
**MEDICAL SPECIALITIES WITH A HIGHER
PROPORTION OF MALPRACTICE LITIGATIONS IN
CATALONIA BETWEEN 2005-2015**

FINAL DEGREE PROJECT

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“Primum non nocere”

Agraí al Dr. Josep Ramis, la implicació i l’ ajuda
del qual a fet possible aquest projecte.

Només puc repetir aquestes famoses paraules:
“Alea jacta est!”

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1. ABSTRACT

Background: A medical error or adverse effect (AE) is a fault that occurs during the delivery of health care that has caused damage to the patient. In Spain, the incidence of patients with AE related with healthcare was a 9.3% and about a 42.8% of the AE are avoidable. Spanish data suggest that we are facing an everyday problem. Each country has a different health, economic and legal situation.

Medical malpractice could be defined as a misguided exercise or practice without skill by a physician or other professional, causing damage to the health or the condition of the patient. It has some legal consequences; it is used the term of medical responsibility or liability: moral, civil, criminal and administrative.

It is extremely problematic to establish common standards between countries. Consequently, it is needed a specific analysis of the situation, in order to determine the context of AE in our country.

Objective: The main aim of this study is to determinate which is the specialty or group of medical specialties with a highest proportion of malpractice legal procedures during, regardless of the used courts: civil, penal, etc.

Methods: This is an observational, longitudinal and retrospective study. Secretaries all around Catalan court will use TEMIS database in order to identify all judgments about medical liability in Catalonia during 2005-2015. Secretaries will send us this information in an anonymous way, deleting all persona data about doctors and patients.

Key words: medical error, medical malpractice, adverse effects, medical liability, lawsuits, Catalonia.

2. INTRODUCTION

2.1 Adverse Effects or Medical Errors; different words but the same meaning.

Nowadays, medical error related to health system is a reality. The quality and results of health care are related to it. That is why, it is a problem of international concern and it has a great interest to all those who provide health services. This matter is inexhaustible, complex, controversial and difficult to study, for these and other reasons produces certain rejection in its approach. In addition there is a certain degree of ignorance among health workers, about its definition and legal consequences.

Risk 0 does not exist in medicine, in the same way it does not exist in other areas of life. Any medical act has some consequences for the patient and the health professional, too. Generally, we can define the concept of risk in the following manner: the probability that damage will occur. According to Dr. Mulà Rosias, forensic doctor and gynaecologist, the risk can be summarized with the following equation:

$$\textbf{Real Risk} = (\textit{dangerousness} + \textit{vulnerability}) - (\textit{prediction} + \textit{response capacity}).$$

The elements of risk of real risk are dangerousness and vulnerability. The first one refers to the probability and the second one refers to the susceptibility of receiving the impact. However, there are factors that modify the risk, they can increase it or decrease it, even delete it. Here is where our prediction and response capacity come into play. For example, in a cloudy day there is a certain risk of rain, which will depend on atmospheric factors. If we go outside well-equipped and with an umbrella, consequences will be much lower for us and our clothes. The same way works in real risk of adverse effects.

The increasingly complex health care systems, together with more vulnerable, highly informed and demanding patients, conform a clinical environment in where adverse effects (AE, from now) related to health care practice appear.

Health care necessarily involves risks. The professional working in an "imperfect environment" must know what is the risk associated with their work. We talk about AE as the general term to describe any undesirable situation (or factor contributing to causing an undesirable situation) that has caused injury or disability or extension of stay and/or death. AE result from a medical intervention, or in other words, it is not due to the underlying condition of the patient (1)

AE may be avoidable or inevitable, but the barrier that separates them is sometimes very tenuous. Inevitable AE tend to be conditioned by the characteristics of the patient or the natural history of the disease. (1,2)

AE are also called medical errors. According to the Institute of Medicine of the USA (IOM); **medical error** is an adverse event or about to be produced, which mostly can be prevented, with the current knowledge of science. Errors depend on two kinds of failures: either the correct action does not proceed as intended (an error of execution) or the original intended action is not correct (an error of planning). Errors can happen in all stages in the process of care, from diagnosis, to treatment, to preventive care. (3,4).

Synthesizing and interpreting the findings in the literature pertaining to medical errors or adverse effect in health care is complicated due to the absence of standardized nomenclature. But like any other phenomenon that is going to be studied, its definition is necessary, because the problem which is not defined, cannot be measured, and in consequence it cannot be prevented or eradicated.

However, most authors agree in the following definition. **Medical error** is a fault that occurs during the delivery of health care that has caused damage to the patient, it is the failure to fully implement an action plan as it was proposed or using a wrong plan to achieve an objective. It could be related to the organization and implementation of the medical service, through multiple and complex mechanisms. None of the medical areas is exempt of them.

Medical error has no bad faith; it is not necessarily connected with an inexperience, recklessness or negligence involving moral and legal responsibility. (3–6)

Due to the great variety of errors, there is difficulty in classification despite being easily recognizable; mistakes included in transfusions, related to medications, surgery in a wrong site, surgical injuries, suicides preventable, nosocomial infections, intra-institutional burns, ulcers for pressure and wrong identification of the patient... As an attempt to categorize such errors, Lucian Leape and colleagues (5) classified them in diagnostic, therapeutic, preventive and other; in order to group errors and facilitate their study and prevention.

