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Analysis of adverse events concerning gynecological and obstetric patients

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SUMMARY

Introduction. The dynamic development of medical sciences, growing awareness of patients' rights and increasing influence of the media on the public opinion are potential sources of greater patient–physician tension.
Aim. The article is aimed at evaluating the significance of the problem and, after a detailed analysis of complaints from 20 years, formulating guidelines which might be useful for reducing the number of adverse events and their consequences in the field of gynecology and obstetrics.
Material and methods. The material used for the study was the data from 296 proceedings related to complaints about adverse events occurring in patients of outpatient healthcare centers and gynecology/obstetrics hospital departments in the years 1994–2014, selected out of 4,565 complaints in these areas.
Results. The analysis demonstrated a growth in the number of complaints filed to the Regional Spokesperson for Professional Liability of Physicians (RSPLP) and an increasing rate of complaints related to gynecology and obstetrics, which was, however, characterized by a simultaneous decrease in their justifiability. In total, only 8.2% of the complaints were considered justified. The majority of the complaints concerned events taking place at the beginning of the week, but their rate of justifiability was the lowest. The complaints concerned usually events occurring in the afternoon or at night.
Conclusions. It seems justified to introduce standard procedures using evidence-based medicine and an efficient obstetric data collection system, which should delimit the overlapping competences of physicians and midwives caring for the patient in the peri-delivery period. It seems justified to introduce examinations to check psychological predispositions of candidates to medical studies and trainings in stress management at work. It would be advisable to implement a system of mediation and maintaining contact of physicians and hospital representatives with patients and their families. It would also be helpful to introduce generally accessible information in healthcare centers, and to educate patients. Also, the introduction of work organization and staff-related solutions eliminating fatigue and discouragement seems to be reasonable.
Key words: medical error; gynecology; obstetrics; patients' rights; cesarean section; professional liability

INTRODUCTION

In common understanding, an adverse event (AE) equates a medical error. Neither notion is defined in legal codices [1]. In accordance with generally accepted definitions, an adverse event is any undesirable and unexpected event which was or could be the cause of damage to one or more patients receiving medical care. An adverse event means damage caused during treatment or being an effect of treatment, but, at the same time, having no relationship with the natural course of the disease or medical condition of the patient [2].

This term includes also medical errors, the responsibility for which lies not only on service providers, but also on a healthcare center functioning in a specific healthcare system. The notion of an adverse event indicates that it does not necessarily result from the fault of one or more people, but also from the imperfection of some elements of the system.

The need of increasing patients' safety and prevention of adverse events in healthcare is

pronounced by the documents of the World Health Organization (WHO), the Council of Europe and the European Union (EU). For example, they state that:

- the problem of adverse events has been reported as an important factor causing failures in medical care and increasing healthcare costs, which was published in the WHO resolution from 2002. The Member States were obliged to become aware of the scale of the problem, which may have a significant impact on their healthcare policy, and to introduce appropriate preventive measures. Moreover, the WHO initiated the World Alliance for Patient Safety [3].
- in the Luxembourg Declaration of Patient Safety of 5th April 2005, the European Commission (EC) for the first time presented practical activities aimed at increasing patient safety. Simultaneously, the EC emphasized the need for implementation of these activities in everyday practice and more efficient proceedings in the case of errors.
- the document called „Patient safety as a European challenge" signed in Warsaw on 15th April 2005 declares the need for development of appropriate programs on the national and international level.
- the Council of Europe (2006) recommendation emphasizes the need for improved patient safety and prevention of adverse events. This document contains elements concerning both the healthcare policy and medical practice.
- the recommendation of the Patient Safety and Quality of Care Working Group for the High Level Group on Health Services and Medical Care of the EC (2007) concerns the improvement of EU patient safety.
- the EU Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare-associated infections indicates that insufficient safety level is a serious health issue and a significant financial burden in the case of limited funds for healthcare. In some countries, activities aimed at registering adverse events as part of healthcare quality improvement programs have been given an adequate statutory and financial support. In Poland, these issues are regulated by the Act on Accreditation in Healthcare of 6th November 2008 [4].

