**OTOLARYNGOLOGY NEGLIGENCE CASES THAT MIGHT NOT BE BASED UPON CONCEPTIONS OF FAULT**

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**ABSTRACT**

This paper seeks to illustrate the assumption that in certain medical procedures (normally not considered of high complexity) there may be skill-based active failures which might (all likelihood) not be based upon conceptions of fault. This is due to situational factors beyond the control of an ordinary physician practicing the particular specialty. These factors may have strong influence on the authority of a physician over their abilities.

A review of the Greek case law regarding malpractice in otolaryngology was performed to identify lawsuits that concerned routine procedures which involved arguably erroneous medical maneuvers. The presented and discussed cases are used to illustrate the assumption that is adopted by this paper. From the analysis of the specified cases emerged the hypothesis that some erroneous medical maneuvers may cause serious untoward medical occurrences even if the deviation from the standard of medical duty of care (or diligence / prudence) was only slight (borderline). In summary, under particular circumstances it may be exceedingly difficult to draw a sharp distinction between avoidable and unavoidable complications caused by such maneuvers. Some technical medical errors resulted from routine medical procedures might be viewed as (in all likelihood) unpreventable. These errors might be classified as (quasi)no-fault errors.

***Key words:*** *Medical error; Medical negligence; Otolaryngology; No-fault compensation system; Greek case-law.*

**Introduction**

Some routine medical negligence cases should not be based upon strict conceptions of fault because they may be regarded as being *too complex and difficult*. In evaluating adverse outcomes in hindsight many of these cases concern errors committed during the provision of health care, which could not be practically prevented, namely, it would be (almost) impossible for an ordinary careful, prudent, diligent and skilled physician within the relevant specialty to prevent the occurrence of certain medical complications. Interestingly, when it comes to “technical errors” resulting from routine medical procedures for which we may not believe a physician is held to too high a standard, the tolerance to human performance should not be viewed as on-off issue.

The point raised in this paper is that expected complications, frequently incumbent in certain surgical procedures approximating anatomical danger zones should not be seen as breaches in the standard of care. In this perspective, the author defends the assumption that such errors fall onto a continuum between culpable errors (fault-based errors, namely, those clearly incompatible with a medical specialty’s standard of care, i.e. surgery) and no-fault errors, namely, errors that are inherent in surgical development and as such are incompatible with a breach in the applicable surgical standard of care. Indeed, physicians’ authority over their effective abilities may be thought of as falling along a continuum between the ordinary abilities that physicians have and the constraints (internal and external) that adversely affect such abilities. Accordingly, the medical liability may be thought of as falling onto a continuum between completely avoidable (full-fault) and completely unavoidable (no-fault) error. Indeed, in reality it is not always easy to draw a sharp demarcation line between negligence-based medical errors and no-fault errors. Those cases falling nearby the “no-fault” extreme of the continuum ought to be considered quasi-“no-fault” errors and should be addressed appropriately.

In light of the proposed alternative considerations, likelihood may be viewed as suitable criteria for determining whether a given case of technical medical error could be thought of as rather falling near (if not exactly on) the “no-fault” extreme of a continuum between “no-fault” and negligence-based errors, or not. If certain errors (both *ex ante* and *ex post* considered) were in all likelihood unpreventable errors, the relative medical negligence cases should not be based upon conceptions of fault, in light of the following assumption: Provided that a physician is neither a contractor nor a builder, at the core of medical liability should not be what finally happened in the external world but what happened in physician’s mind (conscious brain) while carrying out a particular medical procedure. Therefore, from a civil right perspective in the context of medical liability system, it would be fair in certain routine cases of a slight deviation (if at all) from medical standard of care (or diligence / prudence), to address physician’s liability through the “no-fault compensation system”. In this direction, I underscore the importance of the role of medical associations in addressing some cases of medical malpractice. A rigorous scrutiny, perhaps carried out by a specific (robust, empowered and impartial) committee of experts, seems to be necessary.

In this perspective, I attempt to further illustrate my point by providing a nuanced insight into some exemplary cases of malpractice due to erroneous maneuvers in otolaryngology, which were identified from updated Greek medical malpractice case law.

The limited number of the cases (due to the fact that these only cases have been decided by the Greek courts while concerning medical malpractice due to erroneous maneuvers in otolaryngology) is exemplary of the herein theoretically advanced position. I recruited and analyzed the here specified cases of medical malpractice in otolaryngology to (practically) illustrate the following (theoretical) proposal advanced in this paper: In certain medical procedures that normally are not considered of high accuracy or complexity, there may be skill-based active failures, which in all likelihood are largely due to factors beyond the control of an ordinary physician practicing the particular specialty. All the cases specified here concerned routine procedures involving technical human error (erroneous medical maneuver) that –in the here advanced opinion-might be caused by borderline deviations from the standard of “good medical practice” (in terms of inaccurate execution of a medical procedure). These procedures normally are not considered “too complex and difficult”. Importantly, there are subspecialties of otolaryngology (i.e. functional endoscopic sinus surgery, so-called FESS, that is high-accuracy surgery) that are concerned with “too complex and difficult” surgical procedures from which may result errors that in all likelihood even a well-experienced, skilled and prudent surgeon could not avoid.

In light of the here advanced position, under the holding circumstances and in the particular anatomical context of each single case, the line of distinction between culpable fault-based errors and no-fault errors may be considered blurred. The blurriness of this line varies among the court cases specified here. Not all the cases are equally classified as to the various degrees to which these errors can be classified as *reasonably avoidable.*  Some of them could be positioned more near the no-fault error benchmark, whereas other cases could be positioned more closely towards culpable fault-based error.

In all the cases discussed, the claimants were seeking compensation for injuries or death arguably incurred based upon malpractice. The medical misadventures cited in their malpractice claims were related to failure or delay in providing the correct treatment, however, were not confined solely to alleged erroneous medical maneuvers of the defendant practitioners.

It should be noted that descriptive technical terms were considered necessary to highlight certain factors related to the alleged negligence, so that the readership could better understand why the herein advanced theoretical consideration might be practically illustrated (to a greater or lesser extent on the fault-based curve) by the analysis of the specified cases.

