Quality in health service/Kakovost v zdravstvu

»CRIME AND PUNISHMENT« IN THE MENOPAUSAL HEALTH CARE

»ZLOČIN IN KAZEN« PRI VAROVANJU ZDRAVJA V MENOPAVZNEM OBDOBJU

Ivan Fistonić,[1] Petar Lozo,[2] Marina Fistonić[3]

[1] RIM Ob/Gyn Office, Preradovićeva 10, 10000 Zagreb, Croatia
[2] Poliklinika Lozo, Miroslava Krleže 5, 23000 Zadar, Croatia
[3] University Department of Psychiatry, KB Dubrava, Av. G. Šuška 6, 10000 Zagreb, Croatia

Abstract

Background *In the past thirty years, there has been a significant rise of public and private health institutions' interest in the prediction and management of medical risks. The need of risk management is a direct consequence of the growing number of legal actions against medical malpractice.*
The concept of risk management involves three basic processes: risk identification, risk analysis, and risk management. Risk includes an evaluation of vulnerability and management of events that could potentially endanger the operation of a health institution, comprising a balance between the consequential costs of medical malpractice and the costs of risk reduction (anticipation). Thus the potential financial consequences of risk exposure are crucial in the formation of diagnostic and treatment protocols, whereas improvement of the quality of medical care as well as patient protection are the primary aims of risk management.

Conclusions *Postmenopausal health care is not an exempt when considering possible erorrs in medication or medical process per se. On the orther hand menopausal medicine is not only hormonal replacement therapy but also bunch of complementary and alternative specialities involved in the healing process where error could be easily achieved.*

Key words *medical error; menopause; risk management*

Izvleček

Izhodišča *V zadnjih 30 letih se je pomembno povečalo zanimanje tako javnih kot zasebnih zdravstvenih ustanov za napovedovanje zdravniških tveganj in ravnanje z njimi. Potreba po smernicah za ravnanje s tveganji je neposredna posledica povečanega števila tožb zaradi zdravniške napake.*
Koncept ravnanja s tveganji zajema tri osnovne postopke: identificiranje tveganja, analizo tveganja in ravnanje s tveganjem. Tveganje pa vključuje oceno občutljivosti in ravnanja ob dogodkih, ki bi morda lahko ogrozili delovanje zdravstvene ustanove, skupaj z ravnotežjem med posledičnimi stroški zaradi zdravniške napake in stroški za zmanjšanje tveganja (predvidevanje). Tako so možne finančne posledice zaradi izpostavljanja tveganju ključnega pomena pri oblikovanju diagnostičnih protokolov in protokolov zdravljenja na eni strani, na drugi pa sta izboljšana kakovost zdravstvenega varstva kakor tudi varovanje bolnikov primarna cilja ravnanja s tveganji.

Zaključki *Varovanje pomenopavznega zdravja ne izključuje možnosti za napake pri uporabi zdravil ali zdravniške oskrbe kot take. Po drugi strani pa menopavzna medicina ne pomeni samo hormonskega nadomestnega zdravljenja, ampak tudi celo vrsto dodatnih in alternativnih specialnih strok, ki so vključene v proces zdravljenja, kjer zlahka pride do napake.*

Ključne besede *zdravniška napaka; menopavza; tvegana obravnava*

Avtor za dopisovanje / Corresponding author:
Ivan Fistonić, RIM Ob/Gyn Office, Preradovićeva 10, 10000 Zagreb, Croatia

The risk of adverse events in medical processes is associated with the seriousness of the disease, the age of the patient, and the level of emergency, and it is negatively correlated with the skill and experience of the physician. However, it is a paradoxical fact that the number of complaints regarding adverse effects is considerably lower in the fields of oncology and medical emergencies as compared to complaints in relation to routine procedures with an expected favourable outcome.

Elaborated and tested risk management systems come from North America, where they have been part of the standard healthcare networks for more than 25 years.[1] In Europe, such standards have been developing only since the 90s. In Great Britain, for instance, the first trusts dealing with risks and the consequences of legal actions against medical malpractice were established in 1991. Until then damages in such cases had been awarded either the Regional Health Authority Funds or from the National Health Service (NHS) funds. Since 1995, with the establishment of the Clinical Negligence Scheme for Trusts (CNST), a system for risk monitoring, analysis and management in medicine with the validity of a legal act, the monitoring of all risk factors according to the agreed scheme has been mandatory.