As it can be concluded from the aforementioned documents, the way of understanding AEs is crucial from the perspective of designing prevention systems in healthcare. Adverse events are an omnipresent element of treatment and therapy. However, each state should individually undertake all steps and implement all procedures aimed at the minimization of their occurrence, and especially their repeatability.

The causes of adverse events related to physicians or other medical staff may be observed mainly in the complexity of treatment procedures, existence of hidden problems in the system as well as the lack of proportion between the progress in medical technology and opportunities for systematic training for physicians and other medical staff. On the other hand, individual human factors contributing to the occurrence of these events include general imperfections of human nature, such as committing errors during simple activities, health and fitness of the physician, cognitive errors, particular traits of personality and behavior [5].

AIM

The article is aimed at evaluating the significance of the problem and, after the detailed analysis of complaints from 20 years, formulating guidelines which might be useful for reducing the number of adverse events and their consequences in the field of gynecology and obstetrics.

MATERIAL AND METHOD

In relation to the increasing patient–physician tension and quick development of medical sciences, it seems necessary to introduce new solutions aimed at prevention of adverse events in gynecology and obstetrics and mitigation of their effects, for both patients and medical personnel. The article evaluates the significance of the problem and formulates guidelines which may contribute to a reduction of the number of adverse events and their consequences.

The material used for the study comprised data concerning adverse events in patients of outpatient healthcare centers and gynecology and obstetrics hospital departments in the years 1994–2014. These were archival data with final and binding decisions of the Regional Spokesperson for Professional Liability of Physicians (RSPLP), archival cases that, by the RSPLP's decision, were referred to court with a motion for punishment as well as reports of the RSPLP. In the years 1994–2014, the RSPLP

received 296 complaints related to gynecology and obstetrics, 205 of which were subjected to a more detailed analysis, while the rest was referred by the RSPLP to other competent institutions. The study involved the analysis of the most important factors of each adverse event, its participants and consequences.

RESULTS

Using the demographic data published by the Central Statistical Office of Poland for the years 2002–2013 (as of 31st December), the authors calculated the ratio of complaints related to gynecology and obstetrics to the whole population of women living in the Silesian Province (Fig. 1).

It was observed that in the years 1994–2014 the number of complaints made to the RSPLP in relation to all medical disciplines systematically increased. The greatest number of complaints was reported in 2013 (Fig. 2). The observed trend was statistically significant (R=0.709 p=0.0002). The frequency of complaints related to gynecology and obstetrics made to the RSPLP in the years 1994–2014 in relation to all complaints made to this institution is presented in Fig. 3 and 4.

In the analyzed period, an increase in the number of complaints related to gynecology and obstetrics was observed. The trend was statistically significant (R=0.726 p=0.0002). The ratio of complaints related to gynecology and obstetrics to complaints in all medical disciplines also exhibited a statistically significant growing trend. It is worth adding that in the years 1994–2000 the RSPLP did not refuse to start investigation in any case related to this medical discipline (Fig. 5). However, in the years 2001–2013 a significant downward trend in the number of initiated explanatory proceedings was observed (R=-0.715, p=0.0004).

The analysis of the ratio of complaints resolved by referral with a motion for punishment to the cases for which explanatory proceedings were initiated does not show in the years 1994–2013 any significant growing trend in the percentage of complaints resolved by a motion for punishment (R=0.085, p=0.7140).

In the sample of analyzed complaints related to gynecology and obstetrics, a minor prevalence of obstetric cases (n= 114) over the gynecological ones (n=91) was observed. The cases concerned breaches of the patients' rights (20.5%), death (19%) or perinatal injury of the fetus/newborn baby (19%), injury to the reproductive organs (18.5%), removal of the reproductive organs (7.8%), other peri-delivery injury of the patient (6.3%), death of the patient (3.4%), falsification of medical records (3.4%) and illegal abortion (1.5%).

