Liability for Severe Birth-related Injuries in Greece: the Issues of Tort Law and the Possibility of Introducing a No-fault Compensation System

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La responsabilidad por lesiones graves relacionadas con el parto en Grecia: cuestiones de responsabilidad civil y la posibilidad de introducir un sistema de compensación sin perjuicio

Abstract: Severe birth-related injuries constitute some of the most serious healthcare-related injuries, with devastating effects on the children's future quality of life. Both babies and parents confront emotional difficulties, economic burden and increased needs. Tort systems around the world have been proved ineffective, in both compensating and deterring substandard care and the Greek system is not an exception to the rule. The article, after presenting the core problems of the tort system, aims at initiating the relevant ethical discussion from the perspective of the principle of justice and at fostering discussion regarding the potential of establishing an alternative compensation scheme for severe childbirth injuries; a scheme, which will be effective in providing redress quickly and efficiently and enhancing patient safety. Due to the lack of space and relevant data regarding adverse events in Greece, we will not make a detailed description of the specifics of the proposed system. Instead, the basic aims and principles underpinning the system will be formulated, along with some initial ideas concerning the system's core elements.

Keywords: birth-related injuries; medical liability; negligence; Tort system

Resumen: Las lesiones graves relacionadas con el parto constituyen algunas de las lesiones más graves en el sistema sanitario, con efectos devastadores en la calidad de vida futura de los niños. Tanto los bebés como los padres se enfrentan a dificultades emocionales, carga económica y el aumento de las necesidades. Los sistemas de responsabilidad civil de todo el mundo han demostrado ser ineficaces, tanto en la compensación como en la disuasión de la atención deficiente y el sistema griego no es una excepción a la regla. El artículo, después de presentar los problemas centrales del sistema de responsabilidad civil, trata de suscitar un debate ético relevante desde el punto de vista del principio de justicia así como también trata de fomentar la discusión acerca de la posibilidad de establecer un sistema de compensación alternativa para las lesiones graves en el parto; un esquema efectivo en proporcionar una reparación rápida y eficiente y la mejora de la seguridad del paciente. Debido a la falta de espacio y los datos pertinentes a los efectos adversos en Grecia, no vamos a hacer una descripción detallada de las características específicas del sistema propuesto. En su lugar, se formularán los objetivos y los principios que sustentan el sistema junto con algunas ideas iniciales sobre los elementos básicos de dicho sistema.

Palabras-clave: lesiones relacionadas con el parto, responsabilidad médica, negligencia, sistema de responsabilidad civil

1. Introduction

Medical malpractice begins with an injury or an adverse outcome occurring during the provision of medical care (World Bank, 2003). Patients and families suffer from the *emotional* and *financial* burden of adverse outcomes and seek *compensation* for their economic (medical) costs and non-economic damages (World Bank, 2003).

There are two categories of cases, which lead to the birth of a person with serious disease or disability (Fountedaki, 2004; Fountedaki 2006). The first category includes cases, where a doctor's acts or omissions before or during pregnancy lead to a particular health problem (Fountedaki, 2004;

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Fountedaki 2006) The second category ("wrongful life") includes cases, where the birth of a child with a serious health problem is not a direct consequence of a medical procedure, but a result of delayed diagnosis (Fountedaki, 2004; Fountedaki 2006).

Given that the birth process is very important for the child's later motor and intellectual development (Eggermont, 2015), severe birth-related injuries (namely physical injuries occurring during the birth process) constitute some of the most serious adverse events during the provision of healthcare services.

There are a number of birth injury types, with some of them being temporary, and others being permanent and lasting a lifetime (Birth Injury Guide, 2015). Symptoms often vary from one infant to another, and although one infant may have mild symptoms, the same injury may happen to a different infant and cause severe symptoms (Birth Injury Guide, 2015). Examples of birth-related injuries are: *brain-related injuries*, (among which, the leading -and with intense legal interest worldwide- is cerebral palsy), musle-*related* or *physical* injuries such as brachial palsy, erb's palsy, klumpk's palsy, shoulder dystocia, injuries from delivery etc. (Birth Injury Guide, 2015). Causes of birth-related injuries vary (Stanford Children's Health, 2015) and their detailed analysis is infeasible, due to the lack of space. Oxygen deprivation, mechanical injury, infant stroke, infant infection, genetic or congenital abnormalities, maternal substance abuses are some of them with their causality/etiology being highly controversial and complex (Birth Injury Guide, 2015; Siegal et al., 2008).

Even though the severity of symptoms greatly depends upon each child's individual circumstances and the type of injury, the most serious injuries might leave infants permanently disabled (motorically, developmentally and/or cognitively impaired (Birth Injury Guide, 2015; Siegal et al., 2008). Apparently, the emotional and economic difficulties, associated with such injuries, are devastating and constitute a tragedy for the whole family. The needs of both infants and families are increased and diverse, including specialized medical care (such as surgery and a range of therapies to assist with mobility), aids to daily living, training, home adaptations and equipment, special educational support, transport, nursing care (which may be needed round the clock), residential or custodial care and replacement of lost earnings (Chief Medical Officer, 2003; Siegal et al. 2008). Inefficient liability systems certainly intensify the ramifications of these injuries.

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A case of medical liability, which recently caught the media's attention, was the source of inspiration for the present article. Due to medical errors and omissions in two of the largest public hospitals in Athens, a single mother gave birth to twin girls with lifetime cerebral palsy, quadriplegia and psychomotor retardation.

The relevant claim started in 2005 and administrative court proceedings lasted a decade, before a final judgment was reached. The Council of State (supreme administrative court) awarded a total amount of 350.000 euros, in order for the needs of the family to be covered (Protothema, 2015). As stated in the judgment, the girls for the rest of their life will be unable to look after themselves, work, marry, have a family and live a normal life (Protothema, 2015).