Note as well, that the solution advanced in this paper potentially goes well beyond the boundaries of Greece, as it addresses the tort of medical negligence as developed by the courts of many other Western countries.

***Why otolaryngology?***

Ear-Nose-Throat (ENT) surgery is a medical specialty in which a medical error due to a wrong surgical maneuver may occur with a fairly strong likelihood even by a skillful surgeon. Otolaryngology is a medical specialty with a low malpractice claim rate. This explains why the author found few case-law incidents over the years reviewed. In a recent study carried out by the American College of Surgeons, it was established that only 12% of otolaryngologists had received claims against them in the past two years1. A Danish study found an increasing trend in the number of otolaryngology malpractice claims 2. Complications in otolaryngology are seldom severe but strongly surgery-related 3. Meticulous surgical technique is essential to avoid malpractice litigation 4. Not surprisingly, a significant proportion of otolaryngology malpractice claims are related to alleged surgical errors.

In October 2013, based upon data provided by the Doctor’s Company, the largest physician-owned medical malpractice insurer in the United States, “ENT Today”, reported from 2007 through 2011, 53% of the allegations against otolaryngologists were associated with alleged “improper performance of surgery” 5.

From 1995 through 2010, among the 40 claims lodged in the UK for malpractice related to tonsillectomy with or without adenoidectomy (7.7% of the total otolaryngology malpractice claims), the most common injury was postoperative bleeding, followed by nasopharyngeal regurgitation (due to glossopharyngeal nerve injury that may occur during ENT surgery) 6. A German study which included the 50 most common in-patient ENT surgical procedures, such as septoplasty or tonsillectomy with or without adenoidectomy (TE or TA), detected “surgical malpractice” in 6.1% of all cases 7.

The often narrow, difficult and obscure operative field incumbent in ENT surgery, along with potential individual anatomical variations and the close proximity of critical anatomical structures (e.g. skull base, dura mater, brain, internal carotid artery, orbit, cranial nerves, lacrimal duct) make a strong case for why serious complications should be considered at times inevitable, even for the most skilled and experienced ENT surgeons, particularly in the cases of transnasal surgery and Functional Endoscopic Sinus Surgery (FESS). In the author’s opinion, such errors may be classified as “(quasi) system errors” as far as they are (in all likelihood) “accidents waiting to happen”. In case of such errors one can see them as inestimable but strongly militating towards unpreventable adverse events. Under certain circumstances, the borderline between their preventability and unavoidability is blurred.

**Methodological aspects**

A review of the only nationwide Greek legal database (ΝΟΜΟS, INTRASOFT, now INTRACOM) was performed over the period of the past 15 years. Six cases of malpractice due to arguably erroneous ENT surgical maneuvers were identified (out of a total of 8 cases concerning alleged otolaryngology malpractice). More specifically, three of them concerned alleged erroneous surgical maneuver resulting in injury to anatomical structures. One case concerned medical maneuver (which caused laryngeal injury, and hence, a fatal reflex reaction) performed in the post-operative phase and under emergency conditions. The other two cases concerned the preoperative injection of a vasoconstrictor and anesthetic, respectively.

**The Greek medical malpractice compensation legal system**

Under current Greek tort law, medical negligence is considered the failure to provide the care that a reasonably prudent physician *had to* and *could* provide in similar circumstances (art. 28 of the Criminal Code). Anyone who illegally and negligently causes someone else to suffer loss (art. 914 of the Civil Code - CC), moral harm (in case of injury), or mental anguish / emotional distress (in case of death) (art. 932 CC), is obliged to compensate the sufferer. The injured patient or his/her relatives can claim moral harm or mental anguish in the context of the criminal procedure (civil claim, art. 63-70 CC). By and large, a conviction in criminal trials is followed by a conviction in civil trials.

As a general rule, the Civil Courts adopt the acceptance of the Criminal Courts regarding the negligence of a physician. It is important to be highlighted that under Greek law the difference between *medical* negligence for the purposes of the criminal law and *medical* negligence for the purposes of the civil law is not qualitative but quantitative. For the purposes of both the criminal law and the civil law medical negligence is based on the same standards. Besides, the degree of recognition of the potential for hazards, risk and incidents (risk awareness) plays the same role in classifying negligence as conscious (advertent) or unconscious (inadvertent) negligence. Nevertheless, in the civil law context medical negligence is viewed as a matter of degree. There is a clear distinction between simple (or light) and grave, or more egregious criminal negligence.

Although many other jurisdictions limit criminal penalties to egregious cases of medical error, in Greek jurisprudence, criminal allegations of negligence may occur in cases of simple medical error. Furthermore, it is crucial to bear n mind that in Greek jurisprudence the difference between criminal and civil claims is not simply the punishment. Criminal and civil cases do not subject the accuser to the same burden of proof. The burden of proof in civil cases is regulated by civil procedure rules, and most importantly those concerning consumers of services (article 8, Law no. 2251/1994). A claimant need only to prove that a medical error is generally likely to cause the type of injury claimed. In the civil law context, the burden of proof shifts to the physician (essentially res ipsa loquitor) after the claimant proves prima fascia adverse outcome related to the procedure. In establishing actual causality the burden of proof is shifted to the physician, regardless of the complexity and difficulty of the medical procedure. Physicians are presumed liable unless they can raise a sufficient defense to rebut the presumption of negligence, once the Claimant has met their burden of proof.

Conversely, in the Greek criminal law context there is not ‘burden of proof’. The court assesses the evidence freely. This is to say that the taking and assessment of evidence is at court’s discretion and free of presumption. The Greek system leaves it to courts to determine whether there is negligence versus a complication. The claimant has not to prove intention or negligence for a criminal conviction. Besides, in the overwhelming majority of the cases of medical liability (with the exception of cases of very grave recklessness) the prison sentence is suspended and the defendant physician does not actually go to prison.

