JOURNAL
of
APPLIED ETHICS
and
BIOLAW

ISSN 2501-529X
ISSN-L 2501-529X

JOURNAL of APPLIED ETHICS and BIOLAW

published by

the ASSOCIATION FOR EDUCATION AND RESEARCH IN ETHICS AND LAW - EDUCED

www.educed.ro

Subscription for hard copy:

100 Euros/year (4 issues) - including the shipping fees

Payment details: RO68INGB0000999905167265, ING Bank, Iaşi, Romania

Please send us a copy of the receipt by e-mail: contact@biojustice.eu

www.biojustice.eu

JOURNAL OF APPLIED ETHICS AND BIOLAW

Table of content

Defensive Medicine: Myths and Realities

Grigore Tinică[1,2], Mihaela Tomaziu-Todosia[3], Alexandra Cristina Rusu[4], Raluca Ozana Chistol[5,6], Cristina Furnică[7]

1 Professor, MD, PhD, University of Medicine and Pharmacy "Gr.T.Popa" Iaşi, Romania
2 Cardiovascular Surgeon, Cardiovascular Diseases Institute, Iaşi, Romania
3 Economist, University of Medicine and Pharmacy "Gr.T.Popa" Iaşi, Romania
4 Student, University of Medicine and Pharmacy Tirgu Mureş, Romania
5 MD, PhD, Student, University of Medicine and Pharmacy "Gr.T.Popa" Iaşi, Romania
6 Radiologist, Cardiovascular Diseases Institute, Iaşi, Romania
7 Lecturer, MD, PhD, University of Medicine and Pharmacy "Gr.T.Popa" Iaşi, Romania

Abstract: *The phenomenon of defensive medicine has existed for decades in the United States but in Romania it has emerged lately following malpractice litigation and mass media aggression. Defensive medicine develops when doctors prescribe tests or procedures and avoid treating high-risk patients or performing certain high-risk procedures in order to reduce the risk of medical liability. This essay discusses the basis and principles of defensive medicine, analyses its causes and effects and debates the major problems affecting the Romanian healthcare system, notably the cross-border medical assistance. Finally, the authors examine alternatives meant to prevent defensive medicine practices.*

Keywords: *defensive medicine, malpractice, cross-border medical assistance, healthcare system.*

In the early days of medical practice, physicians were self-governed, rarely questioned entities and their issues and problems were not so easily or as widely broadcasted. Experts agree that the root cause of defensive medicine originates from the increasing number of medical malpractice lawsuits that emerged in the early 1800s. "Before the 1960s, legal claims for medical malpractice were rare and had little impact on the practice of medicine" worldwide as stated by Bal BS (1).

Since World War II the demand for medical care has risen to unprecedented proportions, mainly due to the accessibility of medical insurance and the governments' efforts to make health care accessible to the masses. Coincidentally, the availability of resources could not sufficiently increase to meet this growing demand. This progression had direct results, such as an escalation of medical costs, an increase in dissatisfaction with the

health care system, a sense of crisis and the realization that medical resources were severely limited. Nowadays, the large variety of technological mediums facilitates the population in acquiring information, thus decreasing trust in qualified specialists and medicine itself. The progress of scientific technology increased public expectations about the ability and capacity of medical science, patients easily assuming that all diseases can be cured. The general discontent inevitably led to a rise in litigation and a more defensive approach among physicians (2).

According to the president of the Florida Medical Association defensive medicine is a "response to a pandemic of malpractice litigation and has become an undeclared standard of care, the inherent costs of which are passed along to patients and health care providers" (3).

The regulating authority recognises a number of converging definitions that apply to the term *defensive medicine*:

- *Clinical decision is motivated primarily by the desire to protect oneself from a medical malpractice suit or disciplinary or professional action* (4);
- *Medical treatment that involves more tests, operations, etc. than a person really needs because a doctor is worried that a claim or complaint may be made against them in court if they make a mistake in the treatment they give* (5);
- *The practice of ordering tests, procedures, and visits or the practice of avoiding treatments for patients considered at high-risk, in order to prevent medical malpractice claims* (6).

