability of HCPs. The prevailing medical liability system has significant shortcomings in that it does not appear to perform its primary functions satisfactorily. It does not work as means for providing patients with malpractice compensation, rarely applies meaningful corrective justice, and is ineffective in preventing substandard care through the perception of risk.[48]

Protection of HCPs after an adverse event

Five other participating countries referred to professional legal privileges when disclosing a safety incident (from admission of the disclosure in subsequent litigation). Those who defend the goodness of the 'Apology Laws' do so based on their potential to promote greater openness and transparency after an adverse event, given that they are expected to offer some legal guarantees to the professionals involved. Although the results of studies on the impact of these laws on liability are inconclusive, they suggest that this legal protection neither increases nor decreases liability risk.[39,49,50,51] The effect of these rules on the frequency with which HCPs report adverse events to patients and offer them an apology is unknown. Ultimately, these laws, as we know them, are not a panacea since they are limited in the coverage of expressions and do not guarantee the quality of the apology. However, they could perhaps contribute to transparency in healthcare and patient safety while equalizing the opportunities for all patients to access the civil justice system.[52]

Some countries have sought alternatives by introducing other legal reforms in this context such as No-Fault Compensation Systems. Belgium,[53] Denmark,[54] Lithuania,[55] New Zealand,[56] Norway,[57] and Sweden[58] are examples of this approach. The available evidence suggests no association between the measures of malpractice liability risk in its current form and the health care quality and outcomes.[48] In the New Zealand case, the system of no-fault compensation for medical misadventure, while it does not generate a higher level of claims-making and receipt than tort jurisdictions, nevertheless attracts claims well targeted in relevant respects. However, these claims are associated with incidents that have not been the result of substandard care, and that would probably not receive consideration in a civil liability system. So, without other procedural changes, a move to a no-fault system does not necessarily address issues of low and selective claims-making and receipt.[59] Therefore, no-fault systems do not appear to reduce adverse events or claims, although they may be more respectful of patients and help reduce their suffering after a poor health outcome.

Finally, we must understand the impact on patient safety when professionals see their responsiveness compromised and doubt their ability to make practice and decisions. The need for support for HCPs after adverse event seems to be clear if the important policy goal of patient safety is to be achieved.[32] Given the profound and long-lasting impact an adverse event may have on HCPs, institutional support is required.[60] In this study, most respondents reported that there is no institutional support for HCPs to help cope with the emotional impact of being involved in a safety incident or less than 25% of the institutions of their country, which increased the risk of new adverse events.

Limitations

The purpose of the study was not to provide a specific legal analysis, but to offer an overview of the international approach to patient safety. As such, it is not intended as a comparative legal analysis. The participants' responses may have a local bias, especially in the case of countries organized politically and health-wise into regions or states with a certain degree of independence. To reduce this bias, key informants were instructed to cross-check information with other key informants in their country. However, this process was not recorded, and we cannot provide data on where this instruction was followed. In some cases, the reception of more than one response per country made it necessary to merge the responses for analysis. The way in which legislation and regulation govern patient safety in different jurisdictions depends on a range of factors relating to the structures in each country and the sociocultural, economic, and political environments therein. However, we suggest the analysis here offers some generally applicable insights on legal approaches to patient safety at an international level. Finally, as this study started in 2019, some rules/instructions or laws may have changed from the time data collection began until now.

Conclusions

The data obtained from this study serve as a preliminary study that shows the great variety of scenarios that exist.

Despite notable advancements in the field of patient safety, including the development of legislation and relevant policies, there is wide variability in the degree of development and implementation of policies that guarantee the quality of care and respect for patients' rights after an adverse event. In general, the prevailing situation on the international scene is the existence of a strategic basis based on reactive risk management. According to international guidelines, safety incident reporting systems are a reality, although as the findings of this research suggest their focus on learning is not always guaranteed. Even though there are approaches that enable HCPs to learn from adverse events whilst ensuring the protection of patients' rights, our research suggests that institutional support to HCPs when reporting a patient safety incident or disclosing an adverse event is limited. No-fault compensation or other alternative compensation schemes are still not used in most countries surveyed, minimizing opportunities to cultivate a 'just-culture'. There is a long way to go. While there is no universal best solution, numerous initiatives are now in place to ensure the safety and respect patients' rights following an adverse event. Some of these, such as tort reform, 'Apology Laws', or compensation acts, are legally binding, while others, such as CRPs, mediation systems, and other alternative medical dispute resolution schemes, are not necessarily legally binding. Future studies should delve deeper into the outcomes of these systems, not only with a focus on costs and litigation but also in terms of patient safety and patient satisfaction. They should also explore the factors and conditions that ensure successful implementation. Furthermore, any such measures must be accompanied by dissemination among HCPs and appropriate training.