In recent years, there has been a rapid increase in malpractice litigations in Greece 8,9. Over the period 1998-2009, 64 out of the 101 final judgments of the Greek Supreme Court (“*Areios Pagos*”) concerning medical malpractice were judgments of conviction 10. In Greece 8 (as in Italy 11, Portugal 12and the USA 13), there has been a tendency to “objectify” medical liability (though by its very nature, it should be regarded as subjective), resulting in increased legal threat against physicians in the context of the existing negligence-based system 8,9. According to legal theory of Greek civil law (originating in the French civil law theory), the physician is obliged to provide the means to obtain a particular result (*“obligation de moyens”*), not to obtain the particular result (“*obligation du resultat*") 8. In this perspective, medical liability is purely subjective liability and should be regarded as such. However, the “objectification” of (civil) medical liability means that the physician’s “obligation of means” tends to become “obligation of result” (contractor’s civil liability) 8. Article no 8 of Law 2251/1992 establishes even for the physician the “contractor’s civil liability” and reverses the burden of proof against the physician, namely, the physician has to prove the nonexistence of his/her negligence 14. This regards both the contractual and tort civil liability of physical persons, legal persons and the public 14. The law aims to protect the “vulnerable” injured party (plaintiff) 14. Physicians are often sentenced to pay a disproportionately large amount of compensations.

The courts impose civil liability for acts or omissions that lie in the space between legality and illegality. Importantly, disciplinary committees of professional medical associations fail to play an important role in malpractice litigation 8. Greek judges experience pressures (that go beyond the ordinary) by society (the media etc) to protect the “vulnerable” victims of medical negligence 8. Besides, in Greece, there is a conflict between physicians and lawyers with regard to the concept “complication”: Lawyers view it as a negligence-based event. Physicians view it as a statistical possibility 15. This conflict of considerations along with the steadily increasing number of malpractice claims, foster the practice of the so-called “defensive medicine” (positive or negative) 16,17, which among other negative impacts on patients may increase the healthcare costs This is important in times of economic crisis.

**Greek case law regarding negligence in ENT surgery**

**Case 1**

In the Judgment No. 1135/1993 of the Supreme Court (“*Areios Pago*s”), the otolaryngologist was trying to achieve tamponade for stopping heavy nasal bleeding that occurred during transnasal surgery aiming to straighten a deviated nasal septum. The ENT surgeon was putting pressure using forceps directly on a piece of gauze which he had inserted into the nasal cavity, against the bleeding area. He applied too much pressure on the forceps towards the inside of the nose. Due to the pressure applied by the physician, the forceps were shifted from the gauze towards the upper part of the nasal cavity, thus breaking the cribriform plate of the ethmoid bone. As a result, a 3-euro-coin-sized hole (defect) was created resulting in open communication between endocranial and nasal cavities. As a result, a quite large volume of air entered the endocranial cavity, causing swelling of the nasal mucosa and of the right sinus, resulting in radiological finding of an hyperdense mass at the right caudate nucleus of the endocranial cavity, communicating hydrocephalus of the lobe, meningoencephalitis, and inflammation of the brain ventricles, due to antibiotic-resistant staphylococcus and Candida fungus. The otolaryngologist who performed the operation left for a trip abroad without informing the director of the department or the physicians on duty. Diagnosis of the complication was done through CT scan performed 6 days after surgery, when hydrocephalus and encephalitis were detected. The patient’s surgeon was aware of what had happened, and hence, he should have informed the doctors who succeeded him in the treatment of the patient, by transferring them both information and responsibilities. At that point, he possibly showed advertent negligence. The Court sentenced him to a term of 18-months’ imprisonment, suspended for three years, for violation of the commonly accepted rules of medicine and violation of the objectively justified standard and duty of care, since he failed to perform the surgery *lege artis*. He caused the formation of the hole at the cribriform plate of the ethmoid bone, namely, he was sentenced for medical error in a surgical procedure due to erroneous maneuver. The judgment of the court did not state (as it should) whether the negligence was advertent (conscious) or inadvertent (unconscious) negligence.

**Case 2**

Judgment No. 3127/2009 of the Three-Member Court of Appeal of Thessaloniki (on appeal from judgment No. 9772/2007 of the Three-Member Misdemeanours’ Court of Thessaloniki) concerned another case of medical error during a tonsillectomy (TE), with local anesthesia administered by the surgeon himself, so that “a greater part of tissues were resected from the operative field than that required for the treatment” (excessive tissue resection), resulting in a disorder of the glossopharyngeal nerve, that translated into nasal speech and rhinolalia aperta (hypernasal speech), as well as reduced mobility and sensory disturbances to the soft palate and faucial arches of a 20-year-old patient. The injury of the glossopharyngeal nerve was established through an expert report two years after the surgery. The surgeon was found (by a majority of 2:1) guilty of medical malpractice.

**Case 3**

In Judgment No. 4639/2002 of the Three-Member Court of Appeal of Athens, which ratified the Judgment No. 40751/2001 of the Three-Member Misdemeanours’ Court of Athens, a physician on duty was sentenced to a term of one year’s imprisonment (suspended) for having inserted, in an “abrupt and unskillful manner”, the metal nozzle of the tube of a suction device used for removing the excretions that had accumulated postoperatively in the airways of a 16-year-old female patient who had undergone surgery for turbinate hypertrophy and removal of a small nasal spine, which caused her suffocation. Insertion of the nozzle requires great diligence and skill because of the anatomic structure and narrowness of the laryngeal aperture. Otherwise, it may cause injuries and uncontrolled stimulation of the vagus nerve, which under hypoxic conditions caused by the obstruction in the airways and the fall of blood pressure to 70 mmHg, may lead to cardiac arrest. The fine nerve endings of the region were stimulated and cardiorespiratory reflex reactions were produced. The result was cardiac arrest and death of the patient. Post-mortem examination revealed injuries of the laryngeal aperture, “hemorrhagic diathesis starting from the corniculate cartilage on the left, passing through the ipsilateral cuneiform cartilage and extending up to the ipsilateral aryepiglottic fold, as well as hemorrhagic diathesis occupying a part of the piriform sinus on the left”. The nature and location of the injuries confirmed their iatrogenic nature. According to the Court the physician inserted the nozzle of the suction device tube “hastily”, “carelessly” and “abruptly” 18. This is a medical error of clumsy medical handling, for which the physician was sentenced to a term of one year’s imprisonment (suspended). It is to be noted that, in this particular case, the physician had rushed to the case, just after the initial obstruction of the airway arose, but precious time lost in attempting to repair the suction device, which was out of order, for half an hour. In another floor of the hospital there was another available suction device, but in the physician’s view the transfer of the patient would be very risky. This situation put the doctor in a condition of high stress. It is worth noting that no mitigating circumstances were recognized in terms of criminal responsibility, although she had acted under conditions of “emergency” and high “stress”.

