

# Summary of five years of operation of the out-of-court system for pursuing patient claims in Poland – a retrospective analysis of applications for evaluating medical events

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**Abstract. – OBJECTIVE:** Providing health services involves a risk of medical events and adverse events. The transparency and quality of the healthcare system have a direct impact on patient's safety. One of the measures of the quality of health services is monitoring and reporting these irregularities, as well as analysing the causes of their occurrence. The aim of this study was to present the principles of the functioning of the Regional Commission for Evaluation of Medical Events in Szczecin and to analyse medical events in the West Pomeranian Voivodeship from 2012 to 2017.

**MATERIALS AND METHODS:** The analysis included applications for evaluating medical events and documentation collected for the purpose of conducting cases by the Regional Commission for Evaluation of Medical Events in Szczecin. The study was retrospective. All applications for evaluating medical events that were received by the Regional Commission for Evaluation of Medical Events in Szczecin in 2012-2017 were analysed. The study was conducted from October 2017 to December 2018.

**RESULTS:** The retrospective analysis of the years 2012-2017 revealed 42 medical events and 120 adverse events. The most common medical events were health disorders (33.3%) and bodily injuries (30.9%). Out of the 42 medical events, 34 (80.9%) were for surgical procedures and childbirth. The most common procedures were orthopedic (26.6%) and surgical (23.5%) procedures.

**CONCLUSIONS:** Medical events and adverse events should be reported so that they can be

analyzed, conclusions can be drawn, and remedial measures can be introduced.

*Key Words:*

Adverse events, Medical record review, Patient safety, Risk management.

## Introduction

Ensuring the highest quality of healthcare services is now a top priority for healthcare systems in all countries of the world. Despite healthcare professionals' efforts to ensure patient safety, the incidence of adverse events continues to rise. Every year, 47.2 million adverse events occur during 421 million hospitalizations worldwide. In 2018, the Global Ministerial Summit on Patient Safety held its annual meeting of Health Ministers in Tokyo from 14<sup>th</sup> to 15<sup>th</sup> April. The watchwords were patient participation in the treatment process and focus on the patient as the subject of the medical services provided. Implementation of these principles is to ensure patient safety and high quality of medical care. The Tokyo Summit ended with the adoption of the Tokyo Declaration on Patient Safety. According to its provisions, decision-makers have to take measures to improve patient safety by 2030<sup>1-3</sup>.

The World Health Organization (WHO) warns that 40% of patients worldwide are harmed during outpatient treatment, whereas in hospitals, the figure is about 10%. There are 134 million adverse events in about 150 middle- and low-income countries, and 2.6 million lives are lost annually due to medical errors. Additionally, four out of ten patients are harmed as a result of medical services provided in primary and outpatient care, and 80% of these injuries could have been avoided. In the Organization for Economic Co-operation and Development (OECD) countries, 15% of hospital expenditures can be attributed to treatments related to inadequate patient safety in medical facilities. Surgical procedures can cause complications in up to 25% of patients. Annually, one million deaths occur during surgery or in the perioperative period<sup>4-7</sup>.

WHO emphasizes the need for urgent action to improve patient safety worldwide and reduce the incidence of injuries resulting from health services. The cost of prevention is lower than the cost of treating the consequences of inadequate patient care. WHO recognizes patient and healthcare worker safety as a global health priority and calls on healthcare workers, policy makers, patients and the healthcare industry to voice their opinions on safety in healthcare facilities. In May 2019, the 72<sup>nd</sup> World Health Assembly designated the 17<sup>th</sup> September as World Patient Safety Day to draw attention to the problem of adverse events occurring during the provision of medical services<sup>8,9</sup>.

Adverse events cannot be completely eliminated. Even with the introduction of a quality control system with maximum reliability, legal regulations, and supervision, a certain margin of medical errors is inevitable. The specificity of specialist medical services means that there is a risk of adverse effects of treatment. However, medical facilities must take measures to minimize their occurrence. On the other hand, patients who have suffered injuries or have been harmed as a result of medical services should have this harm remedied and receive compensation or redress for the harm suffered. In Poland, until 2012, aggrieved patients could only pursue their claims through civil law in common courts of law<sup>10-15</sup>. In 2011, an out-of-court compensation system was introduced. Its scope includes adjudication of medical events by voivodeship commissions for evaluation of medical events. The introduction of the out-of-court civil procedure for claiming compensation for damages arising from the provision of medical services was motivated by:

- lengthy court proceedings lasting up to ten years;
- high cost of judicial redress for patients;
- growing awareness of patients to assert their rights;
- an increasing number of medical error cases brought to court;
- obsolescence of the benefits awarded, owing to the length of the proceedings<sup>16-18</sup>.