According to NHS estimates, the number of malpractice suits rose from 500 in 1975 to 6,000 in 1992.[2] Damages awarded from NHS funds amounted to £1,000,000 in 1975, £200,000,000 in 1996, and £500,000,000 in 2001. Ongoing legal actions involve £ 1–2 billion.[3] More than 50% of the financial burden are claims associated with instances of malpractice in obstetrics, followed by suits regarding gynaecological, emergency medicine and orthopaedic malpractice (cosmetic surgery being an individual category outside the NHS system).

A report from the National Patient Safety Agency (NPSA)[3] found a significant rise in the number of medical errors. Namely, the number of medication errors reported to the NHS has more than doubled in two years. In 2005, 36,335 incidents were reported, rising to 64,678 in 2006 and 86,085 in 2007. A total of 96% of these incidents resulted in low or no harm to patients, but 100 resulted in serious harm or death. The most exponent reasons of malmedication were the wrong dose, medicines being missed or delayed, the wrong drug, the wrong quantity, and mismatching.

One of the first studies stressing malpractice in medicine, a Harvard study[4] from the US, mentions 4% of hospitalisations in the state of New York being a result of adverse events (unintentional consequences of medical treatment). Out of these, 70% were short-term events without serious consequences, but 7% of the patients suffered permanent consequences (1% of all hospitalised patients). Studies conducted in Utah and Colorado[5] showed similar findings, as well as an Australian study, which reports 16.6% hospitalisations due to adverse events related to treatment (half of which were preventive tratments).[6] A British pilot study reports approximately 850,000 adverse events out of 8,500,000 annual hospitalisations (10%).[67]The examples of differences in the estimation of adverse events related to medical treatment necessitate further prospection and the design of uniform malpractice evaluation protocols.

It is difficult to estimate the financial burden of funds designed to cover medical malpractice claims. However, a surgical procedure resulting in an adverse event involves at least an additional operation, longer hospitalisation, longer clinical care, follow-up visits, etc. In Britain it has been estimated that each adverse event results in additional 8 days of hospitalisation, i.e. an additional annual cost of £2 billion.[7] Moreover, adverse events in medicine involve deep personal traumas. The patient suffers additional pain, disability, psychological stress which continues through the legal process, etc. The medical staff is also subject to psychological consequences, feelings of guilt and shame due to the mistake committed, with depression continuing well into the litigation process.

Investigation and analysis of clinical incidents

Excellent incident identification and analysis forms have long been in use in high-risk professions (aviation, nuclear and oil industries, etc.), and are the main promoters of safety intitiatives.[8] The expression »human factor« commonly appears when the causes of large-scale disasters are investigated, but a rash pointing towards someone's »fault« often hides a much more complex truth. Therefore, the identification of an obvious deviation from a prescribed form is only the immediate cause of the incident, whereas a more thorough analysis usually reveals a whole sequence of interactive events originating from an inadequate working environment or a wider organisational context. The understanding of the causality of events leading to the adversity by means of the above-mentioned comprehensive approach is increasingly used in practice when investigating and analysing medical incidents. The roots of the immediate causes of adverse events are often found in bad communication and inadequate supervision, exhaustion from working overtime, badly organised on-call duties, inadequate and superficial training, insufficient experience, etc.[9]

A comprehensive and functional protocol is an idispensable factor in the analysis of clinical incidents. It must foresee the possibility of evaluation of a considerable number of events leading to the adversity. The first step should be the identification of problems which can arise in the process of medical care (wrong estimation, skipping steps on the algorithm scale, a liberal approach to common practice, proceedings, or standards, etc.). With every identified problem, the investigator records concomitant events and the patient's condition (e.g. heavy bleeding, a drop in blood pressure), along with other possible factors that may affect the medical care process (the patient's distress at being unable to follow instructions). Finally, organisational circumstances which may cause malpractice are recorded and evaluated. Therefore every investigational protocol should estimate: all individual factors (e.g. insufficient knowledge or experience); the course of medical proceedings (e.g. the lack or inadequacy of

protocols for specific situations); the harmonisation within the medical team (e.g. bad communication among the staff); the working environment (e.g. overwork, staff shortages, unavailable equipment).[10]

Apology for medical error

Regrets and apologies due to medical errors remove the sting from most cases, and eliminate the anger that pushes most patients and families to file a medical malpractice lawsuit. If a lawsuit is still initiated, these apologies make of or a great defense because it is hard for a plaintiff's attorney to make a jury/judge angry at a physician/hospital who tried to do the right thing, including offering fair compensation[11].