The Judgment No. 4639/2002 of the Three-Member Court of Appeal of Athens was adopted by the Three-Member Administrative Court of Appeal of Athens (Judgment No. 15/2007) which considered the civil claim.

**Case 4**

The Judgment No. 159/2011 of the Supreme Court (“*Areios Pagos*”) concerned local injection by the otolaryngologist of an adrenaline (vasoconstrictor) / lidocaine (local anaesthetic) solution to the highly vascular nasal mucosa of a 36-year-old patient, who was found normal (without problems) in the preoperative evaluation. The injection was done in a single dose, rather than by slow and successive injections that would have allowed an eventual adverse reaction (untoward medical occurrence) of the patient to be promptly detected by the monitors. The absorption of the injected substances from the highly vascular nasal mucosa was rapid. The patient developed hypertension and ventricular fibrillation, which resulted in death due to adverse reaction. The physician was sentenced to a term of 3-years’ imprisonment (suspended). His negligence was considered inadvertent. The Three-Member Administrative Court of Appeal of Larissa (Judgment No. 1286/2013) which considered the civil claim repeatedly focused on the need for injecting the adrenaline/lidocaine solution ‘slowly’.

**Case 5**

The Judgment No. 1438/2001 of the Supreme Court (“*Areios Pagos*”) concerned a case of medical error of both an ENT surgeon and an anesthesiologist, who administered pentothal (anesthetic) at too fast a rate and, possibly, at a larger quantity than prescribed (5mg/kg of body weight), during a tonsillectomy (TE) performed on an 8-year-old patient. The ENT surgeon continued with the surgery, despite the detection of signs of suffocation (dark colour, cyanosis, and dyspnea). Both of them were sentenced to a term of 15-months’ imprisonment (suspended for three years), for negligent homicide.

**Case 6**

The Judgment No 2447/2013 the Three-Member Administrative Court of Appeal of Athens concerned a medical error occurred during surgical procedure being performed to correct a deviated septum. In attempting to treat an unusually in amount hemorrhage a unipolar diathermy was used, which caused a split to the mucous membrane of the nasal septum located on the other (not deviated) side of the septum, directly across from where on the deviated side a split was surgically created. As a consequence, there was a risk of perforation of the septum. Finally, the sputum ended up with a perforation. The Court accepted negligence. Although the defendants (ENT surgeons) were found also negligent for other acts, in this case, I confined my focus to the starting and most important act: the erroneous formulation of a split on the healthy side of septum.

Below, I go into the cases 1 and 2 to shed light on the particularities of the medical procedures in order to illustrate the argument that there may be negligence based technical errors which can hardly be distinguished from errors that should not be based upon conceptions of fault.

**Study on case 1: Development of CSF fistula during septoplasty.**

Septoplasty is one of the most common operations in ENT surgery 3. Cerebrospinal fluid (CSF) leak is reported as a well-recognized and dreaded complication of ENT surgery 19. When it occurs after septoplasty (as a relatively rare complication), it is mainly attributed to a defect in the cribriform plate induced inadvertently by a physician during the surgical procedure (iatrogenic complication) 19,20,21. Fractures in the cribriform plate (often resulting in CSF leakage, although tension pneumocephalus, a life-threatening complication without rhinorrhea, is reported in literature as a rare complication of septoplasty) 22,23, are related to poor technique or inadvertence, such as in the following cases: poor angling of dissection forceps, elevation of forceps beyond the ethmoid roof 20,24, and forceful removal of the perpendicular plate 20,25 of the ethmoid (by applying a multidirectional force) 20. “Slit-shaped dehiscence at the horizontal lamella of the cribriform plate” may also be observed 25. Surgeons should consider the occurrence of an undiagnosed encephalocele (e.g., an occult anterior skull-baseencephalocele is reported) 19, or the occurrence of meningoencephalocele formation after septoplasty26. A CSF fistula may be developed in connection with septoplasty. Notwithstanding, according to Onerci et al, no such report exists in the English literature 20. CSF fistulas during septoplasty seem to be very rare. Onerci et al report one case of iatrogenic CSF fistula after septoplasty20. Another case is the one that the Greek case-law has dealt with (Judgment No. 1135/1993 of the Supreme Court, here case 1), to the best of my knowledge. In the case of Judgment No. 1135/1993 of the Supreme Court, surgeon’s inadvertence resulted in perforation of the cribriform plate in attempting to control bleeding occurred during septoplasty. In my opinion, this case is exemplary of the in this paper advanced position because the serious complication might be viewed as being “in all likelihood unavoidable”, provided that the subjective perception of the surgeon (who was under stress) played an essential role.

To avoid the occurrence of a CSF fistula, multidirectional force is to be avoided. Preoperational accurate knowledge of the possible anatomical variations is essential. Importantly, the ethmoid roof level may be different on each side (right and left) 20. Onerci et al state that “the distance between the highest level of the ethmoid labyrinth and the cribriform plate at the anterior cranial fossa varies between 0.6 and 11.7 mm. The distance from the floor of the nasal cavity to the cribriform plate is 38- 52 mm” 20. Bony structures in the anterior cranial fossa are very thin and dura mater is tightly attached to them 20.