The questionnaire covered a wide variety of situations, some of them potentially complex, so a study combining interviews with in-depth interviews could provide new sources of information in the future and complement or qualify what is presented in this work.

Acknowledgments

The participation of the healthcare professionals whose responses are synthesized in this study is gratefully acknowledged.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the European Cooperation in Science and Technology, (grant number CA19113).

ORCID iDs

Eva Gil-Hernández https://orcid.org/0000-0002-4619-0503
Mary-Elizabeth Tumelty https://orcid.org/0000-0003-0459-4793
Reinhard Strametz https://orcid.org/0000-0002-9920-8674

Supplemental material

Supplemental material for this article is available online.

References

1. Panagioti M, Khan K, Keers RN, et al. Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis. *Br Med J* 2019; 366: l4185.
2. McPherson S and Wendler MC. Safe clinical practice in prelicensure nursing students: a concept analysis. *Nurs Forum (Auckl)* 2020; 55: 513–522.
3. Agbabiaka TB, Lietz M, Mira JJ, et al. A literature-based economic evaluation of healthcare preventable adverse events in Europe. *Int J Qual Health Care* 2017; 29: 9–18.
4. Gyberg A, Henoch I, Lepp M, et al. Written reports of adverse events in acute care - A discourse analysis. *Nurs Inq* 2019; 26: e12298.
5. Haukland EC, Mevik K, von Plessen C, et al. Contribution of adverse events to death of hospitalised patients. *BMJ Open Qual*. 2019; 8(1): e000377.
6. Slawomirski L, Auraaen A and Klazinga N. The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. *OECD Health Working Papers* 2017; 96: 67.
7. Hemmelgarn C, Hatlie M, Sheridan S, et al. Who killed patient safety? *J Patient Saf Risk Manag* 2022; 27: 56–58.
8. Chuang YT, Ginsburg L and Berta WB. Learning from preventable adverse events in health care organizations: development of a multilevel model of learning and propositions. *Health Care Manage Rev* 2007; 32: 330–340.
9. Wachter RM and Pronovost PJ. Balancing "No blame" with accountability in patient safety. *N Engl J Med* 2009; 361: 1401–1406.
10. Wu AW, McCay L, Levinson W, et al. Disclosing adverse events to patients: international norms and trends. *J Patient Saf* 2017; 13: 43–49.
11. Mira JJ, Romeo Casabona CM, Urruela Mora A, et al. La seguridad jurídica de los profesionales sanitarios. Un requisito para lograr una mayor calidad asistencial. *Derecho y Salud* 2017; 27: 94–110.
12. Tumelty ME. Plaintiff aims in medical negligence disputes: limitations of an adversarial system. *Med Law Rev*. 2023; 31(2): 226–246.
13. Seys D, Wu AW, van GE, et al. Health care professionals as second victims after adverse events: a systematic review. *Eval Health Prof* 2013; 36: 135–162.
14. Cuschieri S. The STROBE guidelines. *Saudi J Anaesth* 2019; 13: 31.
15. World Health Organization. WHO MiNDbank: More Inclusiveness Needed in Disability and Development. *Country Resources*, https://www.mindbank.info/collection/country (2022, accessed 22 July 2022).