The particular case summarizes some of the problems and inefficiencies of the current legal and justice systems and their impact on children suffering from severe birth-related injuries and their families. After providing some information regarding medical errors in Greece, we will identify the basic issues of tort liability systems. Then, we will make a reform proposal, which could remedy the shortcomings of the current system, by making the latter effective in achieving the core objectives any reform in this area should aim at; namely, ensuring the injured children's and their families right to compensation, enhancing patient safety and securing the financial feasibility of the liability system. Since it is the very first time the particular discussion opens in Greece and there is no official data regarding birth injuries and related claims, the detailed description of the procedural and financial aspects of a new system is infeasible. Hence, we will focus on the formulation of the core *principles*, the fundamental *objectives* and the key *features*, on which a future reform attempt should be based. Our proposals will be based on alternative models for compensating medical injuries (operating in Europe and the US) and the relevant literature.

2. Medical Errors in Greece: The Current Situation

In Greece, the assessment of the nature and total financial burden of medical errors is difficult and cannot be accurately approached, due to the lack of data from an organized information system (Riga et al., 2014). Based on the few available sources of information, we will try to present the current situation.

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According to the Eurobarometer of the European Commission (2014), 78% of the Greek respondents think it is likely patients could be harmed by hospital care and 71% of the respondents think it is likely patients could be harmed by non-hospital healthcare. Moreover, 20% of the Greek respondents have -personally or through a member of their family- experienced an adverse event while receiving healthcare (European Commission, 2014).

According to the findings of a survey based on Greek Courts' decisions from 2000 to 2009, the specialty Obstetrics-Gynaecology is among the specialties, which appear to have increased involvement in medical errors, being the most injurious specialty concerning the mean compensation amount (612.561 euros) and the second most injurious regarding frequency of compensation awarded per specialty (Riga et al., 2014). Furthermore, 18.2% of the adverse events resulting in permanent disability involved the specialty of Obstetrics-Gynecology (second highest rate) (Pollalis et al., 2012).

Generally, the amount and level of compensation awarded by courts for medical errors in Greece is worryingly high, with the frequency and the amount of mean compensation increasing dramatically in the late years (Vozikis & Riga, 2008; Riga et al., 2014). Although there is no data regarding the frequency of claims for severe birth-related injuries, the fact that Obstetrics-Gynecology is among the high-risk specialties, shows that any reform proposal, associated with the particular specialty, is a step in the right direction.

Given that the majority of the reported medical negligence cases are those involving serious harm to patients (permanent disability or death) and, eventually, reaching the courts (Pollalis et al., 2012), there are adverse events with serious consequences, for which a claim is never filed and events, with less serious ramifications, which are rarely reported. Consequently, the total lack of official data from an organized national reporting system permits limited approaches to the current situation of medical errors in Greece and hinders precise estimations and firm conclusions.

3. Fundamental Issues of the Tort System

Despite the theoretical and practical disparities between them, malpractice systems around the globe are divided into two general categories: tort litigation systems (the

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majority) and administrative/ "no-fault" systems. In tort litigation systems, medical liability is attributed and compensation is awarded, based on the health provider's negligence/fault. *No-fault* systems, established in some countries, exclude the element of fault from the attribution of liability. Even though the term no-fault is not the most suitable one (since most liability systems or reform proposals, presented as "no-fault", do not actually provide for compensation based on strict liability (Siegal et.al, 2008)), we will use it, as health lawyers are certainly more familiar with it.

Greek legislation can result in criminal, civil and disciplinary sanctions for physicians, in case of medical negligence. The Greek redress system is a traditional tort system. Even though according to the Greek Civil Law a claim for medical negligence can be based on contract or tort law (or –cumulatively- on both of them), tort is the *prevailing* legal basis.

Most patients and their families initiate *criminal* proceedings (for manslaughter (article 302, Penal Code) or for dangerous or serious or fatal bodily injury (articles 309-311, Penal Code)), in order to enhance their legal position and their chances of receiving compensation from the Civil Courts. According to the Greek Civil Code's concept of tort, whoever harms another person illegally and culpably is obliged to compensate him (article 914, Civil Code). The conditions of liability for compensation based on the tort law are: (a) the unlawful act or omission, (b) the fault, (c) the damage and (d) the causal link. The notion of *medical malpractice* is central to the Greek medical liability system. According to legal theory and court decisions, *medical malpractice* is the physician's professional conduct, which does not conform with the diligence/care, imposed by the medical profession and necessary in the particular case, usually because the doctor does not follow his professional standards or because he violates the rules of medical science and art (leges artis) (Fountedaki, 2003; Fountedaki 2007). Medical malpractice is the foundation of contractual and tort liability of the physician and is considered a case of unlawful conduct, with its unlawfulness being based on both unwritten law and specific legal provisions (see Code of Medical Ethics law n. 3418/2005) (Fountedaki, 2003; Fountedaki 2007).

Despite their differences, fault-based systems around the world present similar inefficiencies, as they share common principles and key concepts, based on which liability is attributed (such as negligence, fault, causation etc.). According to the vast majority of international literature, the tort system performs poorly, in respect

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of its goals of *deterring* unsafe practices, *compensating* persons injured through negligence and exacting *corrective* justice (Keeton et al., 1984). Tort law neither alleviates patients and their families from the negative consequences of injuries nor makes the practice of medicine safer by preventing substandard care. Due to the lack of relevant research and literature in Greece, we will try to approach the problems of the Greek system through international literature and data (making adaptations, if necessary). Besides, the Greek system probably faces the same problems as other traditional tort systems and, hence, the information and arguments analyzed below would undoubtedly be proved useful to Greek policymakers, if they decided to reflect on the possibility of introducing a radical reform.

3.1. Tort System and Compensation: Inaccuracy, Ineffectiveness and Unfairness

3.1.1. Malpractice Claims and Healthcare-Related Injuries

Although the basic goal of the tort system is to adequately and fairly compensate those injured, due to substandard care (Common Good, 2006), research has shown that it fails to achieve it.

An extended study by Harvard University (Harvard Medical Practice Study, 1990) showed the problematic relationship between malpractice claims and injuries (Studdert et al., 2004). Only a small proportion of those, who are eligible, actually file a claim (Localio et al. 1991; Studdert et al. 2000). Only about one in four injuries related to hospital treatment can be attributed to negligence (Brennan et al. 1991; Thomas et al. 2000), and, thus, the majority of injured patients cannot access the compensation system. Furthermore, due to the known and indisputable uncertainty of the negligence standard (Bovbjerg & Berenson 2005), in practice, claimants only relatively rarely prevail in relevant claims (Baker 2005; Studdert et al. 2006).