The aim of this special procedure, an alternative to the court route, was to simplify and facilitate the process of pursuing claims for harm suffered by patients as a result of medical services provided to them in hospitals. Since 1<sup>st</sup> January 2012, there have been Regional Commissions for Evaluation of Medical Events (further in the text referred to as “commissions”) in all 16 voivodeships in Poland, appointed by voivodeship governors. The commissions examine cases based on the applications submitted by patients, their legal representatives or heirs. Their aim is to determine whether the medical service was provided in accordance with the guidelines, standards, rules, and legal norms, i.e., in accordance with current medical knowledge<sup>19-22</sup>.

The commissions determine whether harm in the form of death, disorder of health, bodily injury, or infection, has occurred as a result of the provision of medical services. They determine whether the above-mentioned harm occurred as a result of a diagnosis resulting in inappropriate treatment, a form of treatment, the performance of surgery, or the use of a medicinal product or medical device that were incompatible with current medical knowledge<sup>19-22</sup>.

The commissions analyze the evidence by assessing the real situation and comparing it to the situation required by the applicable legal regulations. In the course of the investigation, the commissions do not question the evidence, determine the amount of compensation/redress, make allegations, or indicate the guilty party<sup>19-22</sup>. In the application for evaluating a medical event, the patient indicates a proposal for the amount of compensation and redress. If a medical event is ruled, the insurer of the hospital is obliged to present a proposal for compensation and redress<sup>10,23,24</sup>. The maximum amount claimed in the case of a bodily injury, health disorder or infection with a biological pathogenic agent cannot be higher than 100,000 PLN (465,000 euros), and in the case of death, it cannot exceed 300,000 PLN (1,395,000 euros). The claimant will not receive

**Table I.** Sociodemographic characteristics of the applicants.

	All applicants, n = 279	Women, n = 146	Men, n = 133	$\chi^2/z$	df	p
Age (Mean):	51.5	50.7	52.2	0.654		0.513
Place of residence:						
city over 100,000	167 (59.8)	88 (31.5)	79 (28.3)			
city from 10,000 to 100,000	78 (28.0)	42 (15.1)	36 (12.9)	0.819	3	0.845
city up to 10,000	7 (2.5)	4 (1.4)	3 (1.1)			
village	27 (9.7)	12 (4.3)	15 (5.4)			

a pension as a result of the proceedings before the commission<sup>23,24</sup>.

The investigation of medical and adverse events is a tool for improving the quality of healthcare and allowing patients to assert their rights. Studying trends in this area can therefore provide valuable information for healthcare managers. The hospital accreditation system itself means an obligation to collect and analyze data on medical activities, adverse events, hospital infections, deaths, rehospitalizations or reoperations. This leads to continuous improvement in the quality of services and patient safety<sup>25,26</sup>.

The aim of the study was to analyze the frequency and causes of medical events in Poland on the example of the West Pomeranian Voivodeship. The results of this study will contribute to the identification of areas that require enhanced efforts for patient safety.

## Materials and Methods

The study was retrospective and covered 279 applications for evaluating a medical event, which were submitted to the Regional Commission for Evaluation of Medical Events in Szczecin (the Commission) in the period from 1<sup>st</sup> January 2012 to 31<sup>st</sup> December 2017. The Commission covers the West Pomeranian Voivodeship, located in north-western Poland, with a population of 1.7 million people<sup>27</sup>. The consents of the Bioethics Committee (consent No. KB-0012/42/01/18) and the presidents of the Regional Commission for Evaluation of Medical Events in Szczecin of the first and second term were obtained.

The study was conducted from October 2017 to December 2018. The research material consisted of applications for evaluating a medical event submitted to the Commission and case files consisting of medical documentation, opinions of medical specialists, and testimonies of applicants and appointed witnesses. Medical events were analyzed on the basis of the above-mentioned doc-

uments in accordance with Sheldon's 'medical control', where the quality of services provided in healthcare is assessed on the basis of, among others, information from controlling and judicial institutions<sup>28</sup>. The applicants were patients of Western Pomeranian hospitals, and they were mainly residents of this voivodeship, but some were from other voivodeships. Among them, there were 47.7% men (n=133) and 52.3% (n=146) women. The sociodemographic characteristics of the applicants are shown in Table I.

The results presented in this paper are the result of the Commission's findings.