- Diagnostic errors: mistake or delay in diagnosis, fail when using indicated tests, use of outdated therapeutic tests, fail to act on the results provided by a test...
- Therapeutic errors: Inappropriate or unnecessary care, error in the method or the dose of medication, error in the administration of the treatment, error in surgery, avoidable delay in treatment or in response to an abnormal test, etc.
- Preventive errors: Failure to provide a prophylactic treatment, inappropriate monitoring of treatment, etc.
- Others: communication, equip...

Medical errors can also be divided according to their causes(5):

- Overuse, by excess on service: unnecessary treatment or who have little chance of benefits (for example: use of antibiotics in infections of probable viral origin).
- Underuse, by inadequacy of services: do not use or delay service or potentially adequate treatment, which brings as a consequence complications, premature death and high costs.
- Misuse, by improper diagnosis: errors in diagnosis, delay on conduct or treatment and cause adverse events. Diagnostic errors are associated with proportionally higher morbidity than other types of medical errors.

According to Jesús M. Aranaza, AE can also be classified by the consequences on the patient. According to their degree of severity, we find 3 groups or categories(2):

- Serious EA: It causes the death of the patient, residual disability at discharge or requires surgery.
- Moderate EA: It causes an extension of the hospital stay of at least 1 day.
- Mild EA: Injury or complication not included in the other two categories.

The explanatory model of the causal chain of an adverse effect supports that systems failures are more important than people failures. In order to understand the causes of AE, they can be divided into active failures and passive failures (latent conditions).

On the one hand, passive failures are those related to the administrative and production system, they are system weaknesses. Latent conditions are the inevitable “resident pathogens” within a system. They arise from decisions made by designers, builders, procedure writers, and top-level management. Such decisions may be mistaken, but they need not be. All such strategic decisions have the potential for introducing pathogens into the system.

Latent conditions have two kinds of adverse effect: they can translate into error-provoking conditions within the workplace (for example, time pressure, understaffing, inadequate equipment, fatigue, and inexperience), and they can create long-lasting holes or weaknesses in the defenses (untrustworthy alarms and indicators, unworkable procedures, design and construction deficiencies. The importance of passive failures lies in that multiple passive failures can promote the emergence of an AE, and latent conditions perpetuate AE.

On the other hand, active failures are errors committed by health professionals while they perform health care. Active failures have a direct and usually short-lived effect on the integrity of the system defenses. They are defined as failure on the activity or unsafe acts that increase astonishingly the chances of an AE. Among them we find failures of attention, distraction, omission, and breach in the procedure...

In addition there are various conditions that increase the chance of committing an AE, regardless of the type. These conditions are numerous and varied, especially related to working conditions: work overload, lack of definition of tasks, insufficient training, inadequate supervision of tasks, communication failures, obsolete resources, improper maintenance of facilities, inadequate standardization of processes...

Institutions promote and execute new defense plans to create and modernize the system barriers in order to minimize the AE. A clear example is “Plan de Calidad para el Sistema Nacional de Salud” (April 2007)(7), presented by the Ministry of Health of Spain. It contains six major areas of action to response the great challenges of our health care system, including the patient safety as a national priority, design and establish a national system for notification of adverse effects, to strengthen the systems of evaluation of the quality of services and centers for blood transfusion...

These defenses, barriers, and safeguards occupy a key position in prevent AE. Their function is to protect potential victims and assets from local hazards. They are mostly effective at this, but there are always weaknesses. In an ideal world, each defensive layer would be intact. In reality, they are more like slices of Swiss cheese, having many holes—although, unlike in the cheese, these holes are continually opening, shutting, and shifting their location. The presence of holes in any one “slice” does not normally cause a bad outcome. Usually this can happen only when the holes in many layers momentarily line up to permit a trajectory of accident opportunity— bringing hazards into damaging contact with victims (1,6).

Finally, there is another category separated from AE: **Near misses or incidents**. Incidents are a poorly defined category that includes those situations in which there were no AE, or those events that were "on the verge" of occurring. It is an action or omission that could have harmed the patient, but finally it do not damaged him as a result of random or prevention. You could say that an incident is indistinguishable from an AE except from the result; the presence or not of lesions in the patient (1,2,8,9).

Dr. Heinrich was a pioneer of health and safety. His studies suggested an approximate proportion of a serious AE for each 30 minor AE and for each 300 near misses (incidents without damage). Recently, the distribution has changed. There is a severe AE for each 10 minor AE and for each 600 near misses (8). These results were based on the study of 1.5 million incidents, which define an "iceberg model" in order to define the ratio between adverse events (major and minor) and incidents.

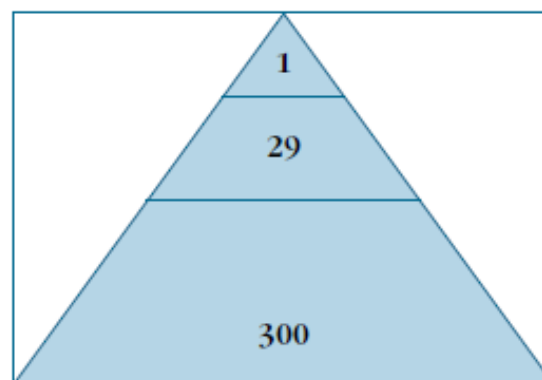


Figure 1: Heinrich pyramid (8)

2.2 Epidemiology; the past and present situation.

Medicine is a rapidly changing science. Technological advances and improvement in knowledge have made that new protocols and treatments are established within a few years. Medicine used to be ineffective, but simple and safe. Nowadays, medicine is effective, but complex and relatively dangerous. Therefore, the adverse effects related to medical care are increasing year after year.