Both in Romania and worldwide the constant threat of malpractice suits led to an extensive use of defensive procedures among other practices such as professional liability prophylaxis, partial or complete abandonment of medical practice and medical malpractice liability insurance.

According to the Medscape's Ethics Report 2014, a significant percentage of physicians noted that they would or might engage in defensive medicine to protect themselves. When asked if they would ever perform a procedure that may not be medically warranted because of malpractice fears, 20% of physicians responded "yes", 24% said "it depends", 56% said "no". In Medscape's 2010 survey, only 16% had responded "yes" to that question (7).

In 2014, physicians in three hospital medicine services were asked to estimate the defensiveness of their own orders. The survey became part of the Cleveland Clinic study and showed that 28% of 4,200 orders were

estimated as partially defensive, and 2.9% as completely defensive (8).

Over the last 50 years, several trends facilitated the practice of defensive medicine (9):

- Expansion of medical industrial complex;
- Service ethic to business "ethic" of marketplace;
- Medicine from cottage industry to employment by systems;
- Increasing sub-specialization;
- Near-collapse of primary care;
- Growing system fragmentation;
- Decreased continuity of care;
- Increasing bureaucracy;
- Decline in professional sovereignty;
- Novel diagnosis and therapeutic methods.

In the USA, defensive medicine is responsible for 5% to 9% increase in healthcare costs, in Italy for 10.5% of the total healthcare spending in the public sector and 14% in the private sector, while in Romania, 91% of physicians recommend more tests than necessary, 41% prescribe more drugs than guidelines recommend, and 74% of patients coming to general practitioners (family doctors) receive an unnecessary indication for specialty consultation (patients now use the internet to search for diagnoses and treatments). The standard of care is evolving and growing alongside the technological changes and some physicians might feel vulnerable if they chose not to approach the diagnosing process aggressively (9-12).

Constant technological advances, class medical uncertainty are increasingly difficult to accept for both physicians and patients. Medical certainty increases as the probability of a disease grows from zero to 100%, and the only way to achieve this certainty is to raise the number of diagnostic tests. A structured educational plan aimed towards informing the public can aid people to understand that medicine is not a perfect science.

According to the Romanian law, malpractice is subject to both penalty and civil trials, although most patients decide to go for penal complaint as no tax is required the medico-legal expertise is paid by the state in penal trials compared to civil trials when taxes are required and the medico-legal expertise is supported by the complainant (13).

Penal trials lead to increased costs for the state and an indirect increase of healthcare costs. Most Romanian patients sue to get financial compensation in the absence of objective evidence. Thus, a new trend of *doctor-hunting* has emerged, secondary to media manipulation. Lawyers specialized in medical malpractice have started surfacing in

Romania, a tendency that raises the possibility of a tort-like reform, as was the case of USA.

A significant proportion of physicians believe that medical malpractice trials affects the doctors' professional reputation even if they are not found responsible for a fault causing harm.

Defensive medicine may be positive or negative, depending on the situation (14):

- "Positive" defensive medicine means the use of tests or procedures with little expected medical benefit in an effort to avoid malpractice claims;
  - record keeping - accurate and up to date medical records;
  - follow-up - doctors have a duty to make sure that there are practice systems which ensure that they follow up on investigations, referrals and procedures;
  - effective communication with a patient will inevitably reduce the risk of a subsequent claim or complaint;
  - ordering "clinically relevant" tests - physician training encourages a culture of completeness regardless of cost or effects on others patients; practitioners are fascinated by high technology and may erroneously perceive that more tests are by definition equal to better care;
  - overtreatment - therapeutic management is more than what the occasion demands or diagnostic or treatment application procedures are applied without conceivable indication;
  - continuity of care - signs and symptoms have disappeared, when maximum repair and rehabilitation have been achieved, or when the best possible cure has been attained.
- "Negative" defensive medicine entails declining to supply care that has expected medical benefit in order to avoid malpractice affects mainly high-risk patients:
  - "avoidance behaviors" - may sometimes increase the number of claims;
  - "assurance behaviors" - increases the time of preoperative investigation with economic repercussions;
  - "time factor" - delaying or not performing a surgical procedure.