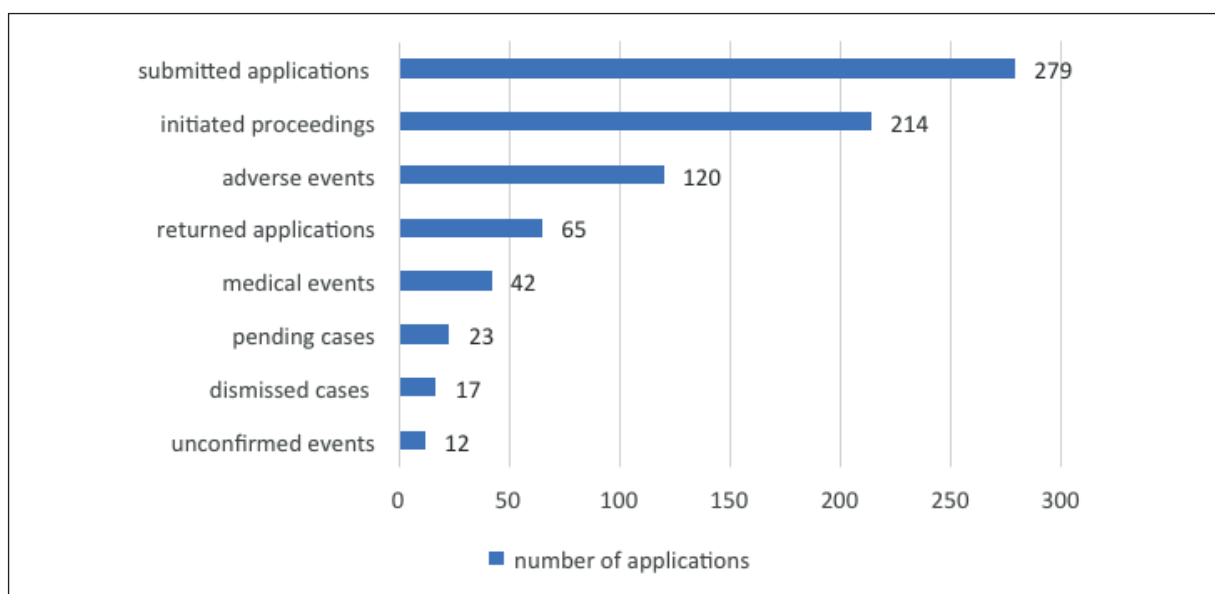
## Statistical Analysis

Descriptive statistics were used to describe the variables. Frequency difference analysis was performed using the Chi-square test of independence. A z-test was used to calculate the differences between quantitative variables. A condition for using tests based on contingency tables was to ensure sufficient expected counts for the fractional frequencies. Cochran's interpretation (1952)<sup>29</sup> – where none of the expected counts can be < 1.0, and no more than 20% of the expected counts can be < 5.0 – was used.

All calculations were performed using the STATISTICA package, version 13.3 (TIBCO Software Inc., 2017). Verification of the null hypothesis was conducted with a pre-assumed level of statistical significance of 0.05.

## Results

In the period under consideration (years 2012-2017), the Commission received 279 applications to evaluate a medical event. There were no statistically significant differences between the number of women and men, who submitted applications [ $\chi^2(1)=0.606$ ;  $p=0.436$ ]. Both groups were not statistically significantly different by age or place of residence. 65 applications were returned