It all began in the 90's in the USA. They are the pioneers of medical error and its theoretical bases. At this time, began to appear early alarms and concerns for the safety of patients. They started thinking about adverse effects related to health care. In the beginning, they talked about AE as all those consequences that prolonged hospital stay, produced a sequel after the medical discharge or were responsible for the patient's death.

The first study that provides data about the extent of the problem was done in 1991, using a group of patients hospitalized during 1984; it is known as "Harvard Medical Practice Study" (10,11). This research involved 51 selected hospitals in the State of New York on a cohort of 30,000 inpatients. They found that the prevalence of AE was 3.7% and estimated that a 50% of AE could have been prevented, they were avoidable. In this study, the most common adverse effects were those related to side effects of medications, followed by infection of the surgical wound and complications with surgical technique. The "Harvard Medical Practice Study" laid the foundation for the future studies(11). The methodology that they established will be the basis of all subsequent studies in USA and all around the world.

More than one decade later, a second study of similar size, was carried out in Utah and Colorado by the Houston Medical School, University of Texas(12). They revised 14,700 clinical histories of patients discharged during 1998, in 28 stratified hospitals by variables of activity (number of medical discharge per year), geographic dispersion, medical teaching pre and postgraduate, and type of ownership (private/public).

They found a 2.9% of adverse effects, of which 6.6% were related to the death of the patient. The most frequent were linked to surgical interventions, followed by drug-related and, finally, those related to medical procedures.

Since then, it arises in Anglo-Saxon field, a line of research which explores, in different countries and health services, the frequency of AE. All the published studies confirm the existence of non-intentional damage to the patients; the proportion varies between 16.6% in Australia and 7.5% in Canada. In New Zealand described an 11.2% and a 10.8% in the United Kingdom. (2,3,5)

In our country, the concern about AE linked to health care arrived, too. This worry was included in a law; “Ley 16/2003, de 28 de mayo, de cohesión y calidad del Sistema Nacional de Salud.”(13) This law promotes measures of coordination and cooperation of health public administrations in order to ensure the right to protection of health of citizens, with the common goal of ensuring the fairness, quality and social participation in the national health system. Moreover, it includes the need to implement a registry of those AE that may result in a security issue for patients in clinical practice.

One of the most important studies in the Spain was carried out in 2005 by “*La Agencia de Calidad del Sistema Nacional de Salud*”, it was called “*Estudio nacional sobre los efectos adversos relacionados con la hospitalización en España*” (ENEAS)(2,14). It was a retrospective cohort study, in which a representative sample of 5.624 patients discharged in 24 hospitals around the country was revised. They detected 1.063 patients with AE during the hospitalization, of which 525 were related with a moderate or high probability with health care.

The incidence of patients with AE related with healthcare was a 9.3% (95% CI: 8.6% - 10.1%). A 37.4% of the AE were related to the medication. Nosocomial infections of any kind represented a 25.3% of the total number of AE and a 25.0% were related to technical problems during a procedure. A 17.7% of the patients with EA accumulated more than one. Patients older than 65 years and having a more than weeklong stay presented a greater risk of suffering an adverse effect. A 42.8% of the AE were avoidable.

2.3 Medical responsibility, legal basis and consequences.

This study will use some legal jargon with the purpose of defining those medical errors under juridical review. That is why, it is necessary to know the legal and ethical bases that regulate medical practice, to establish the basic concepts on medical liability and define different legal ways that a medical error can be judged.

The Spanish Constitution (15) recognizes and defends various rights closely linked with the medical practice. Article 43 recognizes the protection of health as a fundamental right. Article 15 recognizes the right to life and to physical and moral integrity without; in any case, they can be subjected to torture or to inhuman or degrading treatment or punishment. Article 18 talks about the right to honour, personal and family privacy and self-image. The State has the duty to promote and protect a standard of living in order to ensure access for all citizens to basic services of optimal quality, in this case health system.

Rights of patients are recognized in "*Ley 14/1986, de 25 de abril, General de Sanidad*" (16). the Code of ethics of the Medical Council (17) also establishes some basic rights such as right to decent health care, rights to confidentiality, to information, to autonomy and to decide his own health process and right to equality and non-discrimination, among many others.

In addition, all these health services should be provided by professionals and technicians with sufficient knowledge, expertise, in order to ensure the quality of the service. The *Lex Artis* or Law of art has an outstanding importance (18). *The Lex Artis* refers to the standard that determines the diligence (good professional conduct used). One of the fundamental pillars of the *Lex Artis* and the Code of ethics of the Medical Council is the consent of the patient for any medical act he will receive. It is also recognized in "*Ley 14/1986, de 25 de abril, General de Sanidad*".

The paradigm shift in the doctor-patient relationship is well known. A paternalistic relationship has been used for centuries. Where the activities of health professionals, was governed by the principle of charity, in which the doctor acted in accordance with the wishes of the patient, but also without their will, or even against it. Therefore the patient had nothing to say about his own medical process. It was a one-way relationship, where the doctor had all the knowledge and power of decision. Currently, the principle of patient autonomy is the fundamental pillar of any medical act. The patient has the power of self-determination which must be respected by the doctor, who may not impose coercive treatments despite being well-intentioned.