The incidence of defensive medicine practices varies depending on medical specialty and particular circumstances and is increased in certain cases (15):

- when the disease or condition to be detected or prevented could result in death or disability;
- when early detection of the disease or condition changes therapy;
- when it can be expected that the change in the therapy will make a difference on the patient's state of health;

- when the diagnostic test or the alternative treatment has reduced risks and is available on the spot.

The final results of positive defensive medicine are an individualized approach, development of risk assessment systems (scoring algorithm), preventing medical claims in case of ictus or death by following specific guidelines and not exposing patients to unnecessary surgery.

The Office of Technology Assessment raised an interesting point in asking if the desire of limiting medical malpractice must be conscious to be considered a defensive practice of medicine. How can one claim that doctors are practicing defensively if they do not know they are doing it? The study argues that in time, several procedures, which were originally consciously practiced for purposes relating to medical liability, could become medically indicated procedures. Physicians have integrated these practices into their daily lives so they are no longer aware of the original motivation that led them to prescribe these tests. They came to believe that it was good medical practice, the legal standard of care (6).

Diagnostic tests conducted for defensive purposes may be those prescribed automatically; such practices might have no significant influence or might not impact the way the doctor decides to treat his patient.

The trend towards defensive medicine burdens an increasing number of traditional patient-doctor relationships. The emphasis of medicine is shifting from curative to defensive. Diagnoses and prognoses are becoming understandably more uncertain. There has been a general loss of authority affecting the patient-doctor relationship especially, while the media prejudices the patient through irresponsible provision of information.

Although the financial and professional costs of malpractice liability are real, the primary impact on physicians is psychological. Physicians report that a malpractice claim causes a short-term decrease in self-esteem while 20-40% reported symptoms of clinical depression, anger, fatigue, or irritability, long-term changes in behaviour or personality, as well as physical illness. The anxiety caused by a lawsuit is certain to manifest for a long period of time. The average time between the filing of a claim and its resolution is approximately 33 months, although it may take longer than 48 months. Moreover, a claim is often not filed until 20 months after the incident, leaving the physician enough time to speculate as to whether a particular

patient will bring a suit after an adverse outcome (16, 17).

The probability of defensive performances is directly proportional to the specific risk level. Among surgical specialties, cardiovascular surgery is at high-risk of litigation. A meta-analysis performed by Jena et al. reveals a 19% per year probability of facing a claim for cardiovascular surgeons in the US. The type of treatment and time factor are key points in the evaluation of defensive approaches among cardiovascular surgeons (18). Availability of "less invasive" endovascular procedures influences "inexperienced" surgeons that might abuse them in order to avoid increased risks, although endovascular therapies are very efficient weapons only for an experienced clinician, at the end of an adequate learning curve.

The physician's liability for the defensive practice of medicine is, firstly, a failure to inform and obtain consent because he does not disclose proposing a medical test for defensive reasons. As we know, consent must be free and informed, but in the case of defensive medicine, the patient will not be made aware of the defensive purpose of the intervention. The fault may be that of a breach of the duty of care. For untimely diagnostic tests, the doctor exposes the patient to unnecessary risk caused by fear of the trial and not exclusively for medical reasons (19, 20).

The common causes of allegation in cardiovascular surgery are:

- known, worldwide recognized, morbidity and mortality rates (no 0% mortality procedure);
- delay in diagnosis (primary and secondary assistance);
- delay in treatment;
- failure to diagnose an associated medical or surgical condition;
- improper consent before an invasive maneuver;
- inaccurate or incomplete medical records;
- incomplete preoperative evaluation;
- surgery avoidance in high-risk cases;
- inexperienced teams;
- anesthesia or intensive care error;
- cardiopulmonary bypass error;
- intraoperative incidents and accidents;
- improper postoperative treatment;
- early postoperative complications.

In order to diminish the risks, each patient should be evaluated by a heart team and registered according to the international risk scores.