In 2002, the University of Michigan Health System launched a program with three components: acknowledge cases in which a patient was hurt because of medical error and compensate these patients quickly and fairly; aggressively defend cases that the hospital considers to be without merit; and study all adverse events to determine how procedures could be improved.[12] Before August 2001, the organization had approximately 260 claims and lawsuits pending at any given time. As of August 2005, the number had dropped to 114. The average time from the filing of a claim to its resolution was reduced from approximately 21 months to less than 10 months. Annual litigation costs dropped from about $3 million to $1 million. The health care system has begun to reinvest these savings in the automation of its patient-safety reporting systems. Since the implementation of this program, the University of Michigan Health System has expanded the number of practicing clinicians and faculty members in high-risk fields such as obstetrics–gynaecology and neurosurgery.

The policy of extreme honesty, practiced since the late 1980s, has reported reduced lawsuits and settlement and defense costs. Only three cases have gone to trial in 17 years, with the average settlement being $ 16,000, compared with the national average of $ 98,000.

Risk management in gynaecology and obstetrics

Proportionally, the largest numbers of malpractice suits occur in the fields of gynaecology and obstetrics.[13]

In gynaecology, most complaints are associated with family planning, abortion and sterilisation. Patients suffering from malignomas initiate litigation less frequently since their expectations are minimal, whereas complaints are more commonly filed by patients whose malignancy was diagnosed as a result of a screening procedure. Hysterectomy, commonly performed for trivial reasons that are not life-threatening, may result in adversities like ureteral lesions or lesions of the urinary bladder, as well as healing by second intention, which may cause surprise and disappointment. Recently, adverse events resulting from minimally invasive surgical procedures have almost always raised doubts about the surgeon's skill and experience.

Obstetric practice involves a wide spectrum of situations which may result in damage to the child or mother. Perinatal asphyxia, shoulder dystocia, vaginal delivery after a previous Caesarean section, and anal sphincter lesions are the most frequent complaints resulting in legal action.

Problems associated with signed forms giving consent for obstetric procedures or operations present a separate category altogether. Unconscientious acts in obstetrics are usually associated with bad communication and delayed action with far-reaching consequences. In communicating with the patient, the physician too often relies only on the signed consent document. In fact, a signed generalized form is not proof enough that the procedure has been consented to by the patient. A pregnant woman or a woman in labour often does not understand or has not been adequately informed on a specific procedure; consequently, her consent, based on insufficient information about the risks involved, does not fully protect the obstetrician from responsibility in the case of malpractice.[14] The real expression of the doctor/patient relationship should lie in the patient's »choice«. Most gynaecological patients or pregnant women are young and fit, seeking routine pregnancy monitoring or lesser interventions for the purpose of life-quality improvement or fertility control. Therefore, a signed consent document should comprise the elements specific of the patient and treatment in question, thus ensuring that the patient's signature means that she has been given sufficient information on the benefits and risks involved, and making the decision regarding the procedure her choice. However, a patient may refuse a recommended course of treatment for any number of reasons; but patients who are unable to do so, or have limited communication abilities, should have the chance to obtain help according to established professional guidelines, regardless of the signed document. Therefore, a signed consent document obtained in the terminal stages of delivery or other urgent obstetric conditions is sometimes of little validity. Conditions such as umbilical cord prolapse, placental abruption, or heavy haemorrhage simply do not leave enough time for a detailed explanation of the required procedure, and a woman during delivery, affected by drugs or excruciating pain, cannot be considered competent to provide informed consent. Some of these situations may possibly be addresed in advance by better antenatal education and care.

In foreseeing and managing risks likely to arise in the delivery room, the mutual trust among the obstetrician, midwife and woman giving birth is of invaluable help. Time spent with the woman during the early stages of labour results in better communication, which can be the key in the process of understanding and accepting advice in emergencies.