This paradigm shift is reflected with various laws, which include:

- Article 10.12 of "*Ley General de Sanidad*" recognizes the right "to use claim routes".
- "*Ley 41/2002*" which regulates rights and obligations in the field of clinical documentation and information.

Medical malpractice (18,19) could be defined as a misguided exercise or practice without skill by a physician or other professional, causing damage to the health or the condition of the patient. This fact breaks the trust that the patient puts on the professional. With independence of the results of malpractice in the patient, it has some legal consequences. We talk about **Medical Responsibility or Liability**.

Medical Responsibility finds its legal basis in the legal and social need that all doctor respond to authorities for the damages caused by voluntary or involuntary, avoidable or inevitable faults, in the exercise of their profession. Responsibility due a medical malpractice can be divided into four very different definitions:

.) **Ethical, Disciplinary or Moral Responsibility** (20) : it is the breach of any of the rules of the code of medical ethics. It can be defined as the obligation of the health professional to answer for the consequences that might result from his performance against the ethical and moral code. Ethics committees of *Col·legi de Metges* or the general Council of *Col·legi de Metges* will decide the punishment.

.) **Civil Liability** (20,21): The medical act responds to a contract for the provision of services, where the right to claim may be born if it has failed or has not met well. It is specifically contained in the law of contracts and almost contracts, *art 1.089 of Código Civil*. Civil liability is based on the compensation for damages and prejudice as a result of causing pain, neglect or default in the fulfillment of their obligations.

In this case we may talk of negligence or fault; it is the omission of the diligence which required depending on the circumstances of the person, time and place,

There are three main types inside the civil liability:

- **Contractual civil liability:** it is caused by the breach of the contract or almost contract. However, the contract established between the doctor and the patient has certain peculiarities. According to the doctrine of the Supreme Court of Spain, it is not a contract of result, and it requires only an obligation of means, which consists in providing the care that requires the patient's health, adjusted to current scientific and ethical principles. It is based on article 1.1101 of *Código Civil*.
- **Non-contractual liability:** article 1902 of *Código Civil* requires reparation of the damage caused to third parties without such damages are necessarily consequence a legal relationship between the two parties which means there is no contractual relationship. This liability is generated in the reality, independently of the contractual relationship. It may occur when the patient enters emergency services.
- **Civil liability with a criminal origin:** criminal acts produce on many occasion personal damages and prejudices that cannot be resolved by the criminal courts. Article 1.092 of *Código Civil* establishes that civil obligations related to criminal process will be also evaluated. This type of liability comes together with the criminal one, but it is independent.

.) Criminal Liability (20,21): It is the type of responsibility which produces more concern among health professionals. In the field of criminal responsibility, it is necessary to prove that there was guilt; two forms of guilt can be distinguished: as a result of deliberate or recklessness.

On one hand, the law talks about willfully medical acts, when the criminal knows what makes and also wants to do it; i.e. the doctor acts consciously and voluntarily in order to achieve the result that he/she seeks and to produce a damage. On the other hand, recklessness does not seek the result, so there is no intention to damage or harm to the patient.

There are several circumstances where a doctor is criminally responsible for their actions:

- The doctor acts as a man, regardless of their professional status. So in crimes where there is no professional relationship (thefts, blackmailing...) the doctor in question will be criminally responsible with independence of his profession.
- When the doctor takes advantage of their professional status to commit the crime. As for example an anesthetist who violates a woman under anesthesia. Also they will be tried by criminal courts and their professional status will increase penalties.
- There are several criminal offences directly associated with the medical profession and the health of the people. Such as omission of duty relief, denning assistance or abandonment of health services, disclosure of professional secrecy or falsification of certificates.
- Very different nature reckless behaviors that are sanctioned by the legislator, such as murder, abortion, injury, injury to the fetus and substitution of children, genetic manipulation.

.) **Administrative Liability** (20,21): It is based on “Ley Orgánica 6/1998 de 13 de julio”. It regulates the judicial procedure in which the Administration absorbed (at least in the early days) claims for negligence committed by the staff at your service. However, the administration shall move the compensation on the doctor if the damage is a consequence of a deliberate act, negligence or guilty.

3. JUSTIFICATION

Safety in clinical practice is an essential pillar in quality of health care. In order to receive a safe clinical attention it is needed three main objectives: identify the clinical diagnostic and therapeutic procedures safer and more effective, ensure that they apply to who need them and make them correctly and without errors. Measure the risk linked to health care is a matter of utmost importance for our medical system, in its health dimension as economic, legal, social and even media (related to the media coverage).

Alarm about adverse events is not new. As I have already mentioned; long ago, there was a clear concern about the negative effects of AE in health care. However, since the appearance in 1999 of the report by the Institute of Medicine (IOM) *To err is human* (4), the issue of safety of patients has captured the attention of the public worldwide, health care providers and politicians in a very pronounced way. The report from the IOM estimated that about 44,000-98,000 people die each year in U.S. hospitals as a result of AE . These figures exceed mortality in traffic accidents, breast cancer, or AIDS (22).