16. World Health Organization. *Global Patient Safety Action Plan 2021–2030: Towards eliminating avoidable harm in health care*. Geneva: World Health Organization, 2021.
17. Chegini Z, Arab-Zozani M, Shariful Islam SM, et al. Barriers and facilitators to patient engagement in patient safety from patients and healthcare professionals' perspectives: a systematic review and meta-synthesis. *Nurs Forum (Auckl)* 2021; 56: 938–949.
18. Martin-Delgado J, Martínez-García A, Aranaz JM, et al. How much of root cause analysis translates into improved patient safety: a systematic review. *Med Princ Pract* 2020; 29: 524–531.
19. Hibbert PD, Thomas MJW, Deakin A, et al. Are root cause analyses recommendations effective and sustainable? An observational study. *Int J Qual Health Care* 2018; 30: 124–131.
20. World Health Organization. Patient Safety Incident Reporting and Learning Systems: Technical report and guidance. 2020.
21. Lee W, Kim SY, Lee S, et al. Barriers to reporting of patient safety incidents in tertiary hospitals: a qualitative study of nurses and resident physicians in South Korea. *Int J Health Plann Manage* 2018; 33: 1178–1188.
22. Giraldo P, Sato L, Sala M, et al. A retrospective review of medical errors adjudicated in court between 2002 and 2012 in Spain. *Int J Qual Health Care* 2016; 28: 33–39.
23. Mira JJ, Lorenzo S, Carrillo I, et al. Lessons learned for reducing the negative impact of adverse events on patients, health professionals and healthcare organizations. *Int J Qual Health Care* 2017; 29: 450–460.
24. Kusano AS, Nyflot MJ, Zeng J, et al. Measurable improvement in patient safety culture: a departmental experience with incident learning. *Pract Radiat Oncol* 2015; 5: e229–e237.
25. Kusumawati AS, Handiyani H and Rachmi SF. Patient safety culture and nurses' attitude on incident reporting in Indonesia. *Enferm Clin* 2019; 29: 47–52.
26. Verbakel NJ, Langelaan M, Verheij TJM, et al. Effects of patient safety culture interventions on incident reporting in general practice: a cluster randomised trial. *Br J Gen Pract* 2015; 65: e319–e329.
27. Radhakrishna S. Culture of blame in the national health service; consequences and solutions. *Br J Anaesth* 2015; 115: 653–655.
28. Moore J and Mello MM. Improving reconciliation following medical injury: a qualitative study of responses to patient safety incidents in New Zealand. *BMJ Qual Saf* 2017; 26: 788–798.
29. Liukka M, Steven A, Moreno MFV, et al. Action after adverse events in healthcare: an integrative literature review. *Int J Environ Res Public Health* 2020; 17: 1–18.
30. Wu AW, Shapiro J, Harrison R, et al. The impact of adverse events on clinicians: what's in a name? *J Patient Saf* 2020; 16: 65–72.
31. Coughlan B, Powell D and Higgins MF. The second victim: a review. *Eur J Obstet Gynecol Reprod Biol* 2017; 213: 11–16.
32. Schwappach DLB and Boluarte TA. The emotional impact of medical error involvement on physicians: a call for leadership and organisational accountability. *Swiss Med Wkly* 2008; 138: 9–15.
33. Disclosure Working Group. *Canadian Disclosure Guidelines: Being open and honest with patients and families*. Edmonton, AB, Canada, https://www.patientsafetyinstitute.ca/en/tools Resources/disclosure/Documents/CPSI%20Canadian%20 Disclosure%20Guidelines.pdf (2011).
34. Carrillo I, Mira JJ, Guilabert M, et al. Why an open disclosure procedure is and is not followed after an avoidable adverse event. *J Patient Saf* 2021; 17: e529–e533.
35. Mulyana D, Dida S, Suminar JR, et al. Communication barriers between medical practitioners and patients from medical practitioners' perspective. *Pertanika J Soc Sci & Hum* 2019; 27: 2797–2811.
36. Ghalandarpoorattar SM, Kaviani A and Asghari F. Medical error disclosure: the gap between attitude and practice. *Postgrad Med J* 2012; 88: 130–133.
37. Birks Y, Entwistle V, Harrison R, et al. Being open about unanticipated problems in health care: the challenges of uncertainties. *J Health Serv Res Policy* 2014; 20: 54–60.
38. Giraldo P, Corbella J, Rodrigo C, et al. Análisis de las barreras y oportunidades legales-éticas de la comunicación y disculpa de errores asistenciales en españa. *Gac Sanit* 2016; 30: 117–120.
39. Robbennolt JK. Apologies and medical error. *Clin Orthop Relat Res* 2009; 467: 376–382.
40. Bender FF. "I'm sorry" laws and medical liability. *Virtual Mentor* 2007; 9: 295–299.
41. Gallagher TH, Studdert D and Levinson W. Disclosing harmful medical errors to patients. *N Engl J Med* 2007; 356: 2713–2719.
42. World Health Organization. *World alliance for patient safety: WHO draft guidelines for adverse event reporting and learning systems: from information to action*. Geneva: World Health Organization, https://apps.who.int/iris/handle/10665/69797 (2005).
43. Gallagher TH, Mello MM, Sage WM, et al. Can communication-and-resolution programs achieve their potential? Five key questions. *Health Aff* 2018; 37: 1845–1852.
44. Agency for Healthcare Research and Quality. Communication and Optimal Resolution (CANDOR), https://www.ahrq.gov/patient-safety/settings/hospital/candor/index.html (2016, accessed 21 October 2022).
45. Mello MM, Roche S, Greenberg Y, et al. Ensuring successful implementation of communication-and-resolution programmes. *BMJ Qual Saf* 2020; 29: 895–904.
46. Wang M, Liu GG, Zhao H, et al. The role of mediation in solving medical disputes in China. *BMC Health Serv Res* 2020; 20: 1–10.
47. Rodrigo de Larrucea C. Derecho y Salud no van siempre de la mano. *La mediación en sanidad*, https://carmenrodrigodel-arrucea.wordpress.com/2018/04/24/la-mediacion-en-sanidad/ (2018, accessed 21 October 2022).
48. Mello MM, Frakes MD, Blumenkranz E, et al. Malpractice liability and health care quality: a review. *JAMA - Journal of the American Medical Association* 2020; 323: 352–366.
49. McMichael BJ, Van Horn RL and Viscusi WK. 'Sorry' is never enough: how state apology laws fail to reduce medical malpractice liability risk. *Stanford Law Rev* 2019; 71: 341–409.
50. Madden D and Tumelty ME. Open disclosure of patient safety incidents: legislative developments in Ireland. *Med-leg J Irel* 2019; 25: 76.
51. Pinnington D. The Apology Act, 2009: Sorry is no longer the hardest word to say. *Slaw. Canada's online legal magazine*, 2009, http://www.slaw.ca/2009/12/09/the-apology-act-2009-sorry-is-no-longer-the-hardest-word-to-say/ (2009).