In the case of a CSF fistula, the symptoms appear immediately after septoplasty. This happened in the aforementioned case that the Greek case law was dealt with (Judgment No 1135/1993 of the Supreme Court) as well as in the case reported by Onerci et al 20. CSF leakage typically occurs after 12-22 weeks 25. Notwithstanding, Soni et al. reported a case of CSF leakage occurred 2 weeks after septoplasty 19.

During septoplasty (especially endoscopic septoplasty), a surgeon may use some anatomical landmarks in order to reduce the probability of complications. Interestingly, Seth et al. state that “the inferior turbinate and vertical middle turbinate attachment may be used to guide the extent of cartilage resection” 27. Some of these landmarks may not be totally reliable. Schultz-Coulon recommend the use of a microscope in order to obtain an optimal visualization, and sparing of the junction area between the lamina quadrangularis and perpendicularis28.

In ENT surgery, and especially in rhinology, the standards of care are changing. Svider et al. put it best in saying that these standards of care are changing “with the advent and popularization of numerous technological innovations” 29.This, in combination with anatomic variations in rhinology make the surgeon’s negligence hard to prove.

**Study on case 2: Nerve lesions during TE.**

Nerve lesions may occur during ENT surgery due to errors in surgical procedures, resulting in deterioration of the patient’s quality of life. In pharyngology, especially in the procedure of tonsillectomy (TE) with or without adenoidectomy, lesions of the shaft or tonsillar or lingual branches of the ninth cranial nerve may develop, resulting in taste disorders, ageusia (with potential secondary depression and weight loss), as well as motor disorders of the soft palate, resulting in nasal speech/ rhinolaliaaperta, or regurgitation, or a combination of both 30,31. Velopharyngeal insufficiency following palatine tonsillectomy is reported in the literature, and hence, preoperative evaluation of the anatomical variations in the velopharynx is recommended 32. A very rare but distressing type of lesion of the ninth cranial nerve due to a surgical ΤΕ procedure is the underdiagnosed secondary glossopharyngeal neuralgia. A few cases have been recently reported in the literature (2006, 2011, 2012) 33-35. When dissection at the ΤΕ is performed at an incorrect surgical plane, an injury of the ninth nerve may possibly occur because of the proximity of the nerve’s course to the tonsillar fossa 36.

Not only there is close proximity between the cranial nerves and the area where ΤΕ is performed, but there are also some different motor and sensory pathways in the same nerves. The lingual branch of the ninth cranial nerve serves the sensory pathway of the posterior tongue. The tonsillar branches of the ninth cranial nerve carry taste information from the caudal part of the palate (according to human and animal studies). They also contain sensory information from the soft palate. The palatine nerves from the maxillary nerves (branch of the fifth nerve) provide innervation to the left palate 31. Therefore, the same medical error may result in complications that could be classified into different severity. Lesions of the superficial petrol nerve endings, of which the course is difficult to determine, may occur during the surgical procedure of TE.

The lesion of the hypoglossal nerve occurs less frequently during TE in comparison with the lesion of glossopharyngeal nerve, because of the deep anatomical position of the nerve 30,37. A lesion of the hypoglossal nerve can hardly ever occur without serious concurrent bleeding, because of the proximity of the nerve to the carotid artery branches. During TE, an injury of the aberrant courses of the internal carotid artery may occur 38.

Interestingly, Moore et al. argue that iatrogenic nerve lesions may occur in all branches of medicine and some of them are probably unavoidable 39.

**Comments**

The cases specified above concerned some rare complications caused by erroneous surgical maneuvers in otolaryngology. In my view, in all of them there was evidence of inadvertence rather than a decision-related medical error since there was no evidence of significant lack of attention paid by the physicians in what concerns surgical maneuvers. On the other hand, it should be noted that serious failures such as a) the failure to pass on information to colleagues before going on leave (case 1) or b) the failure to notice that a patient is becoming cyanotic (case 5), imply considerable lack of attention. Hence, these failures no way could be classified as “system errors”.

With regard to case 1, it is not clear whether under the particular circumstances (hemorrhage in a narrow and obscure surgical field, with anatomic variations, where a surgeon may easily become disoriented and confused) it would be possible even for an ordinary surgeon who is skilful, experienced and diligent to be aware of the borderline between due and excessive pressure he/she is exerting on the cribriform plate of the ethmoid bone. In addition, it is worth mentioning that the cribiform plate is so thin that it can be broken during the intra-operative phase without such an adverse event becoming perceivable by the surgeon (especially under the circumstance of a local hemorrhage in a narrow and obscure surgical field) even though he/she is a skilful, experienced and diligent surgeon.

As regards the case 2, the so-called “excessive tissue resection” may occur in TE, resulting in nerve injuries. However, it is crucial to bear in mind that there may be cases where it may be (almost) impossible for an ordinary surgeon (who is skilful, experienced and diligent) to distinguish the due tissue resection from the excessive one. Accordingly, a dissection at an incorrect surgical plane may also occur in TE without more than insignificant lack of attention (if at all) on the surgeon’s part. In the area of the pharynx, inside the same nerves, there are different sensory and motor pathways transferring relevant stimuli from different anatomical regions. It is difficult to make accurate detection of the anatomical course of a nerve, especially of its branches and endings. Great awareness of which nerves are at risk and in what context is required 39. It is also to be noted that aberrant vessels run at the oropharynx, rhinopharynx, and close to the tonsil fossa 38. Some nerve injuries in ENT surgery might be classified as ‘in all likelihood unpreventable’.

In the cases 4 and 5, the distinction between a faster and a slower injection rate might be practically unclear, provided the unpredictable factor patient’s “idiosyncrasy” (untoward reaction to drugs). However, the aforementioned distinction might become less unclear if the total injection would be performed in slow and successive injections.

It is to be noted that the Greek case law fails to recognize limited criminal liability for physicians who committed a medical error while working under conditions of high stress (case 1 but, mostly, case 3). In case 3, the Court of Appeal which considered the civil claim was aligned with the Criminal Court and accepted that the physician had not acted “gently” and “diligently” in an anatomic area which is “extremely sensitive” and “risky”.

**The core concept of the in this paper adopted legal perspective**

Before going on, I would like to present what perspective I am seeking to adopt and why, theoretically analyzing the core concept of my assumption.