Many foreign countries have performed numerous studies about medical error and medicine. These studies revealed a complex and changing reality depending on the country in question. That is why; it is a difficult task to generalize those results in our country. Each country has a different health, economic and legal situation. It is extremely problematic to establish common standards between countries, especially in what refers to the incidence of adverse effects. Results vary greatly, for example; in the United Kingdom 10% of hospital admissions, i.e. 850,000 events a year were due to medical adverse effects. In Australia, the rate of adverse events was 16.6% among admitted patients and a 7.5% in Canada among others (3,18,).

Consequently, it is needed a specific analysis of the situation, in order to determine the context of AE in our country. In Spain, the ENEAS study (2) determined the incidence of AE; it was a 9.3% (95% CI: 8.6% - 10.1%). A 42.8% of the AE were avoidable. Spanish data suggest that we are facing an everyday problem.

Therefore, the high frequency of AE or medical errors related to daily clinical practice it is the first argument to support this study. It is unthinkable that thousands of people are suffering negative consequences in her or his health process. In addition, these harmful effects are produced by medical errors.

This is a reality, this is happening every day in our country and all around the world. *Primum non nocere* or the code of non-maleficence is one of the major ethical principles of medicine. Disturbingly, that is not a truth in many cases. In a clear and serene manner, I refuse to accept this fact as an admissible statement.

Furthermore, as it has been documented, in our country and in many others, nearly half of the medical effects are avoidable. I can only see it as an encouraging fact to all health professional. There is still a long way to go to identify and prevent medical errors in day-to-day medical practice. This is another strong argument to encourage medical researches about this topic and to discover specific aspects and characteristics related to AE.

From another point of view, the economic aspect is also a reason to explain the relevance of this study. The cost of medical errors is enormously high. For example, in the United Kingdom (14,24) a longer hospital stay as result of AE it costs approximately 2,000 million pounds a year and \$ 400 million a year that state must pay for compensations. In United States these costs reach a value between 17,000 and \$ 29,000 million a year. On the other hand, it should also add the wear that it produces in confidence and the satisfaction of patients. There is not specific data about the economic cost about of medical error in our country. However, it is clear that each avoidable error is a cost to our health system. If every mistake joined together, the cost of all of them reaches millions of euros sums.

Moreover, these unnecessary costs produce a violation of the ethical principle of Justice. If we spend unnecessary resources to correct consequences of AE, then there are no resources for an equitable distribution. Each avoided error would save a considerable amount. This money-saving could be used in protecting the needs of patients.

Each medical error produces a consequence. In the best case, these errors have no translation into patient's safety as our defense systems prevent it. But it is not always the case, some errors produce suffering, damage to the patient which can vary greatly: minor damage, disability, death of the patient, et cetera. Avoiding sensationalism and overstating the situation, it can be argued that if we do nothing to prevent them, we will be complicit in every result, every injury, every disability, every death...

Numbers reflect people and in this specific situation, each number means a failure in our health system. Doctors cannot be considered solely responsible for them, although they may be the only guilty in some isolated cases. The doctor is part of a complex network. The health system is much more than just doctors.

So we must not fall into the trap of demonizing doctors, only in necessary cases. But even in those cases, the health system and their defenses are guilty too; since they have not stopped the error. Each error is the translation of a failure on our health system. This study aims to be a humble contribution towards the safety of patients. Each discovery, however small it will be, it can be of an enormous importance in prevention.

4. HYPOTHESIS.

Medical specialties with the highest proportion of malpractice litigations, regardless of the used juridical way (civil, criminal, etc.), are Traumatology, Gynaecology and Surgical specialties, which include cosmetic surgery or reconstructive; in Catalonia during 2005-2015 (a period of 10 years).

5. OBJECTIVES.

5.1 Primary Objective.

The main aim of this study is to determinate which is the specialty or group of medical specialties with a higher proportion of malpractice legal procedures during the 2005 and 2015 in Catalonia, regardless of the used courts: civil, penal, etc.

6. METHODS.

6.1 Study design.

The present study will be an observational, longitudinal and retrospective study.

The best way to study medical specialities with a higher proportion of malpractice litigations is collecting all final verdicts by the judge, of all possible legal courts involved. That is why; the study design consists in an observational and longitudinal study, as we will gather the maximum number of legal sentence during a period of 10 years. Finally, in order to obtain a fast conclusion of the study, it will be a retrospective one (2005-2015). Since all legal information related to malpractice trials is recorded, stored and guarded in the court who judged the fact. Consequently, we can immediately start finding the needed information.

6.2 Study Population.

Population of the study will be all doctors who are licensed (registered) in one of the 4 official colleges of Physicians in Catalonia:

- . Official College of Physicians of Barcelona (COMB, in Catalan).
- . Official College of Physicians of Girona (COMG, in Catalan),
- . Official College of Physicians of Tarragona (COMT, in Catalan).
- . Official College of Physicians of Lleida (COMLL, in Catalan).

In order to determine the real total number of licensed doctors; this study will use information from the Government of Spain. It was posted nearly the middle of observational period, 2009-2010. This information (24) provides data about registered doctors in all different regions of Spain (*Comunidad Autónoma*). In addition, it divided them according to their medical specialties, and it will be tremendously useful to study our main objective.

6.3 Sample

Our sample is already fixed as a number that cannot be altered. In this case our sample matches our study population. Its size cannot be modified since it is given in advance. The main objective is to determine which specialty or specialties has a higher proportion of judicial proceedings. Therefore, we will divide registered doctors according to their specialty. However, in some medical specialties of Catalonia, there are few doctors exercising. For this reason, it is necessary to put together specialties with fewer members, to achieve an adequate sample power.