Out of all reported complaints, almost one third applied to primary care hospitals (32.7%). One-fifth of the complaints concerned adverse events taking place in private medical practices (20%), and slightly smaller numbers of events happened in tertiary care (19%) and secondary care hospitals (16.6%). The cases related to

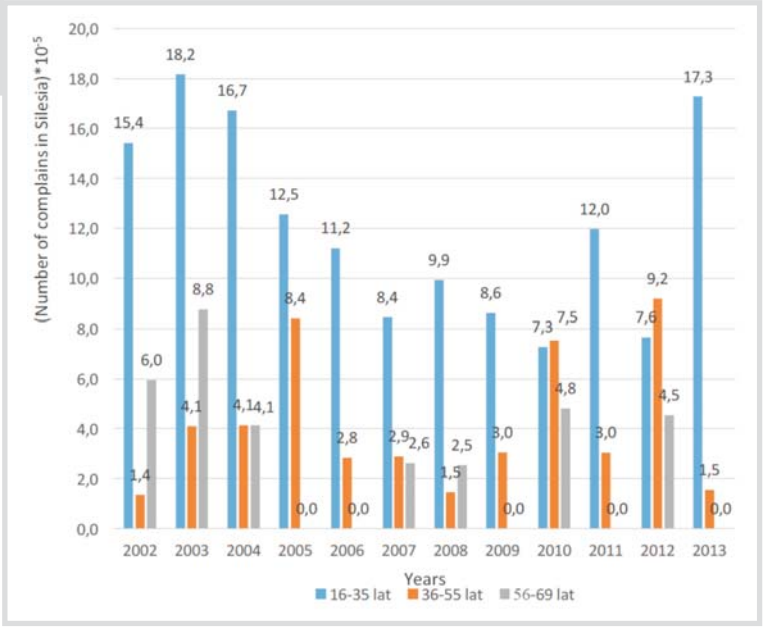

Fig. 1. The number of complaints in the population of women from Silesia in 2002–2013

private clinics, outpatient healthcare centers and emergency care stations were only a few percent of all complaints (4.9%, 3.9% and 2.9%, respectively). Every second complaint related to an event taking place in emergency care stations (50%) and every tenth complaint related to private medical practices were considered a medical error.

The number of justified cases slightly increased with the hospital referral grade. None of the complaints about events taking place in private clinics and outpatient healthcare centers was deemed justified.

The analysis of the days of the week on which the reported adverse events occurred showed that most complaints concerned events happening on Tuesdays (33.7%) followed by Mondays (18%) and Wednesdays (16.6%). Complaints concerning events from the second half of the week (Thursday and Friday) were a bit less frequent (12.2% each). Complaints related to events happening at the weekends were relatively the rarest (Saturday 5.4%, Sunday 2.0%). None of the complaints related to Monday was considered justified. The reported events happening from Tuesday to Friday were