In this paper, I am attempting to defend my assumption by citing examples from the Greek case law concerning malpractice in otolaryngology. Nevertheless, these cases are specified as exemplary of applicability of the in this paper advanced assumption across all medical specialties, at least when it comes to medical maneuvers performed in course of medical procedures, which, whether *ex ante* or (most likely) *ex post* might (in all likelihood) be considered *too* complex or risky. That is to say, that the complexity or riskiness of these procedures extends beyond a certain degree from the standpoint of an *objective bystander*, namely, one who is in possession of all relevant facts, not only those which are visible from his or her standpoint.

Negligence usually includes doing something that an ordinary, reasonable, and prudent person would not do, or not doing something such a person would do considering the circumstances, situation, and the knowledge of parties involved. Consider a medical (i.e. surgical) procedure as a sequence of micro-movements, namely, micro-maneuvers. In case that the aforementioned “objective bystander” reconstruct (through envision, in hindsight) the micro-movements of a particular surgical procedure instant by instant, some of these micro-movements might be found to be erroneous, whilst in all likelihood not being *ex ante* foreseeable from the perspective of an ordinary physician of the relative specialty, due to the fact that the complexity of these micro-movements is too high, namely, goes beyond a certain degree. A physician may unwittingly engage (or fail to engage) in a *bodily movement* (muscular contraction) resulting in injury.

Beyond that certain degree of complexity and riskiness, society cannot expect from an *ordinary*, reasonable, and prudent physician to perform correctly a particular maneuver under particular circumstances. The available diagnostic possibilities (i.e. availability of imaginative methods appropriate to pre-operatively investigate the surgical field) should seriously be taken into account. A physician who committed a particular erroneous maneuver should be regarded as having engaged in mistake of fact reducing or eliminating the physician’s civil liability or criminal culpability if an ordinary, reasonable, and prudent physician working under similar circumstances could in all likelihood not adapt his or her micro-maneuvers to the conditions of the particular patient so as to correctly perform the particular medical procedure. This “mistake of fact” is born of unconscious ignorance “of a past or present material event or circumstance or a belief in the present existence of a material event that does not exist or a belief in the past existence of a material event that did not exist.” 40

**Between culpable and no-fault error**

There are cases of erroneous medical maneuvers resulted from routine medical procedures (as the above anticipated), in which a sharp line of distinction between medical negligence (culpable error) and no-fault error may be difficult or exceedingly difficult to be drawn. In case of an erroneous medical maneuver, if an ordinary physician (namely, a physician of ordinary experience, skillfulness and diligence) of relative specialty, working under similar circumstances would (in all likelihood) have a great deal of difficulty in perceiving and assessing the risks related to his/her every minimal muscular effort in attempting to perform a certain maneuver, the particular erroneous medical maneuver might be regarded as falling on a continuum between negligence and (quasi-) “no-fault error”.

It should be highlighted that it is notoriously difficult to be ruled out with certainty that a given erroneous medical maneuver was practically unavoidable, namely, constitutes a “no-fault error”. The preventability of an erroneous maneuver may vary from case to case. However, it can be established with considerable likelihood. This likelihood dictates whether a particular erroneous maneuver might be regarded as falling near the one or the other extreme of the continuum, namely, whether it might be classified as (quasi-)negligence (in case of low degree of preventability) or quasi-no-fault error (in case of highest degree of preventability). It is nearly impossible to develop reliable criteria for distinguishing between a medical maneuver that constitutes a “no-fault” error with certainty and a medical maneuver that constitutes an “in all likelihood no-fault” or “quasi-non-fault” error.

In case of a considerable likelihood of preventability it would be unfair to regard the erroneous maneuver as negligent maneuver, because it would be inconsistent with the consideration that what happened in physician’s mind during the execution of a procedure should be at the core of medical negligence. I go into this consideration. Provided that a physician has not obligation to achieve a result in itself but to *provide* the necessary means to achieve a certain result, a physician should be held liable for what he or she *did* (or did not *do*). In light of this consideration, the focus should be shift from the change that a physician induced to the external world towards the physician’s *conscious mind*. Otherwise, the medical liability becomes disproportionately broad and hence, it may negatively affect the relationship (and trust) between patient and physician, the physician’s physical and mental health / well-being (probably causing burnout syndrome), and in the ultimate analysis the quality of the provided health care and patients’ safety.

As regards the cases specified here, in the cases 1, 3 and 6, the adverse event may be viewed as “in all likelihood unpreventable” though in case 2 it is rather “in average likelihood” unpreventable. In cases 4 and 5, the adverse events are rather “in low likelihood unpreventable”.

In short, the line drawn between unwitting (no-fault) human error and inadvertent (culpable, negligence-based) error may be blurry. The preventability of a particular technical error may be thought of as falling along a continuum between on and off extreme cases, namely, between completely avoidable (fault-based) and completely unavoidable (no-fault-based) cases.

This may be due to a variety of distinct factors such as: Fallibilities and risks that are inherent in excellence of a medical specialty, fallibilities that are inherent in physician’s mind (like in any human-being’s mind or related to her idiosyncracy), environmental factors that may influence the physician’s brain functions or bandwidth, as well as the interaction between these factors. For instance, the subjective perception plays the leading role, as, for example, when the physician should have performed a “slow injection” or a “careful penetration of an instrument”, or should have exerted a “mild” but effective pressure on a delicate and brittle anatomic structure (e.g. on a thin bone to stop hemorrhage). A surgeon may be involved in medical litigation for an unavoidable complication due to “unpredictable” situations (i.e., those due to the “idiosyncrasy” or the particularities of the patient, or spontaneous movement of the body of the patient while executing a high-accuracy surgical procedure). Besides, a physician may act under the influence of situational factors (e.g. conditions of extreme stress), especially when working in an extremely sensitive, vulnerable and risky anatomic area.