3.1.2. Tort System and the Judgment of Error and Negligence

Another major weakness of the tort liability system is that the negligence-based standards leave many patients harmed by preventable injuries ineligible for compensation (Baker 2005; Bovbjerg and Berenson 2005). Regarding the tort system's effectiveness in compensating meritorious claims, some studies have been positive (Tagarin et al., 1992; Vidmar, 1995; Sloan & Hsieh, 1990; White, 1994)

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(Sloan et al., 1993), while others have showed fairly indiscriminate compensation of claims (Cheney et al. 1989; Brennan et al., 1996) including one, which showed that the decisive factor of compensation was the claimant's degree of disability and not the presence of negligence (Brennan et al., 1996). Apparently, the current system is ineffective in distinguishing between care that is and that is not negligent and quite often compensation is awarded to patients, regardless of that standard, with the poor outcome often being a key factor in the determination of awards (Common Good, 2006). Although claimants who have experienced negligent care are relatively more likely to get compensation, claimants, nevertheless, receive compensation in about a quarter of the cases, where independent experts would claim that no negligence occurred, and about a quarter of meritorious claims do not receive compensation (Studdert et al., 2006).

The vague concepts of tort law for the formulation of the required standard of care (based on which, the physician's professional conduct is evaluated), the judiciary's lack of technical knowledge and expertise and the significant failings of the basic procedure (medical expert testimony) established in tort systems to help the court go through the relevant scientific evidence, render fault-based liability systems ineffective in the *judgment of error* and the *identification of negligence/fault* (which is the core of the liability determination).

The judges, who have not received special training, are technically unequipped to resolve medical disputes accurately (Panagiotou, 2016). Hence, in their effort to identify negligence and form a comprehensive view on the case (especially concerning issues requiring technical knowledge), judges inevitably rely heavily on medical experts and expert testimony. In Greece, quite often physicians are reluctant to offer their services as medical experts, due to colleague "solidarity" or lack of incentives (for instance, due to the low financial remuneration). Nevertheless, even when they offer their views, their neutrality is highly questionable, because, not infrequently, they show unfortunate solidarity with their accused colleagues. Furthermore, quite often, experts lack the special technical knowledge required for demanding cases. The expert opinion, which constitutes the courts' "eyes" into the complex world of medical science, is not peer reviewed, rarely undergoes public or scientific scrutiny, is not always accompanied with supporting data and is often expressed by someone who is not an expert in the disputed clinical area (MacLennan et al., 2006). Recent research or consensus statements on the topic are rarely mentioned (MacLennan

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et al., 2006). Hence, judges often formulate the required standard of care without informing it with the best clinical practices and the most recent scientific evidence. Given the scientific uncertainty surrounding the etiology of *birth-related injuries* (Siegal et al., 2008), the resolution regarding negligence becomes a daunting task. Consequently, in the context of their effort to reliably resolve the relevant claims by identifying the physician's fault/negligence, judges face significant challenges. They are called to decide on individual cases involving injuries with highly controversial -due to the probabilistic nature of the relevant epidemiological evidence (Siegal et al., 2008)- causality and background information, without having the necessary technical expertise and based on vague legal concepts and problematic technical/ expert assistance. Hence, "it remains a lottery who can and who cannot prove negligence" (Chief Medical Officer, 2003, 110).

3.1.3. Unfairness, Lack of Horizontal Equity and Painful Delays

Even when the tort system does provide redress, it lacks fairness and horizontal equity in payments (Common Good, 2006) and is associated with excessive delays.

Some claimants receive awards that seem generous compared to the injury's severity, while many others receive nothing (Common Good, 2006). Even within the same jurisdiction, awards for similar injuries can vary considerably (Bovjberg et al., 1989). Moreover, the high -due to the length, the adversarial character and the complexity of the procedures of most litigation-based liability systems- legal/ administrative fees intensify the aforementioned unfairness and inequity, especially regarding low value claims.

Although the rationale behind redress is for the victim to be fully compensated and be put back in the position, in which he would have been, if the injury had not taken place, this is almost impossible to be achieved, especially by a court (Vliamos & Chatzis, 2009). Courts seem to be ineffective in the particular area. According to a relevant study, the distribution of compensation by Greek courts is problematic, as the latter grossly underestimate lost future earnings and hedonic/non monetary damages (Vliamos & Chatzis, 2009). Hedonic damages awarded by Greek Courts are only "reasonable amounts" and their distribution is based on the experience and common sense of judges and the ordeal of the victims or their families as perceived by the court (Vliamos & Chatzis, 2009). Consequently, quite often their decisions lack consistency as to the level of damages.

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Given the significance of hedonic damages –which are awarded for the lost enjoyment of life, pain and suffering etc.- for the alleviation of children suffering from severe birth-related injuries, the problematic awards of the Greek courts constitute a worrying issue.

The aforementioned issues are compounded by the Greek financial crisis. In a case against a private hospital, the family of a 23-year old man, who suffered permanent irreversible brain damage after an obesity surgery received the –*insufficient* based on the circumstances of the case and the individual needs of the harmed patient- compensation of 659,000 euros (Huffpost Greece, 2015), even though the family sought a much higher compensation. In another case, the Administrative Courts awarded the mother of two girls born with cerebral palsy, due to negligence, an even lower compensation (350.000 euros). Obviously, the adverse economic conditions prevailing in Greece tend to become a decisive factor, when courts determine the compensation level. In addition, whether the claim is against a public or a private hospital seems to play an important role. Administrative courts, which resolve cases against public hospitals, take the limited financial possibilities of the state into account, when they distribute compensation. Judges inevitably consider the impact of the fiscal crisis on the public health care system, the already suppressed budgets of public hospitals and the potential effect of compensation decisions on their operation. Not infrequently, compensations are paid through cuts in operational costs of public hospitals and resources are diverted from the provision of healthcare to the payment of compensations (Foura, 2011).