Currently, there is a pressing need to assess the current trend in defensive medicine (positive or negative) by focusing on the personal perceptions of the cardiovascular surgeon practicing it and on reporting

and reevaluating any suspicious case with a team of specialist surgeons together with the compliance to the guidelines and runtimes.

Some future possible directions might turn out as feasible paths to be followed in order to avoid abuse of defensive practices (fig. 1).

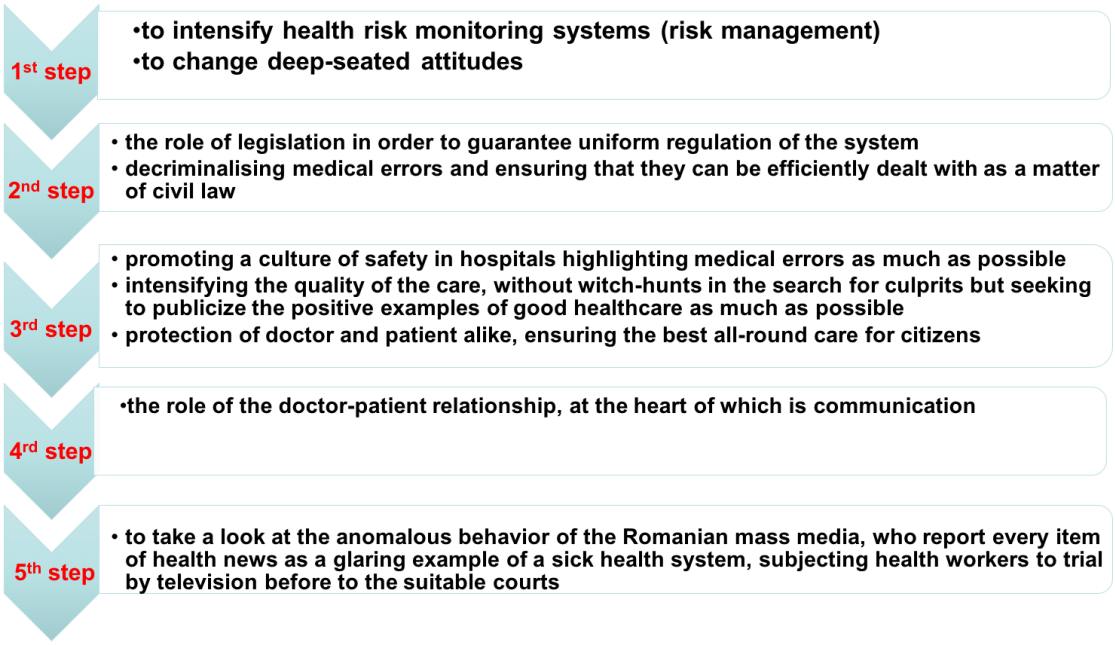

Fig. 1. Future possible directions

Major problems of the Romanian healthcare system

Defensive medicine is a practice impairing an already weakened system by increasing costs, fragmentation and the administrative burden, by decreasing access, technology abuse, medico-legal liability, money leaks, and by overcharging the personnel in the context of staff shortage. According to the Romanian College of Physicians, since 2007 18,000 physicians left Romania to work abroad secondary to insufficient payment, public servant status, being trapped in a conflict of interests between the state, patients, medical personnel, suboptimal work conditions, inadequate equipment, healthcare system underfunding, and stress due to constant malpractice threats. Currently, there is a vacuum in the Romanian malpractice regulations (21) (fig. 2).