Medical errors in menopausal medicine

Lawsuits in long-term care have increased signifficantly in past decades.[15] Therefore, the facilities and the healthcare providers who work in them need to

be aware of several important risk management strategies that can reduce their likelihood of being sued for medical malpractice. There are, however, several areas of practice where a limited amount of additional attention can substantially reduce the risk of being sued.

Recently, first compensations have been settled in the field of menopausal medicine. In the Reno case,[16] a state court jury found Prempro, a hormone-replacement drug (0.625 mg conjugated eqiune estrogens + 2.5 or 5 mg medroxyprogestrone acetate), contributed to the development of breast cancer in three postmenopausal patients. Indictor's lawyers argued that Wyeth officials concealed Prempro's health risks and failed to properly warn doctors and consumers about the drug's cancer link to boost profits. Wyeth's lawyers insisted the company conducted extensive safety tests on the drugs and warned of the risks through prescription labels and information sheets. The company has won two federal-court suits over Prempro as well one case filed in state court in Philadelphia since litigation over the drug began in August 2006. Three menopausal patients (aged 64–69) all used Wyeth's hormone replacement therapy for different lengths of times, according to court records (7 to 15 years). Jurors awarded plaintiffs a total of $47.5 million, $43.5 million and $43.5 million, respectively, in compensatory damages.

The three women's suits, which were combined for trial, are among about 5,300 against Wyeth over its menopause drugs, which include Prempro and Premarin (0.625 CEE). As many as 6 million women took the pills to treat menopause symptoms such as hot flashes and mood swings before a 2002 WHI study highlighted their possible links to cancer.

More than a half of women claim that they had been not properly informed, consulting their health providers about menopause and HRT.[17] Most of information arises from media, not the doctor, inducing confusion and misunderstanding that lead to poor compliance with possible improper administration or adverse event.

Obligation of health provider is to inform correctly the patient of all possible benefits and risks, as HRT is not exempt of secondary effects. Favourable communication between patient and doctor is a key for better understanding and confidentional relationship involving the woman in decision-making process.[18] This series of interactive processes, utilizing proper time and location, will minimize confusion and reduce the prevalence of lawsuits.

Although risk management is generally perceived by clinicians, it should be a part of any professional approach to the patient. Neglecting notorious medical procedure (proper medical history, symptom judgment and examination) leads to false diagnosis, where time spent for consultation is crucial while physicians' interest in menopause critically influence the patients' comprehention and adherence to therapy. Extended medical consultation promotes better compliance through lowering patient fears and dilemmas. Patients and their family members frequently cite poor communication with their healthcare provider as a primary reason they decide to sue.

Inadequate approach includes failing to screen or treat an at-risk woman, inadequate monitoring of longterm therapy and improper follow-up arrangements. Not all women with postmenopausal health problems are suitable for management in a general ob/gyn primary care, and it will be sometimes necessary to refer women with complicated histories to a consultant of other speciallity (mammologist, rheumatologist, cardiologist, etc.)

Important fact is that a full discussion of risks, benefits and alternatives takes place when any intervention is offered. This is especially important in menopausal medicine, where the adverse publicity and bombastic affairs constantly covers front pages, shifting the scientific evidence to tabloid simplification. Therefore, informed consent should be important part od counselling, facilitated by the provision of oral and written information for patients. The discussion should be documented, and the option of writing to the woman with a summary of the discussion could be considered. Simple signed statement, if even ubiquitary in setting, such as »understands benefits and risks of HRT« is unsatisfactory. Informed consent should cover all the generally announced pros and cons towards hormonal replacement therapy. Good communication and well projected consent reduces malpractice cases.[19]

Medical professionals prescribing HRT should aspire to safe practice using guidance from the the menopause covering literature.[20]

Appendix: Risk management in medicine in the Republic of Croatia

Medical risk management in the Republic of Croatia[21] developed under the influence of the same mechanisms affecting western countries in the eighties. In our country, too, the growing number of malpractice suits has been the main impetus for the organisation of a risk management system. For the time being, only analytic mechanisms exist. Although investigational committees for adverse events following medical treatments have been established at all major institutions, they act only locally. The Croatian Institute for Health Insurance has no authority for risk management. In some instances of alleged malpractice, ad hoc committees may be formed by the Ministry of Health of the Republic of Croatia. Nevertheless, action in the sense of risk prevention and management, even if existent, is neither uniform and systematically coordinated, nor implemented on the lines of standardised protocols. The core of a future system has been outlined by the malpractice insurance, used since the mid-90s mainly by physicians within private healthcare institutions. In the academic year 2003/04, the Andrija Štampar School of Public Health introduced the course »Risk Management in Healthcare« as part of the graduate curriculum.