Tort litigation not only undercompensates, but also presents significant delays regarding the resolution of disputes, with the profound financial and emotional ramifications to harmed patients and their families. Lengthy litigation diverts doctors' professional attention from the clinical care to the courtroom (Grad, 1986). In Greece the average waiting time for a claim to be introduced to the Courts of First Instance is 3-5 years and, in extreme cases, it might reach a decade (Fortsakis, 2014). Greece has been repeatedly convicted by the European Court of Human Rights for excessive delays in the administration of justice by civil, criminal and administrative courts (violations of the article 6§1 of the ECHR ("right to a fair hearing within a reasonable time").

From the above, it is apparent that when all patients with negligent injuries are considered, not just those who seek redress, tort systems can be characterized as inefficient, inaccurate and unfair mechanisms for compensation distribution (Studdert et al., 2004). Most patients injured by negligent care do not receive

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compensation, many of them do not even file a claim and among those who do, many are undercompensated, some are unjustifiably compensated (although no negligence actually occurred) and all have to wait for years for the resolution of their cases. As it has been said regarding the US system (but it perfectly applies to the Greek liability system), the current system of tort liability is "neither sensitive nor specific in its distribution of compensation" (Kessler, 2006, 2).

3.2. Tort System and Substandard Medical Care

3.2.1. Deterrence

The tort system has been proved ineffective not only in compensating, but also in protecting future patients by deterring substandard medical practices. *Theoretically*, lawsuits deter physicians by reminding those, who wish to avoid the emotional and financial ramifications of litigation, that they must be cautious while offering their services (Shavell, 1987). Research concerning the performance of the tort system as a means of deterrence of negligent care is limited, (Studdert et al., 2004) since legal deterrence is a hardly measurable phenomenon (Schwartz, 1994). Studies that have attempted to measure it (Harvard Medical Study, 1990; Entman et al., 1994; Sloan et al., 1995) are open to methodological criticism (Studdert et al. 2004). In addition, very few would doubt that the majority of doctors try to offer high quality care, not because of the threat of litigation, but because of their professionalism and training (Chief Medical Officer, 2003). Nevertheless, as errors do occur, tort appears to have provided little incentive for prevention of errors and there is limited evidence that the system actually deters medical negligence (Mello & Brennan, 2002).

The issues of tort law in the area of deterrence are closely related to the previously analyzed failure of the tort system, in respect of the judgment of error and the identification of negligence. Fault, the central legal concept for the attribution of liability in tort systems is highly problematic, due to its vagueness and complexity (Panagiotou, 2016). The relevant theoretical constructions for the formulation of the required standard of care (in Greek law, the concept of the *average prudent doctor*) are barely compatible with the way modern medicine is practiced (Panagiotou, 2016). The notion of fault as defined, interpreted and applied in tort systems does correspond to neither the special characteristics nor the complexity of contemporary medical practice (Panagiotou, 2016). In some cases, even in the same country,

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courts interpret fault differently (Panagiotou, 2016). Thus, the current system confuses physicians, with the latter not knowing what the law exactly expects from them and taking "precautionary measures" for their protection from litigation.

In fact, evidence has shown that tort law may affect the behavior of physicians in undesirable ways, and, specifically by encouraging the ordering of tests and procedures that are of marginal -or no- medical benefit, primarily for the purpose of reducing exposure to liability (Dubay et al., 1999; Localio et al., 1993; Kessler & McClellan, 1996). The field of *obstetrics* has attracted the most thorough search for evidence of *defensive medicine*, but the findings are contradictory (Dubay et al., 1999; Localio et al.; 1993; Tussing & Wojtowycz, 1992; Sloan et al., 1995; Baldwin et al. 1995). Although the empirical evidence concerning the costs of defensive medicine is not definitive, research clearly shows that defensive medicine *does* in fact occur in medical practice (Common Good, 2006).

Even though there is no data regarding defensive medicine in Greece, few would doubt that defensive medicine is actually practiced, given the punitive, individualistic approach to errors, established by the current legal framework of medical liability. In a health care system largely affected by the continuous budget cuts, the practice and related costs of defensive medicine certainly create more problems.

3.2.2. A "Blame and Shame" Game

Despite the development and progress of health care delivery, all doctors -even the best doctors- make mistakes (Gawande, 2007). The great pressures on physicians and the increasing demand for services accelerate the process of health care delivery (Joint Commission, 2005). This acceleration heightens the risk of medical error (Sage, 2003).

Due to the Institute of Medicine's significant report, *To Err Is Human* (Kohn et al., 2000), the frequent occurrence of medical error went public, a new patient-safety movement was born and medical injury came to the forefront of the US health policy agenda (Studdert et al., 2004). Although the report avoided the topic of liability, the connection between patient safety and malpractice is increasingly apparent (Studdert et al., 2004). We should not forget that the legal context of medical liability inevitably affects the approach to medical errors (Panagiotou, 2015). The way liability systems operate inevitably has an impact on the accomplishment of

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initiatives and objectives, in respect of patient safety and quality of care (Panagiotou, 2016). The European Commission's Eurobarometers on patient safety highlighted the need to focus on patient safety in *EU* level. The focus on patient safety led to the Council's of the European Union Recommendation of 9 June 2009 *on patient safety, including the prevention and control of healthcare associated infections* (2009/C 151/01). According to the Preamble "Poor patient safety represents both a severe public health problem and a high economic burden on limited health resources". The focus on patient safety was reiterated in the Directive 2011/24/EU *on the application of patients' rights in cross-border healthcare*.

As stated by the IOM report, 90 per cent of medical errors are the result of failed systems and procedures, which do not accommodate the complexity of health care delivery (Kohn et al., 2000). Systems and procedures, which are properly designed, can efficiently prevent human errors from reaching patients (Kohn et al., 2000). The second IOM report affirmed that safety is a systems property, underlining that the healthcare systems should be help accountable, and that focus should not be solely on individual culpability (Institute of Medicine, 2001). The Preamble (para. 4) of the Recommendation of the Council of the European Union also recognizes that "A large proportion of adverse events, both in the hospital sector and in primary care, are preventable with systemic factors appearing to account for a majority of them".