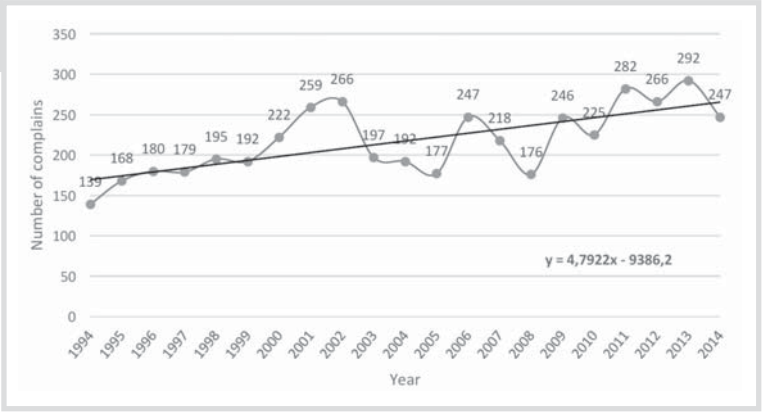

Fig. 2. The number of complaints in years 1994–2014

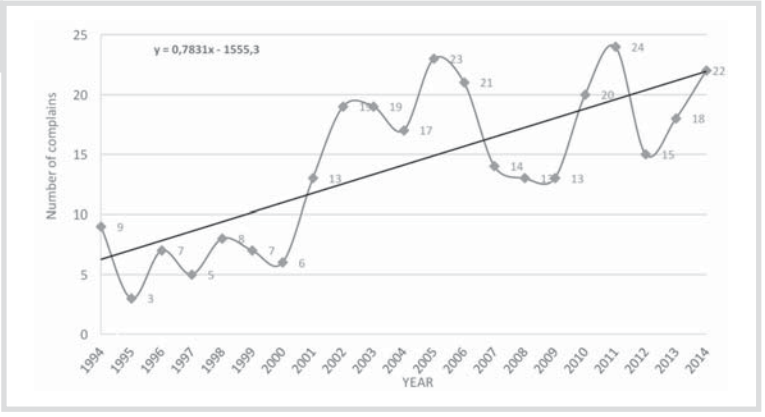

Fig. 3. The number of gynecological complaints in years 1994–2014

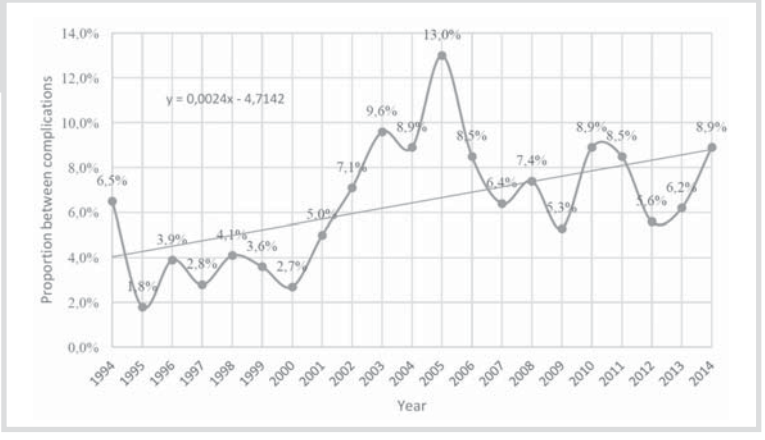

Fig. 4. The proportion between gynecological and all complaints in years 1994–2014

considered justified with variable frequency (from 4.8% to 22.7%) while the ratio of justified complaints about adverse events happening at the weekend was 21.4%.

It is also worth emphasizing that almost a half of the analyzed complaints concerned adverse events taking place at night (46.67%) while the lowest number of complaints (13.33%) was related to events occurring in the morning.

It was observed that in the years 1994–2013 there was a statistically significant growing trend in the number of complaints related to a breach of patients' rights (R=0.726, p=0.0002). Most frequently, these complaints concerned infringement of the right to intimacy and dignity (54.8%), right to access to medical records (16.7%) and confidentiality of the patient-related information (16.7%). The breach of the right to information was the cause of 11.9% of the complaints in question.

In the course of the proceedings concerning the complaints related to gynecology and obstetrics (including withdrawn complaints – 7.8%), a vast majority of them (81.5%) was dismissed as unfounded. The staff proved guilty was punished with a warning (5.8%), prohibition from the pursuit of the profession (1.0%) or a reprimand (0.5%). In 3.4% of the cases, the proceedings are in progress in a common court.

DISCUSSION

The analysis of the authors' own research and literature data [6,7] indicates that out of many medical disciplines burdened with the suspicion of a medical error, most cases concern procedural disciplines, including gynecology and obstetrics. The opinions of the Institute of Forensic Medicine of the Silesian Medical Academy (currently: Medical University of Silesia) evaluating the conduct of physicians indicate that gynecology and obstetrics is one of the medical disciplines with the highest rates of acknowledged medical errors [8]. The authors' own research showed a continuous growth of the number of complaints related to this discipline. This is confirmed by the results of the studies by Jaworski [9] and Zajdel [10]. The aforementioned growth is not characteristic of Poland, but is observable also in other European countries. Kaczmarek and Marcinkowski [11] compared Polish growth tendencies with the British ones. According to their studies, an average annual increase in the number of complaints in the UK is 17% while in Poland it is approximately 14%. The growth results mainly from failure to observe the patients' rights, for example by hindering access to medical procedures and medical records, and providing information about the health condition in a way not clear enough to the patient. Furthermore, Kaczmarek and Marcinkowski [11] observed that the main cause of making a complaint is the breach of the rules of the Medical Ethical Code by the physician. This has been shown also in this study.