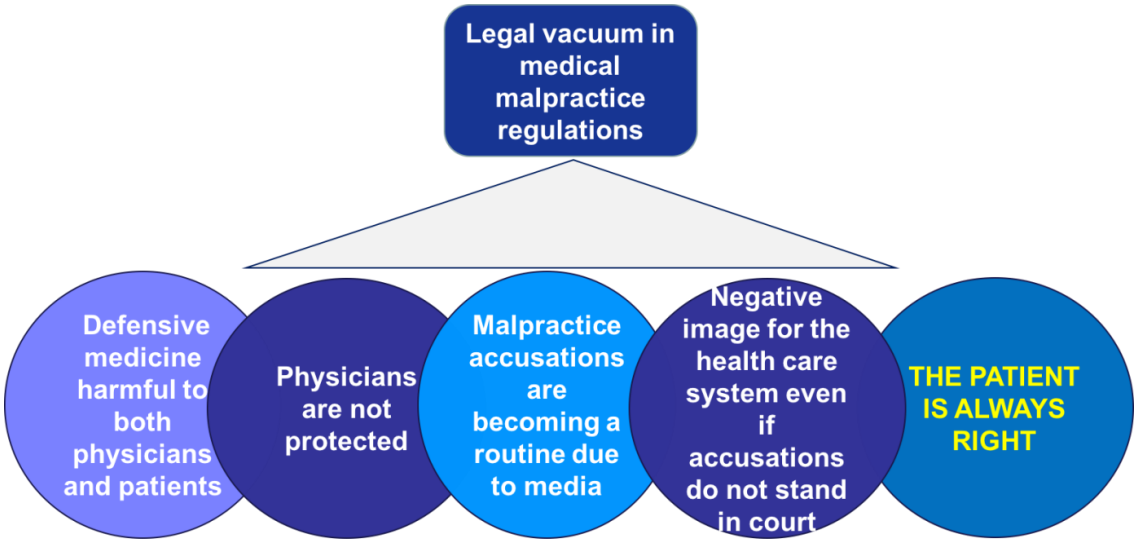

Fig. 2. Causes of the legal vacuum in medical malpractice regulations

Disregarding the trend towards defensive medicine, another major issue of the Romanian healthcare system is the migration of patients towards Western Europe. According to the Romanian law, Romanian patients can apply for healthcare services abroad if necessary treatment cannot be provided in Romania in a reasonable time period, but this is an entirely relative statement, subject to debate. Statistics for 2013 show that the National Health Insurance House had a €192 million debt. In 2013, 1010 Romanians benefited from treatment abroad costing a total amount of €33 million (367 oncologic cases, 265 cardiovascular diseases, 116 paediatric diseases) and the amount increased in 2015 to a total of € 94.618.377 (22):

- 99.23% paid for medical treatment based on medical documents;
- 0.70% paid *a priori* for medical services which were previously supported by citizens having medical insurance;
- 0.07% paid according to court decisions.

Government decision 304/2014 for the approval of Methodological Norms on cross-border medical assistance transposed into national legislation the European Directive 24/2011 that assures the legal framework for reimbursement and recovery of expenditure representing the medical assistance granted in EU (European Union) countries based on international documents with provisions in the field of health to which Romania is party (23).

The type of medical assistance is a subject-matter of the prior approval and several criteria have to be met in order to obtain approval. Among these criteria, we mention "no hospital can provide such services within a medically reasonable term, taking into account the current health condition and potential evolution of the disease of the assured person". Despite this condition, there are patients that undergo coronary artery bypass grafting abroad even if the delay from indication to surgery in Romania is 30-90 days according to gravity compared to 12 months in the UK.

Table 1. Health Care Costs for Treatment Abroad (procedure alone)

Austria (AKH-Wien):
- coronary stent – €2000-€3000
- valve replacement – €14000-€16000
Germany (MediClin Herzzentrum, Lahr and Coswig):
- coronary stent - €3000
France (Georges Pompidou, Pitié Salpetriere, Paris):
- valve replacement – €17000-€18000
Italy (Novara-Azienda Ospedaliera):
- Coronary Artery Bypass Grafting - €3000
Turkey:
- chemotherapy €1000-€2700
- radiotherapy (30 sessions): € 110000
Romania:
- National Programme for Cardiovascular Diseases
- PTCA - €568
- Cardiac surgery -€ 1401
- TAVI -€ 27272
- Congenital Heart Disease (surgery) – €1438

The costs of treatment abroad (procedure alone) far exceed those reported in Romania (table I).

The consequences of this practice are increased healthcare costs and less financial support for the Romanian medical research or medical industry. Most health care services offered abroad can be achieved in Romania with funding. The costs of treatment abroad for 100 patients could buy equipment that would save 1000 similar cases in Romania.