We have used the sample size and power calculation GRANMO. We have compared the two medical specialties with less registered physicians; Orthopaedic and Trauma Surgery (429 licensed physicians) and Anaesthesiology and Resuscitation (491 licensed physicians). If these two groups have a proper study power (>80%) then the comparison with the other specialties it will have it, too.

Accepting a risk of 0.05 in a bilateral contrast with 429 subjects in the first group and 491 in the second, **the power of the contrasting hypothesis is 95%** to detect how statistically significant the difference there is between 0.01 of the first group and the 0.05 of a second.

6.4 Variables.

6.4.1 Independent Variable.

- Medical specialty that the registered physician exercises.

Medical specialties have been divided into different groups to achieve a proper power of the study. For this reason, those specialties with fewer licensed physicians and those who share professional similarities have been grouped. In addition, those specialties with a sufficient number of doctors remain separate individually. Some of them such as Orthopaedic and Trauma Surgery or Gynaecology and Obstetrics are part of our main hypothesis. Therefore, it was considered timely to evaluate them as isolated clusters.

There are 11 different groups:

.) Laboratory, Clinical and Radiological Diagnosis Specialities: with 824 physicians within this category.

- Clinical Analysis (168)*.
- Anatomic Pathology (113).
- Clinical Biochemistry (54).
- Clinical Pharmacology (82).
- Immunology (7).
- Nuclear Medicine (31).
- Microbiology and Parasitology (37).
- Clinical Neurophysiology (30).
- X-ray Diagnosis (302).

.) Surgical Specialties: with 644 physicians within this category.

- Cardiovascular Surgery (33).
- General and Digestive Surgery (410).
- Oral and Maxillofacial Surgery (35).
- Esthetical and Reconstructive Plastic Surgery (39).
- Paediatric Surgery (38).
- Thoracic Surgery (30).
- Neurosurgery (59).

**We use (xx) to express registered doctors in each medical speciality.*

.) Medical and surgical Specialities: with 801 physicians within this category.

- Angiology and Vascular Surgery (74).
- Dermatology and Venereology (112).
- Urology (189).
- Ophthalmology (245).
- Otolaryngology (118).

.) Medical specialties 1: with 1105 physicians within this category.

- Allergology (14).
- Digestive System (189).
- Endocrinology and Nutrition (90).
- Haematology and Haemotherapy (129).
- Neurology (155).
- Nephrology (104).
- Pulmonology (133).
- Medical Oncology (133).
- Radiation Oncology (54).
- Geriatrics (40).

.) Medical specialties 2: with 1149 physicians within this category.

- Occupational Medicine (32).
- Psychiatry (155).
- Public Health and Preventive Medicine (53)
- Physical Medicine and Rehabilitation (113).
- Intensive Medicine (186).
- Internal Medicine (383).

.) Orthopaedic and Trauma Surgery: with 429 physicians within this category.

.) Gynaecology and Obstetrics: with 539 physicians within this category.

.) Family and Community Medicine: with 5257 physicians within this category.

.) Cardiology: with 2014 physicians within this category.

.) Paediatrics: with 1053 physicians within this category.

.) Anaesthesiology and Resuscitation: with 491 physicians within this category.

6.4.2 Dependent Variable.

- The number of medical malpractice court verdicts between 2005 and 2015 in Catalonia.

6.5 Covariables (25,26).

Various covariables of the study are established. All of them are classified into three groups, according to its relation with the accused doctor, with the patient or with the legal process.

Related to defendant physicians:

. Gender: It is described into two categories, male or female. We will use the information available on legal judgments. Secretaries of courts will delete any personal information. The same way, we will do with others covariables.

. Age: The physicians' age in the time of alleged malpractice. It is measured in five years intervals.

. Health System: It is described into two categories, public or private facilities where the alleged malpractice took place.

. Moment of the day: It is described into three categories; it is measured in eight hours intervals. The first group will be defined between 8AM-4PM. The second group will be defined between 4PM- 12AM. Finally, the last group will be defined between 12AM-8AM.

Related to the involved patient:

. Gender: It is described into two categories, male or female.

. Age: The patient's age in the time of alleged malpractice.

Related to the legal process:

. Used legal way: there are three main possibilities about the type of the legal process: civil, penal and administrative.

. Final resolution of the legal file: It is defined into four groups:

- 1) Guilty Verdict, where the physician is condemned, he is guilty.
- 2) Judgment of Acquittal, where the doctor is found not guilty.
- 3) Judicial Agreement, where both parts reach a pact.
- 4) Dismissal.

6.6 Methods of data collection.

The data collection will be abstracted from the court verdicts by the judge in a retrospective way. We will work with a pre-existent database; called TEMIS. It is a judicial database for all Catalan courts, which allows knowing all processes and convictions that accumulates a citizen in any of the jurisdictions: criminal, civil, social or contentious. It also allows searching legal verdicts in a faster way according to the crime or fault it was committed. In this case we will use it to collect all legal judgements related to malpractice litigations. Verdicts of judges are a powerful tool as it must be justified, and brings together all the information related to each case.

Catalonia is the first autonomous community to have a database of this kind, a system that has no precedents in our country since a computer program of this type had never carried out before.