Both the study and official decisions and rulings indicate that the number of cases related to evaluation of the correctness of the physician's conduct has been continuously growing in Poland in the recent years. The authors' own research indicates that the complaints are filed mostly by young women, in the age group 16–35, with higher education, which is probably related to their greater awareness and knowledge of their rights as patients. On the other hand, the increase in the number of complaints is clearly related to the growing

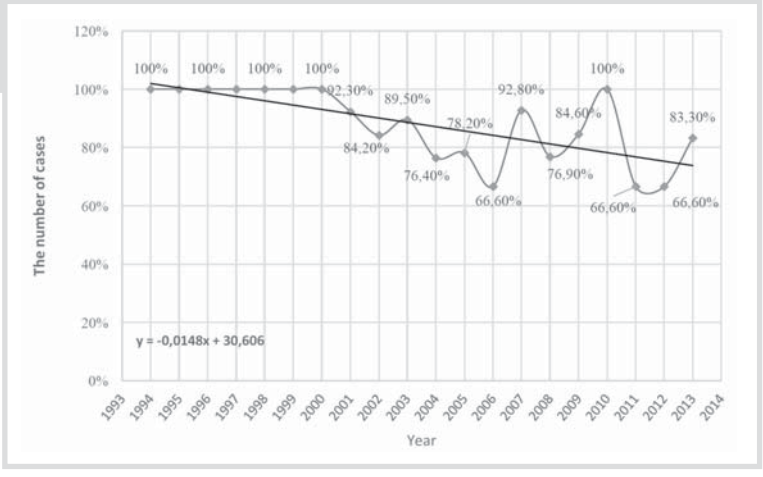

Fig. 5. The number of gynecological complaints and the number of cases in years 1994–2014

dissatisfaction of patients with the solutions introduced in the healthcare system.

Chowaniec et al. [8] explain that excessive and unjustified complaints about physicians stem from the inability to distinguish between a treatment failure (and the consequent lack of an expected therapeutic effect) and a medical error, which is overused in the media that make premature accusations. The present study confirms such an assumption because as much as 91.7% out of 205 cases of complaints related to gynecology and obstetrics, which were selected for extensive analysis, were unjustified. Nasiłowski [12] suggests that outside the group of forensic medicine specialists, the term „*medical error*" is misunderstood. This applies both to patients and their relatives, and situations when the patient could not be cured or when complications limited the expected therapeutic effect.

In the years 1994–1997 and in the year 1999, no case was resolved by filing a motion for punishment to the Office of Professional Medical Conduct of the Silesian Region. The highest number of such motions was observed in the years 2002–2003 and 2006–2007. This goes in line with the results obtained by Kordel [13] in a study conducted on the basis of the cases of the Main Office of Professional Medical Conduct in which the largest numbers of motions were also filed in the years 2003 and 2006.

The literature review suggests that errors made in gynecological and obstetric procedures have various negative effects on health or life of patients, and that such situations are not rare, either in Poland or worldwide. Podciechowski et al. [14] estimate that every year in the USA more people die in hospitals due to negligence of medical staff than due to accidents (road and air accidents) or due to suicide, drowning and poisoning.

In 2009, the Polish National Health Fund financed about 8.3 million hospitalizations. Statistical studies conducted in this period showed that a medical error occurred in every tenth hospitalization, which means that the estimated number of events adverse to patients is very high and significantly exceeds the numbers reported to the RSPLP. According to Sandauera [15], out of 500 analyzed cases directed to the «Primum Non Nocere» Patients' Associations, approx. 80% were initially deemed justified. However, it must be taken into account that the lack of statutory obligation to monitor medical errors makes the actual number of errors unknown. According to various sources, every year in Poland there may be from several thousand up to 20 thousand adverse events. The authors' own research showed that among all complaints related to gynecology and obstetrics there were more cases concerning obstetrics than gynecology. This is similar to the results obtained by Chowaniec et al. [8].