Following the citizens' tendency, some clinics from western EU countries specialized in offering services for Romanian patients (for example, http://www.herzzentrum-lahr.de/Themen/international/ româ -nă. aspx, http://www.herzzentrum-coswig.ro/Home.aspx, http://medical-express.eu).

Although there is a number of cases for which the needed treatment cannot be provided by Romanian hospitals (eg. lung transplantation), for many patients the indication for treatment abroad is arguable and the existence of sabotaging businesses can be suspected as some Romanian companies offer paid consulting and brokerage which, besides raising prejudice against the healthcare system, encourages defensive medicine by stimulating patients to insist on demanding more tests or being sent to a specialist for diseases

that could be treated by the general practitioner. Tertiary referral hospitals are overcrowded and doctors are predisposed to malpractice simply by being forced to deal with a number of cases greater than reasonable.

Possible solutions

Practice guidelines seem like an effective solution to defensive medicine but are difficult to apply in certain situations. A wide range of protocols is necessary because of the difference in the nature of clinical outcomes. The differences in the availability of scientific research, the scope of clinical experience, the degree of certainty on how to approach the various clinical problems, the availability of alternative treatments and other factors require different, flexible approaches to a standard protocol.

Practice protocols are sometimes considered to be a potential panacea to the problems experienced by several organizations involved with providing healthcare. In addition to helping physicians achieve better medical outcomes for their patients, protocols discourage inappropriate care, improve the problems associated with civil liability, reduce iatrogenic accidents and reduce defensive medicine.

Defensive practices can also be prevented through the application of a quality control filter by building a hospital hierarchy according to competence, increasing a physician's competence level, and reforming the health system. Authors from several countries and various national reports proposed reforms angled towards tackling medical liability, reforms that must face dissatisfaction in the traditional system of liability that no longer fully meets its compensatory, punitive and distributive objectives. Proposed reform options vary, ranging from a radical reform which completely abolishes the whole classical system of civil liability law, to maintaining the traditional system and conducting simple provisional reforms on substantive rules of procedure and evidence. The range options should adapt to the particularities of each legal system and must address each of their distinctive problems.

Conclusions

Defensive medicine is very difficult to prove and verify. The effects of this practice are felt not only through medical errors and adverse events but also through over-diagnosis and the escalating costs.

Defensive medicine is also subjective, intuitively obvious to a physician in high-risk clinical practice but is rarely a decision taken purely out of defensive or clinical prudence. Defensive medicine is a direct result

both of the concern for a patient's safety and welfare and the concern for personal liability. Long-ingrained habits of defensive medical care may evolve in time toward standard practice of care while the distinction between physician self-protection and patient interest will be lost in the murky waters of legality.

This progressive trend must be acknowledged and managed as it has the potential of turning, step by step, from trend into standard and consequently be taught to students and doctors alike.

Medical malpractice is considered an epidemic that continues to spread in Romania, leading towards an abuse of defensive medicine (for instance, any patient accusing chest pain has the chance to get a coronary angiography or CT scan even if a chest X-ray shows pneumonia). Physicians and patients should also be warned that exploitation of malpractice may retard adequate treatment and impair patient safety. Public and media should also be made aware that there are many reasons for unfavourable outcomes in medical practice, reasons detailed in statistics, not all of which related to negligence from a healthcare provider. The other side of the coin is reflected in the fact that physicians with more expensive treatment patterns experience fewer lawsuits, providing some justification for defensive medicine tactics.

Regarding cardiovascular surgery, from the perspective of defensive medicine and the consequent medico-legal problems, three key aspects have to be evaluated: indication, timing, and technique used.

Lastly, what must be acknowledged is the fact that among physicians, some degree of defensive medicine will always exist, as long as malpractice risks shadow the doctors' every footstep.