Nevertheless, both the growing awareness about the role failures in health care systems have in leading to most treatment injuries, and the focus on identifying and fixing the dysfunctional systems, are impeded by the "name and shame game" in the existing approach to the resolution of medical disputes (Wachter, 2015; Common Good, 2006). Traditional tort systems seek to assign blame to *individual* doctors for injuries that have occurred during the provision of heath care (Common Good, 2006). At its root, the problem is one of conflicting cultures (Bovbjerg et al., 2001), since tort law approaches medical errors from a *punitive*, *individualistic*, *adversarial* point-of-view, while the patient safety movement adopts *non-punitive*, *systems-oriented*, *cooperative* approaches (Studdert et al., 2004).

The Greek law's concepts of fault and the *average prudent doctor* (based on which the individual physician's conduct is deemed faulty or not), as well as the possibility of parallel criminal proceedings provided by the Greek legal system, inevitably lead to an individualistic, punitive and blame approach to medical errors. Hence, the

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Greek medical liability system, like other litigation-based systems, seeks to target individual physicians, so as to assign blame and provide compensation, on the basis of proof of the physician's fault. This approach clearly undermines any effort for the enhancement of patient safety and the improvement of the quality of care.

3.2.3. A Game of Secrecy

Apparently, in order to understand the root causes of errors, it is essential that the latter be revealed in the first place (Joint Commission, 2005). However, in order to discover the specific contributory factors to adverse events and foster a *culture of safety*, transparency is a necessary condition.

Transparency has become the center of the patient-safety movement: to learn from errors, we must first identify them; to identify them, we must promote an atmosphere that contributes to openness about mistakes (Studdert et al., 2004, 287; Reason, 2000). Transparency includes both honesty with patients about errors and sharing of information about injuries with error reporting systems (Mello et al., 2006). Nevertheless, an *unintended* ramification of the tort system is that it inspires *concealment* of significant information, necessary to enhance the health system's safety (Joint Commission, 2005).

"Before, during, and after litigation, information about injuries and the circumstances surrounding them is very often kept hidden" (Studdert et al., 2004, 287). In their book, Wall of Silence, Gibson and Singh (2003) describe the ways in which information regarding errors is concealed. When it comes to acknowledging and reporting medical error, according to Gibson and Singh (2003), there is too often silence between doctors and patients; doctors and their peers; doctors and the organizations in which they work; and health care organizations and oversight agencies.

An accusation of negligence gives rise to a strong sense of guilt and professional blameworthiness (Hupert et al. 1996). Since physicians believe that they are asked to be open about errors with little or no assurance of legal protection (Studdert et al., 2004), they avoid disclosing information about errors, which could be used against them in the courtroom. Although legal fear is not the only reason for which physicians tend to conceal errors (*ego*, the human desire to *avoid* taking responsibility for bad outcomes, peer *exclusion*, loss or damage of reputation, fear of disciplinary sanctions, doubts that openness will result in constructive changes, and the cultural

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norms of the medical profession (Morreim, 2004; Sage 2004)), exposure to litigation certainly does not facilitate the disclosure of adverse events by doctors (Mello et al., 2006, 473). Consequently, the physicians' interest in patient-safety activities diminishes (Liang, 2000; Gostin 2000; Studdert & Brennan, 2001a), and a "culture of silence" is established (Common Good, 2006) and primarily expressed in two ways: *underreporting* of adverse events to reporting systems and lack of *communication* with patients about medical errors (Studdert et al., 2004), which, in turn, undermine learning from errors and the doctor-patient relationship respectively.

Although the Council Recommendation 2009/C 151/01 recommends that Member States "support the establishment or strengthen blame-free reporting and learning systems on adverse events…", no official error reporting and analysis system has been established in Greece. The provision of cross-border healthcare services in EU level, in the context of the Directive 2011/24/EU, will probably increase pressures to Member States to enhance patient safety by implementing the recommended measures. Consequently, sooner or later Greece will be called to establish error reporting systems, and the dissonance between the culture of tort and the culture of disclosure (such policy initiatives require and promote (Mello et al., 2006)), is likely to erode their efficiency and success.

This is the reason "why the axiom, "you learn from your mistakes" is too little honored in health care" (Joint Commission, 2005, 17). The reporting of near-misses and errors is an essential component of safety programs across safety-conscious industries (Joint Commission, 2005, 6) and the flow of information about adverse events in treatment that experts identify as important for reducing errors, improving the quality of care, and saving lives (Common Good, 2006). As successfully expressed: "the malpractice case tends to be compared to a lightning strike as simply a random event not associated with quality. As such, the conventional wisdom asserts, it is best forgotten and certainly should not be discussed" (Mello et al., 2006, 472).

Physicians avoid open communications with patients about errors (Studdert et al., 2004). Talking to and listening to patients is a fundamental principle of patient safety, which is undermined by tort law (Mohr et al., 2003). Any disclosure effort must include a prompt explanation of what happened and its likely impact, an assurance that an analysis will take place to understand what went wrong, a follow-up based on the analysis to make it unlikely that such an event will happen again

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and an apology (Joint Commission, 2005, 11; Mohr et al., 2003). Studies indicate that injured patients, who have experienced medical injury most want a sincere explanation and apology from their doctors (Dauer & Marcus, 1997). Data from the United Kingdom have showed that even patients, who receive compensation, often remain dissatisfied if they do not also receive the explanations or apologies they seek, or reassurance about the action taken to prevent repetition (Chief Medical Officer, 2003, 110).

However, the provision of such explanations and apologies seems to be the exception that proves the rule, as patients and their families complain about the lack of disclosure and communication, which together with the expensive and wounding litigation exacerbate the physical and emotional devastation of medical error (Joint Commission, 2005, 26). Due to this acrimony associated with litigation and the professional and emotional burden borne by physicians who are accused of negligence, even when physicians feel that an event could have been prevented, they rarely admit to negligence (Mello et al., 2006, 473). Hence, the trust in the doctor-patient relationship is lost as bitterness is induced (Studdert & Brennan, 2001a, 218).

4. The Principle of Justice

Like most topics of medical law, medical liability has its ethical aspects. Given the legal background of the author, the ethical aspects will not be explored in depth. Nevertheless, we will try to foster the relevant ethical discussion by focusing on the principle of justice.