The authors' own research showed that 54.8% of the complaints concerned the lack of respect to the intimacy and dignity of the patients. The vast majority of complaints (81.5%) related to gynecology and obstetrics (including withdrawn complaints – 7.8%) were dismissed as unfounded. The staff proved guilty was punished with a warning, prohibition from the pursuit of the profession or a reprimand. In a small percent of cases, common court proceedings are in progress. Kordel [13] indicated that the rulings are most frequently revoked (in 28.6% of all cases), and a warning is the most frequent form of punishment.

Proving a medical error to a physician or other medical staff is not easy, therefore imposing punishment is not a frequent phenomenon. It was repeatedly suggested that this may be an evidence for the unhealthy „solidarity" of physicians and the indifference of the medical environment to patients' problems. However, as it has been mentioned earlier in this article, also the correct understanding of a medical error or an adverse event should be taken into account.

The results of the authors' own research showed that the number of complaints related to gynecology and obstetrics differs depending on the location where the adverse event took place. The complaints were related mostly to public centers of low referral grade. None of the complaints about events taking place in private clinics and outpatient healthcare centers was deemed justified. This goes in line with the analyses of service quality in public and private healthcare. It is in specialist and private hospitals, and not in primary care hospitals, where we encounter an individual approach to the patient, which increases service quality and lowers the number of errors [16]. Kordel presents the results in a bit different way [13]. However, his analysis also proves that more errors are committed by physicians working in public healthcare centers.

Our study involved the analysis of the relationship between the number of complaints related to gynecology and obstetrics and the day of the week when the adverse event happened. The complaints related to events occurring on

the first days of the week constituted a majority of all analyzed complaints. Complaints related to events taking place in the second half of the week were a bit less frequent, while those related to events occurring at the weekends were the rarest. These results go in line with the studies which confirmed that most errors are made from Monday to Friday (86.8%) [17]. According to the structure of complaint classification, on weekdays patients have worse contact with the physician, which may make them feel treated in an automatic and impersonal way, without respect for their intimacy (often students are present during the examination) and are more prone to accuse the physician of „callousness and malice."

However, the results of the study conducted at the Medical University of Silesia are different, as 90% of adverse events from 88 analyzed cases took place during the weekends and holidays [8]. Probably, this applies to medical errors which were deemed justified, which are described in the following paragraph. The results of the analysis of the relationship between the number of complaints related to gynecological and obstetric events acknowledged as medical errors and the day of the week on which the event happened showed that no complaint related to an event happening on Monday was deemed justified. The complaints related to the events happening between Tuesday and Friday were deemed justified with variable frequency, while those related to the weekends were deemed justified in 21.4% of cases. The higher rate of justified complaints related to weekends may correspond to a growth in actually committed medical errors in this period. This is most probably caused by less experience of physicians on duty (often younger ones), worse diagnostic and therapeutic capabilities, difficulty in performing consultations and cooperation with other specialists as well as a lower number of medical and nursing staff.

The studies also show that the time of the day has an impact on the number of committed errors. Almost a half (46.67%) of the analyzed complaints concerned events taking place at night. The afternoons and evenings corresponded to 20% of complaints each. The smallest number of complaints concerned events taking place in the morning. This shows that fewer errors are committed during scheduled procedures and when the physician is not overworked or tired. The study by Landrigan et al. [18] confirms that by proving that the majority of medical errors are a result of the lack of sleep.