References

1. Bal B. An Introduction to Medical Malpractice in the United States. Clinical Orthopaedics and Related Research. 2008;467(2):339-347.
2. Kessler D. Evaluating the Medical Malpractice System and Options for Reform. Journal of Economic Perspectives. 2011;25(2):93-110.
3. Butler ME. Bill aims to make Florida a friendlier place to practice medicine. Tampa Bay Times. 18.05.2011.
4. De Ville K. Act First and Look Up the Law Afterward?: Medical Malpractice and the Ethics of Defensive Medicine. Theor Med Bioeth. 1998;19(6):569-589.
5. http://www.oxfordlearnersdictionaries.com/definition/english/defensive-medicine?q=defensive+medicine.
6. US Congress Office of Technology Assessment, Defensive Medicine and Medical Malpractice. OTA-H.602, US Government Printing Office, Washington, DC, USA, 1994.
7. Medscape Ethics Report 2014. http://www.medscape.com/features/slideshow/public/ethics2014-part1.

8. Rothberg M, Class J, Bishop T, Friderici J, Kleppel R, Lindenauer P. The Cost of Defensive Medicine on 3 Hospital Medicine Services. JAMA Internal Medicine. 2014;174(11):1867-1868.
9. Hermer L, Brody H. Defensive Medicine, Cost Containment, and Reform. Journal of General Internal Medicine. 2010;25(5):470-473.
10. Toraldo D, Vergari U, Toraldo M. Medical malpractice, defensive medicine and role of the "media" in Italy. Multidisciplinary Respiratory Medicine. 2015;10(1):12.
11. Sekhar M, Vyas N. Defensive medicine: A bane to healthcare. Annals of Medical and Health Sciences Research. 2013;3(2):295-296.
12. Ulmeanu R. Medicina defensiva afecteaza atat pacientii cat si medicii. http://www.sanatateatv.ro/stiri-medicale/prof-univ-dr-ruxandra-ulmeanu-medicina-defensiva-afecteaza-atat-pacientii-cat-si-medicii/
13. *** LEGE nr.95 din 14 aprilie 2006 privind reforma în domeniul sănătății. http://www.cdep.ro/pls/legis/legis_pck.htp_act_text?idt=72105
14. Nahed B, Babu M, Smith T, Heary R. Malpractice Liability and Defensive Medicine: A National Survey of Neurosurgeons. PLoS ONE. 2012;7(6):e39237.
15. Mello M, Chandra A, Gawande A, Studdert D. National Costs of The Medical Liability System. Health Affairs. 2010;29(9):1569-1577.
16. Rubin RMendelson D. How much does defensive medicine cost?. J Am Health Policy. 1994;4(4):7-15.
17. Baicker K, Fisher E, Chandra A. Malpractice Liability Costs And The Practice Of Medicine In The Medicare Program. Health Affairs. 2007;26(3):841-852.
18. Jena A, Seabury S, Lakdawalla D, Chandra A. Malpractice Risk According to Physician Specialty. New England Journal of Medicine. 2011;365(7):629-636.
19. Genovese U, Amato S, Del Sordo S, Mobilia F, Casali M. Defensive medicine and outcomes for medical malpractice liability. Ig Sanita Pubbl. 2014;70(2):235-246.
20. He A. The doctor–patient relationship, defensive medicine and overprescription in Chinese public hospitals: Evidence from a cross-sectional survey in Shenzhen city. Social Science & Medicine. 2014;123:64-71.
21. *** In primele doua luni ale anului, 600 de medici au plecat sa munceasca in strainatate. http://www.formare-continua.ro/index.php/informaii-utile/stiri-medicale/4949-in-primele-doua-luni-ale-anului-600-de-medici-au-plecat-sa-munceasca-in-strainatate
22. *** România are datorii de peste 192 de milioane de euro la spitalele din străinătate. TOPUL RESTANȚELOR în UE. http://www.gandul.info/stiri/romania-are-datorii-de-peste-192-de-milioane-de-euro-la-spitalele-din-strainatate-topul-restantelor-in-ue-12090809
23. HG nr. 304/2014 - aprobarea Normelor metodologice privind asistenta medicala transfrontaliera. http://www.avocatnet.ro/content/articles/id_37164/HG-nr-304-2014-aprobarea-Normelor-metodologice-privind-asistenta-medicala-transfrontaliera.html