"Justice is often regarded as being synonymous with fairness and can be summarized as the moral obligation to act on the basis of fair adjudication between competing claims" (Gillon, 1994, 185). It is linked to fairness, entitlement and equality (Alzheimer Europe, 2010). According to Gillon (1994, 185), in health care ethics the concept of justice can be subdivided into three categories: fair distribution of scarce resources (distributive justice), respect for people's rights (rights based justice) and respect for morally acceptable laws (legal justice). We will focus on the second category, as it is the most relevant to the aforementioned inefficiencies of the tort-based approach to the compensation of birth-related injuries.

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According to the recent decision of the European Court of Human Rights in the case of Lopes de Sousa Fernandes v. Portugal, the inefficiencies of the Portuguese legal system in a clinical negligence case, have led to a violation of the article 2 of the ECHR. The significance of the particular case lies in the fact that the Chamber ruled on issues arising from the administration of justice in a legal system, which faces similar inefficiencies to the Greek one. Thus, useful conclusions can be drawn.

Based on the decision's reasoning (adapted to the aforementioned inefficiencies of the Greek legal system), it could be claimed that although the Greek system provides injured children and their families with means, which, theoretically, meet the requirements of Article 2 (right to life) of the Convention, its mechanisms of redress are ineffective, because the length of the proceedings does not meet the requirement of *promptness*. According to the Court, proceedings brought for the purposes of shedding light on accusations of medical negligence cannot last for such a long time. The Court added that a prompt reaction is essential to maintain public confidence, uphold the rule of law, enable the distribution of information to avoid the same errors being repeated and, thus, contribute to the safety of patients. Hence, the excessive delays in negligence cases can lead to a violation of the Article 2 under its procedural head **(**violation of Article 2 - Right to life (Article 2-1 - Effective investigation).

Furthermore, the quite low compensations awarded lately, the difficulties to win in relevant claims, the culture of secrecy and cover-ups, the increased needs of the harmed children (who confront the devastating consequences of the injuries) and the inefficiency of the health and social care systems create greatly stressing situations for both injured infants and their families. Thus, other human rights are also violated. We could briefly mention:

Articles 3 (Right to the integrity of the person), 24 (The rights of the Child), 26 (Integration of persons with disabilities), 34 (Social security and social assistance), 35 (Health Care) and 47 (Right to an effective remedy and to a fair trial) of the EU Charter of Fundamental Rights

Articles 9 (Right to Safety), 13 (Right to Complain) and 14 (Right to Compensation) of the European Charter of Patients' Rights. The significance of the later for the ethical discussion is great since the Charter of Patents' Rights set the philosophical and

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ethical foundations for a rights-based approach to health care and aimed to promote and protect the health and dignity of individual patients (Mathuna et al., 2005).

Consequently, the Greek state, based on the responsibilities deriving from the ethical principle of justice, must: a) establish effective redress mechanisms for severe birth-related injuries, 2) make health care safer for children born in the future by establishing patient safety measures and policies. Thus, for the major ethical goals of social justice and the protection of the fundamental rights of the vulnerable to be comprehensively accomplished, legal reform necessary.

5. Core Principles, Fundamental Aims and Basic Elements of a Possible Reform: A Small Roadmap for an Effective Liability System

5.1. Conventional or Radical Reform

Obviously the issues of tort law, the inefficiencies of the Greek justice system and the complexity of the cases involving severe birth-related injuries do not contribute to the effective and reliable resolution of the relevant claims. The aforementioned problems, combined with the inefficiencies of the Greek health care and social welfare systems, result in highly problematic situations for those, who probably suffer the most, due to the devastating consequences (i.e. the degree of the disability and the related care needs and costs) of severe birth-related injuries: harmed children and their families. Thus, it is essential that the idea of reform be cultivated and promoted by health lawyers, contemplated by policy makers, discussed between the key stakeholders in the field and widely deliberated in society.

The key goals of any reform in the area should be, on one hand, the alleviation of the victims of health-related injuries through an effective redress mechanism and, on the other hand, the protection of future patients from similar adverse events, through the deterrence of substandard care and the promotion of patient safety. Tort reforms can be divided into two categories: *conventional* reforms and *system* (radical) reforms (Studdert et al., 2004).

Conventional tort reforms aim at decreasing the number of lawsuits, the amount of compensations awarded or the costs of litigation (Studdert et al., 2004). They usually include reforms, which: a) *limit* access to court (for example by establishing panels for the assessment of claims before they reach court, so as to encourage

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settlement or stop non meritorious claims from going to court), b) modify liability rules to reduce the frequency of claims and the size of awards and c) directly deal with the size of awards (for example by setting limits on either total or noneconomic ("pain and suffering") damages) (Studdert et al., 2004, 287-288).

According to Studdert et al. (2004), it is highly questionable whether such reforms can be effective in addressing the tort system's fundamental failings, as this would require more radical reforms. The particular point had already been recognized years ago and, hence, a number of *alternatives* for achieving compensation and deterrence through large-scale moves away from the traditional tort system to alternative frameworks of adjudication were formulated (Siegal et al. 2008).

The basic proposals for radical reform can be divided into three approaches: *alternative mechanisms* for the resolution of medical disputes, abolishment of *negligence* as the basis for compensation (no-fault), and the establishment of enterprise liability (locating responsibility for accidents at the institutional level) (Studdert et al., 2004).

Our scope is to follow a bold and fresh policy approach to the medical liability system, by proposing an *alternative* system, which includes major shifts, in respect of both doctrinal and procedural aspects of the current system. Specifically, the establishment of an alternative mechanism of medical dispute resolution will be combined with a major doctrinal alteration, namely the abolishment of negligence/ fault as the basis for compensation.

Our aim is to formulate the fundamental objectives, principles and features of the system. Our ideas will be based on proposals from the international academic literature and on alternative schemes successfully implemented in other countries (US, Sweden, etc.). The absence of an organized error reporting and analysis system, and the consequent lack of official data regarding adverse events hinder proposals with detailed measures, since their efficacy would be entirely hypothetical and open to question.

We do not intend to provide "magical" solutions, which will fix the fundamental problems of traditional tort law overnight. No reform in the particular area, however carefully contemplated, planned and implemented, can remedy all the failings of the tort system. Our goal is to foster discussion between academics, policy makers and key stakeholders, regarding the possible ways the current –ineffective- liability system could be reformed in the right direction.