52. Fields AC, Mello MM and Kachalia A. Apology laws and malpractice liability: what have we learned? *BMJ Qual Saf* 2021; 30: 64–67.
53. Vansweevelt T, Lierman S and Buelens W. No-fault law on medical accidents in Belgium: an evaluation after six years. *Journal of European Tort Law* 2019; 10: 257–285.
54. Tilma J, Norgaard M, Mikkelsen KL, et al. No-fault compensation for treatment injuries in danish public hospitals 2006–12. *Int J Qual Health Care* 2016; 28: 81–85.
55. Kirklytė I and Litvinas A. No fault compensation for medical injuries (Lithuania). *Practical Law*, https://uk.practicallaw.thomsonreuters.com/w-021-9180?transitionType=Default&contextData=(sc.Default)&firstPage=true (2019, accessed 2 August 2022).
56. Wallis K and Dovey S. No-fault compensation for treatment injury in New Zealand: identifying threats to patient safety in primary care. *BMJ Qual Saf* 2011; 20: 587–591.
57. Jørstad RG. The Norwegian system of compensation to patients. *Med Law* 2002; 21: 681–686.
58. Cooper JK. Sweden's no-fault patient-injury insurance. *N Engl J Med* 1976; 294: 1268–1270.
59. Davis P, Lay-Yee R, Fitzjohn J, et al. Compensation for medical injury in New Zealand: does 'no-fault' increase the level of claims making and reduce social and clinical selectivity? *J Health Polit Policy Law* 2002; 27: 833–854.
60. Ullström S, Sachs MA, Hansson J, et al. Suffering in silence: a qualitative study of second victims of adverse events. *BMJ Qual Saf* 2014; 23: 325–331.