Using foreign experiences may be useful for reducing the number of complaints by limiting the number of committed errors. Currently, the USA focuses on appropriate self-reporting of mistakes [19]. Every physician in a clinic should participate in regular meetings devoted to transmission of data about patients. Thanks to these meetings, physicians are more aware of the obstacles in ensuring appropriate care and therapy, as well as committed management errors. American authors indicate that such meetings are not burdensome and make younger, less experienced physicians cope better with critical situations they are exposed to [19]. Since 1999, the American Institute of Medicine (IOM) has focused on medical errors and adverse events because they take place quite frequently but are rarely reported, and above all they are not discussed with patients and their relatives. In the USA, the prevention of medical errors is also emphasized by universities. For example, the American College of Obstetricians and Gynecologists (ACOG) [20] stresses its long-term engagement in improving patients' safety and service quality by the codification of a set of goals which should be adopted by gynecologists and obstetricians in their practice. The gynecologists and obstetricians from ACOG are encouraged to implement these principles in the hospitals or other places where they work.

Currently, also the students of Polish medical universities are taught to pay attention to errors resulting from overwork or stress. The 6th year students (for example at the Medical University of Silesia) have courses devoted to various aspects of the problem of stress [21]. In situations involving uncertainty, which are challenging for normal problem-solving processes, the ability to tolerate unpredictability and maintain inner motivations become critical. The ability to cope with stress is extremely important in the situations involving the responsibility for the life and health of the patient and her child. Therefore, it would seem justified to introduce entrance tests or examinations checking the predispositions of the candidates to medical studies.

In the light of this study, which shows a large number of costly proceedings, it would be advisable to propose the introduction of a system which would not only consist in internal consultations of physicians regarding the problems of their professional environment, but

also maintaining contact between physicians and hospital representatives with patients and their families. Gmurzyńska and Morek [22] recommend mediation proceedings which could lead to a compensation for an error. Mediation proceedings are a great future and opportunity for Offices of Professional Medical Conduct. They could relieve courts of less serious cases. Furthermore, mediation is conducive to widely understood social education and increase of the sense of justice. Such proceedings are characterized by voluntariness and confidentiality, and their purpose is to mitigate a conflict. This way, the patient or her family become an equal partner to a hospital in the proceedings. In the USA, the alternative methods of solving disputes and conflicts are jointly called Alternative Dispute Resolution (ADR) [22]. The spectacular development of ADR institutions in the USA was above all a practical reaction of institutions (including hospitals) to an increase in the costs of judicial proceedings. The USA, the father of contemporary mediation, has developed many types of mediation which have been introduced also in Europe. However, in Poland the relevance of mediation has been increasing only for the last several years. The development of mediation in our country results also from the recommendation of this type of dispute resolution by international organizations, such as the UN, the Council of Europe or the EU, which issues guidelines recommending the Member States to introduce and promote mediation also in civil proceedings [23]. Although not all cases can be mediated, Polish hospitals are gradually more and more convinced to this method of dispute resolution.

CONCLUSIONS

1. There is a continuous increase of complaints related to gynecology and obstetrics, caused mainly by the greater awareness and knowledge of the patients' rights and the dissatisfaction of patients with the solutions introduced in the healthcare system. This tendency will probably intensify in the future, as the complaints were most frequently filed by young women with higher education.
2. Adverse events which were recognized as medical errors usually happened in „on-duty" conditions and were related to lesser experience of physicians and reduced possibility of using the full diagnostic and therapeutic potential and specialist consultations. Also, tiredness played an important role here.
3. The vast majority of the analyzed complaints related to gynecology and obstetrics were deemed unfounded. This shows that most patients do not differentiate between an adverse event, a medical error and a treatment failure.
4. It seems justified to introduce standard procedures for physiological labor using evidence-based medicine and an efficient obstetric data collection system, which should delimit the overlapping competences of physicians and midwives caring for the patient in the peri-delivery period.
5. Physicians should be trained in medical law and communication with patients more frequently and in a more efficient way.
6. Furthermore, it seems justified to introduce examinations checking psychological predispositions of candidates to medical studies and trainings in stress management at work.
7. It would be advisable to implement a system of mediation and maintaining contact of physicians and hospital representatives with patients and their families. It would also be helpful to introduce generally accessible information in healthcare centers and to educate patients.
8. Also the introduction of work organization and staff-related solutions eliminating fatigue and discouragement seems to be reasonable.

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