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5.2. The Core Objectives of a New Redress Scheme

5.2.1. Effective Redress

The broader goals of efficient compensation and deterrence of substandard care can be achieved only through the accomplishment of other supplementary goals. Patients should be compensated and medical disputes should be resolved in a speedy, equitable, affordable, consistent and predictable manner (Studdert & Brennan, 2001a).

Negligence should be abolished as the decisive standard for compensation, due to its known issues and its inherent uncertainty, and other more *workable* and science-oriented/based criteria should be adopted. Besides, the controversial causation of severe birth-related injuries and the continuing disagreement amongst experts (cerebral palsy constitutes an illustrative example) render the firm and reliable resolution of liability cases based on the concepts of tort law (i.e. negligence/fault) too difficult a task and, thus, point away from tort litigation as the best way of compensating for such injuries (Chief Medical Officer, 2003).

This alteration would contribute to the expansion of the pool of injured patients, who are eligible for compensation (Mello et al., 2006). However, the long-term financial stability and affordability of the system is equally significant and it could be attained through the reduction in claims processing costs and the better cost-control of the system (Studdert & Brennan, 2001b).

5.2.2. Enhancement of Patient Safety and Quality of Care

At the same time, the new system "should strive to send strong quality improvement signals" (Studdert & Brennan, 2001a, 219), facilitate (rather than impede) initiatives for the enhancement of patient safety and quality of care (Common Good, 2006) and bring the latter at the forefront of health policy. These aims could be achieved by encouraging physicians and healthcare organizations to report errors (especially those that cause medical injury) (Studdert & Brennan, 2001a) and participate in the relevant safety initiatives. The enhancement of patient safety and the improvement of health care quality should become the ultimate objective of both clinicians and healthcare institutions.

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5.2.3 Openness, Transparency and Systems Approach to Error

Other key objectives are the establishment of a climate for open discussion regarding adverse events and the improvement of the doctor-patient relationship. The redress scheme should promote (rather than undermine) the honesty and openness of the patient- physician relationship (Studdert & Brennan, 2001a). It would be ideal, if physicians informed their patients both on the occurrence of the injury caused by medical management and on the possible preventability of the adverse event (Studdert & Brennan, 2001a).

Apparently, an individualistic and punitive approach to healthcare-related injuries and a blame culture would not contribute to the accomplishment of the aforementioned objectives. For this reason, the promotion of a systems approach to adverse events is essential. That is not to say that physicians should enjoy disciplinary immunity or that their accountability should be reduced. Although the cases, where patients are harmed by incompetent, dangerous, or malevolent physicians are rare, even a system not based on fault/negligence must establish mechanisms to deal with such doctors, either directly or by referring them to the appropriate disciplinary bodies (Studdert & Brennan, 2001a). In other words, the focus on identifying and fixing dysfunctional systems needs to be balanced with a need for accountability (Wachter, 2015).

5.3. Basic Features of the Reform Proposal

In order for the aforementioned general aims of the reform to be achieved, it is essential that the proposed scheme have certain key elements:

5.3.1. Carve-out, Pilot, Voluntary and Out-of-Court

Changing the current liability system overnight would be technically and economically infeasible, as any reform in this area inevitably requires detailed legal preparation and careful consideration of the financial aspects. That is the reason why our proposal supports a small size, "carve out" redress scheme. Such programs carve out a category of adverse events within a particular clinical area (*obstetrics and neonatology* in our case) from the tort system (Siegal et al., 2008), with the doctrinal and procedural changes, established by legislation, applying only to particular injuries.

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Regarding severe birth-related injuries, a variety of problems within the current system justify the proposal of a carve-out scheme. The most significant of these problems are: the burden of awards, the negative impact of litigation on clinical practice and primarily the catastrophic severity (MacLennan et al., 2005), the permanent character and the devastating consequences of the injury, for both the infants and their families. The existing programs operating in Florida (The Florida Neurological Injury Compensation Association, "NICA") and Virginia (Birth-Related Injury Compensation Program, "BIP") could serve as useful examples.

The scheme would have a *pilot* character and the participation of key stakeholders, such as insurance companies, hospitals and individual obstetricians, would be *voluntary* (following the example of the programs operating in Florida and Virginia). The scheme could begin with a *pilot* project, in order for the design advantages and possible inefficiencies to be identified.

5.3.2. Eligibility Criteria

The non-negligence criteria based on which infants and their families are deemed eligible for compensation should be characterized by good *sensitivity*, *specificity* (i.e., accepting those that meet the standard and rejecting those that do not) (Siegal et al., 2008) and clarity.

An option could be a rebuttable presumption of compensability, with compensation being awarded based on the nature of the *outcome* and a finding that the outcome is *causally* linked to the birth process (rather than on the basis of a finding of negligence or avoidability), following the examples of the schemes in Virginia and Florida (Siegal et al., 2008). In other words, eligibility for compensation should be based on a clear description of those covered by the scheme, the severity of the injury and its consequences. Establishing eligibility criteria based on the degree of disability suffered would be *fairer* as they would be based on *need* (Chief Medical Officer, 2003) However, whether the scheme's threshold of disability should be set high (to let only few claimants to take advantage of the scheme) or relatively low (to allow more harmed patients to receive redress under the scheme) will be decided by policymakers, based on epidemiological data, acquired through research.

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5.3.3. Procedural aspects of claim adjudication

5.3.3.1. Adjudicators

It is essential that adjudicators with appropriate expertise and training make the eligibility determinations. A specialized panel, where all the key stakeholders involved in medical liability cases would be represented in the adjudication process, would constitute a good option. A composition similar to that of the Swedish Patient Claims Panel would serve the specific approach effectively. The panel -following the example of Sweden (Johansson, 2010)- could consist of representatives of the *legal* profession (for example a professional judge), the medical profession, the patients' interests, the insurance industry, and an official of the Greek health care system.

5.3.3.2. Procedure, Decision-Making and Compensation

The scheme should have non-adversarial, easy, user-friendly, less stressful, robust and independent processes for the compensation decisions, without unnecessary barriers, for example due to the cost or the difficulty of getting advice or support (Siegal et al., 2008; No-fault Compensation Review Group, 2011). In addition, timely decisions regarding redress should be made, through the establishment of reasonable time limits for the resolution of relevant claims.