7. STATISTICAL ANALYSIS.

DESCRIPTIVE ANALYSIS

For qualitative variables the results will be expressed as percentages and proportions. For quantitative variables with normal distribution mean $\pm$ SD and for those without normal distribution median will be calculated.

BIVARIATE ANALYSIS:

For bivariate analysis, dependent and independent variables will be compared. For qualitative variables, analysis will be done with chi-squared test or Fisher Exact test. To compare variables with 2 or, 3 groups or more Mann- Whitney test and Kruskal Wallis, will be used respectively. For quantitative variables Student T test will be used when the variable has a normal distribution and Mann- Whitney test for those without normal distribution. Kappa index will be used to evaluate the concordance between GP and radiologist. It will be calculated for the final diagnosis and for the other findings in the ultrasound. It will be considered a good level of concordance a kappa index ≥ 0.80 .

MULTIVARIATE ANALYSIS

In order to avoid confusion multivariate analysis will be done. This analysis will be adjusted for covariates with a general lineal model. The criterion for statistical significance is set at $p < 0.05$. Statistical analysis will be done using Statistical Package for the Social Science (SPSS).

8. ETHICAL ASPECTS.

Data protection is a fundamental right included in the article 18.4 of the Spanish Constitution. In addition, it is regulated by the organic law 15/1999, of 13 December, of protection of data of a Personal nature. This law is complemented by the Royal Decree 1720 / 2007, of 21 December.

This legislation seeks to ensure and protect the fundamental rights of persons in the field of personal data. The data protection Organic Law defines personal data as any information that identifies or makes identifiable to an individual. Thus, name and the surname of a patient and physician are personal data, as well as the number of DNI, email address, background, etc. because all these data provide information about an individual.

However, our case will not be attached to all this legislation about consent, treatment and security of personal data. Since the Directive 95/46 of protection of natural persons, establishes that principles of protection shall not apply to those anonymous data because it is no longer possible to identify the person concerned.

In this study, the Manager of the public file will be the Coordinator Secretary of each province (Girona, Barcelona, Tarragona and Lleida) who will proceed to carry out the process of dissociation and anonymize the information before sending it to us. According to the article 5 of Royal Decree 1720 / 2007, of 21 December, a dissociated data is the one which "does not allow the identification of an affected or interested party".

Consequently, the data that we will receive from the Secretary Coordinator of each Province will be completely anonymous. Therefore it will be excluded from the organic law 15/1999 and its regulations. Hence it is not needed to notify the file to the General registry of data protection, or an informed consent or to adopt the security measures laid down in Royal Decree 1720 / 2007, of 21 December.

The investigators of this project declare that there are no conflicts of interest.

9. STUDY LIMITATIONS AND BIASES.

One of the main problems of the study is confounding bias. It is possible that some medical specialties will have a higher proportion to malpractice litigations but not as a result of a higher risk of medical error. Confounding factors may influence this relation. This limitation will be minimized through a multivariate analysis.

The study is a retrospective review of pre-existing data using a computer database (TEMIS). It is used by the Ministry of Justice all around Catalonia. We believe this data is reliable. Accordingly, the information bias can be avoided.

There are another limitation due our study is a retrospective one. We will receive anonymous information. We will also only receive those data that were collected at the time of the legal trial. Hence it was useful and needed in the legal process. For this reason we cannot have in mind all the covariates as we would like. Despite this, we believe that the main covariates are included in the study and therefore will be considered for a multivariate analysis as it is described below; avoiding confounding bias.

Our main concern is related to the complex legal and judicial situation in Catalonia. Is it possible to translate it in our study? What happens if in a case of medical malpractice an agreement before the sentence is reached? Are cases of settlements before trial common circumstances? All these questions can produce we had less information on the TEMIS database. If it was real, we would arrive to a wrong conclusion or association as a result of having less information. Is it that bad? Well, certainly it is not. Let's explain each situation separately.

All legal process that begins in a courtroom, regardless of the used legal way, is registered and guarded in the TEMIS database. Consequently, if after initiating the legal process an agreement between the parties is done; evidence of the facts will be stored in TEMI. We could access these data. We would not lose information.

If we talk about settlements before coming to trial, it is logical that we will not be able to have them in mind, since TEMIS database only collects the information after initiating the legal process in court, not before. This is why; we have consulted different lawyers who are specialists in medical responsibility of Girona. According to experts, most lawyers (in cases of malpractice) prefer to initiate legal proceedings in the courts before reaching an agreement with the respondent party. Moreover, according to the Official College of Lawyers of Girona; it is considered and a recommended practice.

Why? First of all, it is used as a measure of pressure toward the respondent party. The accused physician will have an insurance company supporting him. Since medical insurance companies are not obliged to pay interest when there is no a legal claim, they tend to avoid negotiation out of court. Instead, in traffic accidents, the article 9 *“Mora del asegurador Real Decreto Legislativo 8/2004, de 29 de octubre”* establishes that insurance companies have a high interest rates if they do not pay It is not necessary a legal claim.

Therefore, the absence of interest in medical liability made that medical insurance companies do not hurry to resolve the issue. They prefer to wait and see if the complaining party is serious or not, until the judicial claim is presented.

In these cases, they will also be recorded in the TEMIS database. Thus, we consider that the majority of cases will be registered in the Catalan judicial database.