The slight/borderline deviation from the standard of care may be imperceptible. Spatial awareness and other perceptual abilities may be thought as falling along a continuum between on and off cases. Therefore, surgeons may misinterpret signals such as those regarding their orientation in space or the assessment of the critical pressure they exert on an anatomical structure in relation to the endurance limits of that particular anatomical structure.

I present as illustrative of this consideration the case of a physician who exerts some pressure on an anatomical structure. I confine my focus to physician’s awareness of that pressure. In my opinion- there are many similarities between this type of awareness (i.e. awareness of the degree of the pressure one exerts on a thin bone surface or a syringe piston) and self-awareness. Self-awareness is a highly complex function and as such it resembles a dynamical system. It is unpredictable from and irreducible to its component parts. It results from dynamic and complex interaction between the activities of constituent parts of the central nervous system, such as neurons or networks 41. As such, it may be falling along a continuum between being and not being in a state of (self)awareness, namely, between on and off extreme cases 41. Given the truth of the aforementioned assumption regarding self-awareness, we may reasonably suppose that physician’s awareness of the pressure she exerts on an anatomical structure is by its own nature also integral property that ranges along a continuum between on and off borderline states. James Reason argued that when people are thinking they recognize patterns. The author suggested that people store schemata in their conscious brain which include the essential features of situations experienced before and the key elements of responses to these situations 42. In analogy to this assumption, one may presume that when exerting pressure on a thin bone surface or a syringe piston the degree of awareness may be determined by analogous situations experienced before. Besides, such influences may result from dynamic and complex interaction between factors as physician’s idiosyncracy, biorhythm, stress, distress and other (mostly environmental) factors. Further, under particular circumstances, such factors may cause the limited human brain bandwidth to become substantially more limited. For instance, these factors may deprive a physician of his/her abilities not only to perfectly reflect and ponder (i.e. as to how much pressure can a particular anatomical structure endure), but also to be fully aware of the degree of the pressure that exerts on an anatomical structure.

**Difficulties in evaluating the events afterwards**

It has already been exhibited above that it is entirely possible that routine medical negligence cases should not be based upon conceptions of fault because they are *too complex and difficult*. Provided that routine medical procedures are rarely “too complex and difficult”, rigorous scrutiny in hindsight of the events that happened while carrying out incorrectly a routine medical procedure, as well as the circumstances under which that procedure was carried out, is required. However, in certain cases it may be exceedingly difficult to *ex post* prove that a medical error resulted from erroneous maneuver(s) should be viewed as occupying a “blurred zone” between no-fault error and negligence-based error rather than being viewed as negligence-based error. Provided that often there is no adequate evidence to *ex post* show that the particular error was reasonably unavoidable from the physician’s perspective, the likelihood of its preventability should be determined by the complexities, difficulties and particularities (if any) of a given case. Hence, the preventability of an error may be regarded as higher or lower as compared to the likelihood of preventability there was in reality. At any rate, the adverse events that result from erroneous medical maneuvers considered “in all likelihood unpreventable” should be classified as (quasi-) no-fault errors. If anything, in case that a medical error is considered negligence-based despite the fact that it cannot be ruled out with certainty, the deviation from the “traditional” consideration that negligence is at the core of medical errors would be counterintuitive. Moreover, it should be highlighted that in the modern healthcare context, the self-evident connection between medical error and negligence seems to need to be largely revised. Sohn remarks that negligence is not at the heart of most medical errors43, thus implying that most medical errors are in reality system errors.

As regards the negligence-based errors, the existing test for negligence should not be reformulated. The change of the physician’s standard of duty of care (as is the case with “ Wilsher v Essex Area Health Authority”) 44 constitutes a fair approach in case that under particular circumstances the physician *could not* meet his/her duty of care.

**The no-fault compensation system**

As is presented below, it is argued that the no-fault system compensation system seems to better serve the purposes of civil medical liability which, by its own nature, focuses on patient (namely, on restoration of damage) rather than on physician (namely, on indictment and sentence or payment of compensation). Sohn arguably states that “a more rational system would focus more on the goals of compensation and improvement, rather than on punishment for those who err” 43. Notwithstanding, medical negligence is a decision-based (namely, based on physician’s mental abilities and skills) failure to meet a requisite standard of care43. However, there are errors which are inherent in the excellence of a medical specialty. This is probably the main reason why French jurisprudence of the courts oscillated between two positions: the quasi-obligation of the physician to secure the safe result by carrying out correctly a surgical procedure, and the obligation of the physician to meet his/her standard of duty care, which are corresponding to the rules of “good medical practice” and prudence 45.

Given the truth of the here defended assumption that unavoidable / unpreventable / unwitting or *in all likelihood* unavoidable / unpreventable / unwitting technical medical errors resulted from routine medical procedures should not be based on conceptions of fault, the implementation of the “no-fault” system would be considered a necessary reform of medical malpractice system. Injuries considered unavoidable (or *in all likelihood* unavoidable) resulted from unwitting errors that occurred in routine medical procedures are proposed as compensation criteria. Importantly, the particularities of each single case should be screened carefully and precisely to be established if the given case of (technical) medical error would be eligible for compensation through the so-called “no-fault compensation system” or not. Therefore, I stress the role of experts committees (perhaps of medical associations).

The so-called “system errors” would be more fairly addressed through the “no-fault” compensation system. Generally speaking, system errors are errors for which the responsibility is institutional rather than individual. In my opinion, there are similarities between the so-called “system errors” and the unavoidable (or “in all likelihood” unavoidable) individual technical medical errors. Perhaps, the distinction between the latter errors and system errors might be viewed as false dichotomy, when considering physician’s body as a living part of the healthcare provision system in the broad sense of the term. This assumption needs to be further theoretically investigated but such a research goes beyond the scope of this paper. However, I go into little details.