Regarding the expert opinion (which inevitably have and will continue to have central role in every redress system) and the relevant scientific evidence, careful planning should be followed, so that their fundamental role in the distribution of compensation and justice can be fulfilled. Thus, non-adversarial processes should be used for expert opinion to be incorporated into the determination of eligibility (Siegal et al., 2008). Moreover, effective mechanisms for obtaining *medical* and *scientific* input and incorporating such information in final eligibility determinations are necessary (Siegal et al., 2008, 526). In addition, *flexibility* to accommodate evolving scientific and medical knowledge is equally important (Siegal et al., 2008, 526). It is significant to inform the assessment of the eligibility criteria and the relevant expert testimony procedures with the best clinical practices and the most recent scientific evidence (i.e. evidence-based medicine such as clinical protocols and guidelines). Reference to the most recent research and scientific evidence is essential, in order for the liability system to

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impact on medical practice in a productive way, by improving it and making it safer. Such an approach would certainly contribute to an effective interaction between *law* and *medical practice*.

The *objectivity* and *scientific integrity* of medical experts are prerequisites for the accomplishment of the aforementioned aim. The neutrality and scientific competence of medical experts could be secured, if the experts were retained and compensated by the adjudication body (Common Good, 2006). They could be selected from lists drafted and constantly updated (in cooperation with the relevant medical societies and associations) based on academic and professional qualifications.

As far as decision-making itself is concerned, it is crucial that the scheme be characterized by internal *consistency*, *predictability*, *horizontal equity* and *fairness*, concerning both the eligibility for compensation and the damages awarded. Moreover, since the aim of the compensation awarded is to put the patients (as far as possible) back in the position in which they would have been, had the injury not occurred, it is essential that the new scheme enhance *flexibility* in award levels to reflect and take account of the circumstances and the needs of the harmed infants and their families (Chief Medical Officer, 2003).

Although the adoption of clear eligibility criteria would constitute a decisive step in the right direction, the effective implementation of the eligibility criteria in the decision-making process requires further measures. Establishing a capacity to use and learn from prior decisions (Siegal et al., 2008) could ensure consistency of decision-making, in respect of both eligibility and redress level. Compensation, being along the lines of the Florida and Virginia models, could cover medical and rehabilitation costs, residential and custodial care, remedial treatment, medicine and drugs, special equipment and travel costs, loss of earnings and *noneconomic damages* (pain and suffering) (Chief Medical Officer, 2003).

Regarding *non-economic losses*, valuations could be based on explicit, rational, and consistent methods (Common Good, 2006). Guidelines for compensating these losses could be created and applied to each claim that is judged eligible for compensation (Common Good, 2006). The use of more sophisticated methods for the calculation of damages, through the admissibility of economists as expert witnesses or through the training of adjudicators in these topics could be an alternative solution (Vliamos

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& Hatzis, 2009). A predetermined injury-specific schedule of noneconomic damages could be another option, ensuring predictability and consistency of the scheme, while, at the same time, contributing to its financial feasibility, by normalizing the distribution of redress. Nevertheless, the potential negative impact of the inflexibility of tariff-based schemes on the liability system's responsiveness to the needs of injured infants and their families should be considered.

Finally, claimants should be provided with all the necessary procedural rights. It is essential that the procedural guarantees provided by the European Convention on Human Rights (ECHR) (and especially the procedural safeguards of Article 6) be ensured for injured children and their families. Furthermore, if the decision-making does not satisfy the claimants, the latter should be provided with the right to appeal and have their case reassessed, in the context of an independent appeal system. In addition, injured children and their families should always maintain the option to have their case considered by a court. Specifically, as it is the case in the Swedish patient injury system, they should be provided with the right either to go directly to court or, if dissatisfied with the decision, to initiate court proceedings within a certain time period (Hellbacher et al., 2007).

Apparently in order for the changes in such a sensitive field to be effective in achieving the core objectives, reform should be *multilevel* (Panagiotou, 2016), including policies such as: the reorganization of patients complaints procedures, the establishment of an obligation to provide explanations and apologies to harmed patients, the introduction of patient safety/quality of care regulations for the enforcement of safety standards and rules, the introduction of comprehensive reforms of the disciplinary framework of doctors, the reform of the legal framework of medical malpractice insurance coverage and the reorganization of the social welfare system (to enhance its efficiency). Especially, given the relatively low- compared to tort law- awards of such schemes, it should be noted that "no fault schemes work best in tandem with adequate social welfare provision" (No-fault Compensation Review Group, 2011, 6). The more comprehensive systems of social welfare and social insurance are, the more acceptable and efficient a no-fault scheme will be.

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6. Conclusions

Apparently, adverse events do occur and will probably continue to occur, since they constitute an integral part of medical practice. Although the Greek legal system provides for criminal, civil and disciplinary sanctions for negligent physicians, claimants need to travel a rough and complex road, until they reach their goal. As far as redress is concerned, the current fault/litigation-based system is ineffective, in both resolving medical liability cases fairly and promoting patient safety. Thus, it does not promote the interests of any stakeholder: injured individuals, their families, clinicians, patients, and the health care system in general. Undoubtedly, a radical reform of the system is necessary, and it could begin with the introduction of a pilot alternative redress scheme for those who- due to the severity of the injuries, the impact of the latter on their quality of life and the consequent increased and permanent care needs- are most affected by the inefficiencies of the tort system: victims of birth-related injuries and their families.

Our proposal outlines the broad aims, the core principles and the general elements of a carve-out redress scheme, which would cover birth-related injuries. Apparently a detailed description of the specific measures and procedures of the system is infeasible. The lack of error reporting systems and relevant epidemiological data create uncertainty regarding the financial impact and the general success of specific measures and, hence, hinder such a detailed proposal. This task is left to policymakers. The article aims at initiating and fostering discussion between academics, policymakers and key stakeholders (patient organizations, hospitals, insurance companies, medical associations etc.), by formulating the fundamental principles and core elements, which could direct a future attempt of reform to the right direction. The establishment of a scheme along the above lines, satisfying most of the aforementioned principles, would probably be a right step.

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