10. WORK PLAN.

The duration of this project is 24 months. Research group is formed by 2 investigators: Alexandre Aguilera (AA) and Josep Ramis (JR). The research team will carry out all tasks of coordination, interpretation and dissemination of the results. In a chronological way, the study is designed in the following stages:

STAGE 0, Study Design (*3 months*): This step is completed

- Bibliographic research.
- Protocol evaluation.
- Researchers: AA

STAGE 1, Study application (*1 month*):

- Design the application
- Send the application to the Secretary Coordinator of Girona; He will resend it to the Secretary Coordinator of Catalonia.
- Waiting time to receive the official permission.
- The Secretary Coordinator of Catalonia accepts our study and allows us access to TEMIS database and its information.
- Researchers: AA

STAGE 2, Coordination (*1 month*):

- Before starting the study.
- First meeting for task organization. In order to solve all the questions and check the protocol to establish a common following of it.
- Researchers: AA and JR
- First coordination meeting with The Secretary Coordinator of Catalonia.

STAGE 3, Data collection (16 months):

- Secretary Coordinator of each Province (Barcelona, Girona, Lleida and Tarragona) will give orders to all Secretaries in all courts of Catalonia.
- Secretaries all around Catalonia will use TEMIS database to collect information about malpractice litigations; regardless of the used legal way. They will also perform the process of dissociation and anonymize the information before sending it.
- Secretaries will send the study information to Secretary Coordination of his/her province. Then, He or She will send this anonymous information to us.

STAGE 4, Statistical analysis and interpretation of results (1 month):

- Statistical analysis of the data: Performed by the Statistical personal.
- Interpretation of results: A meeting between the statistical personal and the researchers will take place in order to analysis results of the study.
Researchers: AA and JR

STAGE 5, Dissemination of results (2 months):

- Write the article.
- Publication.
- Dissemination plan, results will be discussed and presented through conference, presentation, meetings, journal articles and other means of communication.
- Researchers: AA and JR

11. BUDGET

STUDY BUDGET	COST
PERSONAL COST	0 €
GODS AND SERVICES	
Expendable materials, photocopies	250€
Statistical consulting and analysis for study data.	1050€
Unforeseen expenses	100€
DISSEMINATION OF RESULTS	
Publication costs	1000€
TOTAL BUDGET: 2400€	

Researchers AA and JR will not receive any financial compensation for their contribution to the study.

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13. ANNEXES: ANNEX 1: Study Sample, modified from: Oferta y necesidad de especialistas médicos en España 2010-15 (22).

Groups of Medical Speciality		Licensed Doctors	Total per Group
Laboratory, Clinical and Radiological Diagnosis Specialities	Clinical Analysis	168	824
	Anatomic Pathology	113	
	Clinical Biochemistry	54	
	Clinical Pharmacology	82	
	Immunology	7	
	Nuclear Medicine	31	
	Microbiology and Parasitology	37	
	Clinical Neurophysiology	30	
	X-ray Diagnosis	302	
Surgical Specialities	Cardiovascular Surgery	33	644
	General and Digestive Surgery	410	
	Oral and Maxillofacial Surgery	35	
	Esthetical and Reconstructive Surgery	39	
	Paediatric Surgery	37	
	Thoracic Surgery	30	
	Neurosurgery	59	
Medical and Surgical Specialities	Angiology and Vascular Surgery	74	801
	Dermatology and Venereology	112	
	Urology	189	
	Ophthalmology	245	
	Otolaryngology	118	
Medical Specialities 1	Allergology	14	1105
	Digestive System	189	
	Endocrinology and Nutrition	90	
	Haematology and Haemotherapy	129	
	Neurology	155	
	Nephrology	104	
	Pulmonology	133	
	Medical Oncology	133	
	Radiation Oncology	54	
	Geriatrics	40	
Medical Specialities 2	Occupational Medicine	32	1149
	Psychiatry	155	
	Public Health and Preventive Medicine	53	
	Physical Medicine and Rehabilitation	113	
	Intensive Medicine	186	
	Internal Medicine	383	
Orthopaedic and Trauma Surgery		429	429
Gynaecology and Obstetrics		539	539
Family and Community Medicine		5257	5257
Cardiology		2014	2014
Paediatrics		1053	1053
Anaesthesiology and Resuscitation		491	491

ANNEX 2: permission's application to conduct our study

Al secretario coordinador de Girona

EXPONGO

Yo, Alexandre Aguilera Luque, con DNI 43634590W y número de médico colegiado 1245, pretendo llevar a cabo un estudio estadístico sobre la especialidad o especialidades médicas con mayor proporción de litigios por mala praxis, el cual lleva por título *“Medical specialities with a higher proportion of malpractice litigations in Catalonia between 2005-201”*. Este estudio requiere del acceso a las denuncias i las resoluciones judiciales relativas a la responsabilidad médica dentro del ámbito territorial de Catalunya.

SOLICITO

Que se me dé acceso a los datos que constan en el registro interno de los juzgados y Tribunales de las diferentes provincias de Catalunya (TEMIS), en relación a las denuncias y resoluciones judiciales en materia de responsabilidad médica durante el 2005-2015

Que los datos obrantes en el Registro interno sean sometidos a un proceso de disociación para velar por la aplicación de la Ley Orgánica de Protección de Datos Personales.

Fecha y Firma