Sohn states that system error is an “occasional”, “simple”, “unwitting”, “unavoidable” human error 43. The same hold true for unavoidable (or “in all likelihood” unavoidable) individual technical medical errors. System errors are in principle the errors for which the responsibility is institutional rather than individual. A system error is one which is attributable to the healthcare system or bureaucracy. This might be organisational error (staffing, failure to have expert mentorship, etc.) or improper processes (drug carts set out improperly, etc.). Hence, system errors might be things like physicians having to be on call for significant periods of time without sufficient rest. Importantly, the line of distinction between system and individual error may be blurry when it comes to technical human errors resulted from difficult, complicated and complex surgical procedures (that are mostly high-accuracy procedures) such as those carried out in narrow and obscured surgical field, which involved erroneous maneuvers due to physicians’ failure to become fully aware of the pressure they exert on an anatomical structures or of fingers’ position and movement through space (namely, lack of full kinesthetic awareness).

It is argued in literature that the “no-fault” system has a number of advantages as compared to the negligence-based model 46-53. On the other hand, it is argued that the “no-fault” system serves the interests of all the stakeholders involved in medical malpractice: patient, physician, healthcare system, and community as a whole. It is argued in literature that there is a strong public interest in the implementation of the “no-fault system” instead of the existing negligence-based system regarding medical malpractice 43.

Not surprisingly, the “no-fault” system seems to be fair to be applied when it comes to injuries caused during super high-risk surgical procedures, where surgeon negligence is difficult to ascertain 49. Indeed, in super high-risk surgery (e.g. in ESS) even a minimal surgical maneuver may result in a serious complication. This may happen even if the surgeon is experienced, skillful and prudent 54-56.

In Greece, the “no-fault compensation system” found advocates in the legal theory, because of the way the Greek medical liability system works 57. I think that the “no-fault system” in Greece is affordable, as far as it concerns system medical errors only, provided that under the current legal framework the State is under obligation to pay compensation for negligent acts or omissions of physicians working at public hospitals (article 105, Introductive Law of Civil Code). Over the period 1998-2009, the vast majority of judgments of the Greek Supreme Court (“*Areios Pagos*”) concerned physicians working in the public health sector 10. Note, besides, that the “no-fault system” may be funded partially through the private sector.

Besides, under the “no-fault system”, some injured patients may seek nonmonetary types of redress 58. According to Tsimtsiou et al. 59, in Greece, the patients’ desire for open and timely disclosure is very strong, and “exceeds their expectations for financial compensation”. Such a disclosure of medical error reduces remarkably the likelihood of developing litigious intention. This statistical observation might be thought of as encouraging the implementation of the “no-fault compensation system” in Greece. In the following, I provide a comment resulted from the study of the in this paper specified malpractice cases. As emerged from the documents retrieved from the proceedings of the trials, the overriding and ultimate goal of all the claimants were noneconomic goal, namely, to punish those physicians who appeared to have injured them or their loved ones. However, damage awards were inevitably reduced to financial compensation as a means to achieve their ultimate goal. Some claimant wanted to find out what in reality happened. However, this was also pursued as a means to achieve their overarching and ultimate goal: the punishment. According to the in this paper adopted perspective, in case of a medical error that might be viewed as (quasi) “non-fault” error the claimants’ goal would most likely not be the punishment of the physician(s). As a consequence, many claimants may seek noneconomic types of redress. Besides, the amount of the sought compensation might be much smaller (if at all), whilst there might not be criminal cases against physicians.

Interestingly, although under the “no-fault system” the extent of compensation is generally lower than under the tort system 53, with budgets similar to the costs of the tort system many more patients can be compensated 54.

Finally, it is crucial to bear in mind that in contrary to the negligence-based system that “objectifies” (as it has been anticipated above) medical liability, probably according to the business rationale (costs/benefits), under the “no-fault system” physicians could go unpunished, they would be strongly discouraged from practicing defensive medicine, and medicine would be practiced in congruence with the principles of medical ethics (i.e. the principle of “beneficence” or “nonmaleficence”) 43. The “no-fault system” benefits both physicians and patients, and fosters a good relationship between them. Besides, it improves the quality of health care and promotes the public interest. However, the “no-fault system” that eventually will be put forward in a country must be well-designed and carefully adapted to the country’s economy.

**Conclusion**

There are routine medical procedures in which erroneous medical maneuvers may cause serious complications even though the deviation (if any) from the standard of medical duty of care (or diligence / prudence) was only slight (borderline). Under certain circumstances, it may be extremely difficult to draw a sharp line of distinction between avoidable and unavoidable complications caused by such maneuvers. Besides, under particular circumstances it may be very difficult or impossible to make *ex post* effective and reliable judgment about a physician’s negligence. Skill-based active medical failures (i.e. erroneous maneuvers-based medical failures) may be caused by situational factors that may have more or less strong influences on the authority of a physician over their abilities. Given the various degrees of such influences as well as the various degrees of complexity and difficulty in particular medical procedures, the preventability of a medical (technical) error may also be a matter of degree. In conclusion, there are technical medical errors resulted from routine medical procedures that are unavoidable or in all likelihood unavoidable. These errors might be classified as (quasi) no-fault errors.

The adoption of the “no-fault compensation system” by the medical liability system seems to address the aforementioned (unavoidable or in all likelihood unavoidable) errors in a fair manner. I support the implementation of the no-fault system in Greece, within a narrow range inclusive of “in all likelihood unpreventable” human errors resulted from routine medical procedures, such as the errors based on erroneous medical maneuvers that can reasonably be considered almost unavoidable/ unpreventable/unwitting. Compensation of such errors through the no-fault system would offer significant advantages (e.g. compensation in a timely manner, disclosure of the errors). Note, however, that the “no-fault” system’s alleged disadvantages would in all likelihood remain unobserved, provided that the tort system will keep compensating the majority of medical errors.

My ambition is to offer an instrument for making better judgments about medical liability. However, more work is needed to be done to increase awareness of the subject by both judges and politicians, as well as to trigger scholars to further thinking about the truth of the assumption that I defend in this paper.

## Abbreviations

AE=Adenoidectomy

CC=Civil Code

CSF=Cerebrospinal fluid

CT Scan = Computed Tomography Scan

ENT= Ear, Nose and Throat

FESS = Functional Endoscopic Sinus Surgery.

TA=Tonsillectomy/Adenoidectomy

TE=Tonsillectomy

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The author declares that he has no competing interest.

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