Conclusions

There is no doubt that progress in the understanding of the necessity for risk management has been

stimulated by the crisis in legal actions due to medical malpractice. By improving communication between health professionals, patients and their families, archiving good medical documentation, perceiving medical hazards and extending time of medical consultations better compliance and fewer lawsuits will be possible. The system and process of risk management in healthcare will reach full maturity only when it lets go of its original fear of financial repercussions, and starts to aim efforts towards the safety and health of the patients. The goal of contemporary menopausal medicine is not only to prescribe hormonal replacement therapy but also to suggest prospective algorithms for risk control, stressing the communication, in order to reduce errors in medical process.

References

1. Walshe KMJ. The development of clinical risk management. In: Vincent CA, ed. Clinical risk management. 2nd ed. London: BMJ Publications; 2001.
2. Dingwall R, Fenn P. Risk managment: financial implications. In: Vincent CA, ed. Clinical risk management. London: BMJ Publications; 1995. p. 73–87.
3. National Patient Safety Agency Report 2009. Tackling medication incidents and increasing patient safety. Dosegljivo na: http://www.nrls.npsa.nhs.uk/corporate/news/tackling-medication-incidents-and-increasing-patient-safety/
4. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG at al. Incidence of adverse events and negligence in hospitalized patients. New Engl J Med 1991; 324: 370–6.
5. Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. Med Care 2000; 38: 261–71.
6. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The quality in Australian Health Care Study. Med J Aust 1995; 163: 458–71.
7. Department of Health. An Organisation with a Memory. Report of an Expert Group on Learning from Adverse Events in the NHS. London: The Stationery Office; 2000.
8. Wilf-Miron R, Lewenhoff I, Benyamini Z, Aviram A. From aviation to medicine: applying concepts of aviation safety to risk management in ambulatory care. Qual Saf Health Care 2003; 12: 35–9.
9. Tighe CM, Woloshynowych M, Brown R, Wears B, Vincent C. Incident reporting in one UK accident and emergency department. Accid Emerg Nurs 2006; 14: 27–37.
10. Vincent CA. How to investigate and analyze clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management Protocol. BMJ 2000; 320: 777–81.
11. Robbennolt JK. Apologies and medical error. Orthop Relat Res 2009; 467: 376–82.
12. Clinton HR, Obama B. Making patient safety the centerpiece of medical liability reform. N Engl J Med 2006; 354: 2205–8.
13. Fenn P, Gray A, Rickman N. Liability, insurance and medical practice. J Health Econ 2007; 26: 1057–70.
14. Francis R. Consent. In: Clements RV, ed. Risk Management and Litigationin Obstetrics and Gynaecology. London: The Royal Society of Medicine Press; 2001.
15. Stevenson DG, Studdert DM. The rise of nursing home litigation: Findings from a national survey of attorneys. Health Aff (Millwood) 2003; 22: 219–29.
16. Rowatt A, Scofield J, Forrester P. Case Rowatt v. Wyeth Pharmaceuticals Inc., 04-01699, Second Judicial District Court, State of Nevada, Washoe County (Reno), 2006.
17. Edozien LC. Risk management issues in postmenopausal health care. Menopause Int 2007; 13: 144–7.
18. Clinkingbeard C, Minton BA, Davis J, McDermott K. Women's knowledge about menopause, hormone replacement therapy (HRT), and interactions with healthcare providers: an exploratory study. J Womens Health Gend Based Med 1999; 8: 1097–102.
19. Palacios S. The awareness of the menopausal woman concerning the menopausal transition. In: Lauritzen C, Studd J, eds. Current Management of the Menopause. London: Taylor & Francis; 2005. p. 43–9.
20. Panting G. Medicolegal pitfalls of prescribing hormone replacement therapy. J Br Menopause Soc 2006; 12: 34–5.
21. Fistonic I. Personal communication. 2008–2009.

Arrived 2009-09-03, accepted 2009-10-01