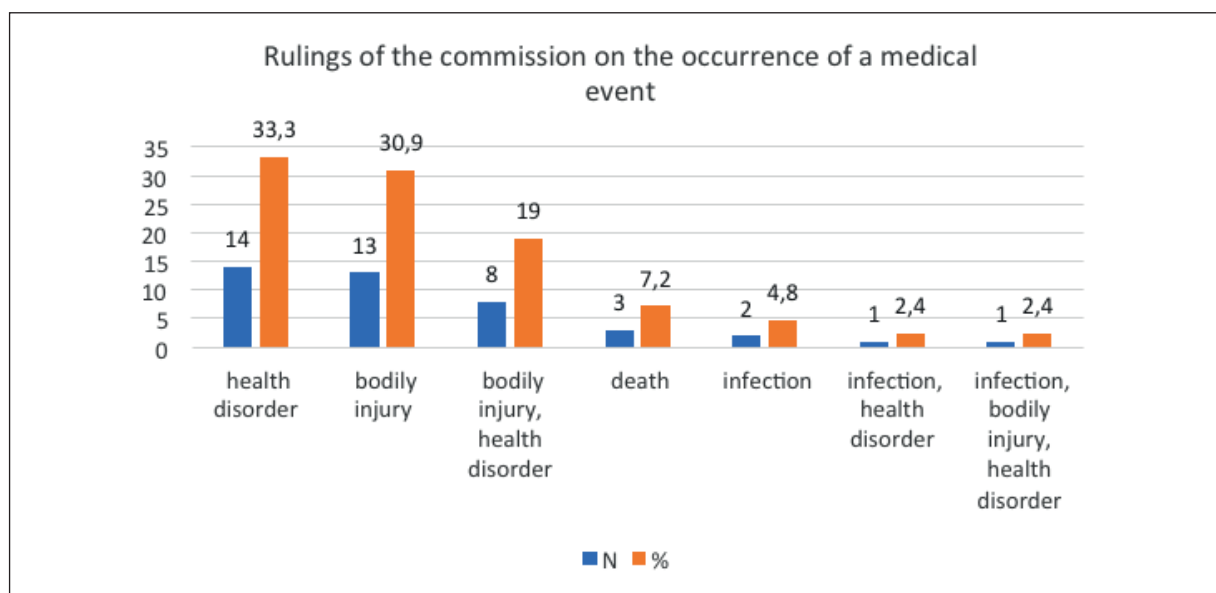


**Figure 1.** Summary of actions taken by the commission regarding applications to evaluate a medical event submitted to the Regional Commission for Evaluation of Medical Events in Szczecin in the years 2012-2017.

to the applicants, most often due to formal deficiencies or late submission of the application. In 68 (24.4%) cases, the applicants were assisted by a professional representative. None of these applications returned to the applicant. In the period analyzed, the Commission identified 42 cases of medical events (Figure 1).

The highest number of decisions of the Commission on the occurrence of a medical event was for health disorders (33.3%), bodily injuries (30.9%), and both bodily injuries and health disorders (19.0%) (Figure 2).

Among the rulings on bodily injury, radial nerve palsy was the most common (23.1%).



**Figure 2.** Rulings of the Regional Commission for Evaluation of Medical Events in Szczecin in the years 2012-2017 on the occurrence of a medical event.

**Table II.** Causes of medical events ruled by the Regional Commission in years 2012-2017.

Rulings of the commission on the occurrence of a medical event	Cause for the ruling on a medical event	N	%	
<b>Infection</b>	<i>Morganella morganii</i> , <i>Acinetobacter baumannii</i> , <i>Staphylococcus haemolyticus</i> , <i>Enterococcus faecalis</i>	1	50.0	
	<i>Clostridium difficile</i>	1	50.0	
<b>Bodily injury</b>	radial nerve palsy	3	23.1	
	arm fracture	1	7.7	
	tooth damage	1	7.7	
	intestinal damage	1	7.7	
	failure to diagnose elbow fracture - abnormal fusion	1	7.7	
	ureteral damage	1	7.7	
	eye damage - loss of vision	1	7.7	
	bile duct damage - duct burn resulting in necrosis	1	7.7	
	leaving a broken drill in the bone	1	7.7	
	malalignment of the hand - bone loss	1	7.7	
	duodenal damage	1	7.7	
	<b>Health disorder</b>	chronic pain, nausea, feeling unwell	3	21.3
		perioperative abscess	1	7.1
obstruction of the radial artery due to prolonged compression		1	7.1	
abnormal, delayed mental and physical development		1	7.1	
chronic abdominal pain, vomiting, feeling unwell		1	7.1	
postoperative urinary incontinence		3	21.3	
testicular loss		1	7.1	
leg paresis		1	7.1	
chronic chest pain, feeling unwell		1	7.1	
chronic pelvic pain		1	7.1	
<b>Death</b>	cardiorespiratory failure	1	33.3	
	multi-organ failure	2	66.6	
<b>Bodily injury (1), health disorder (2)</b>	(1) bladder damage (2) chronic abdominal pain	1	12.5	
	(1) damage to the oesophagus and paralysis of the laryngeal nerve (2) recurrent oesophageal strictures	1	12.5	
	(1) damage to bile ducts and liver artery (2) chronic abdominal pain, vomiting, feeling unwell	1	12.5	
	(1) ulnar nerve palsy (2) arm paresis	1	12.5	
	(1) intestinal damage (2) chronic abdominal pain, vomiting, feeling unwell	1	12.5	
	(1) spinal nerve palsy (2) leg paresis	1	12.5	
	(1) internal bleeding (2) secondary anaemia	1	12.5	
	(1) intestinal damage (2) chronic abdominal pain	1	12.5	
	<b>Infection (1), Health disorder (2)</b>	(1) <i>Clostridium difficile</i> (2) chronic pain, nausea, feeling unwell	1	100.0
		<b>Infection (1), bodily injury, health disorder</b>	(1) <i>Klebsiella pneumoniae</i> ESBL, <i>Candida glabrata</i> , <i>Clostridium difficile</i> (2) loss of a transplanted or healthy kidney (3) sepsis	1

Among the rulings on health disorders, chronic pain, nausea, feeling unwell (21.3%) and postoperative incontinence (21.3%) were the most frequent. The most common cause of death was multiple organ failure (66.6%). The causes of medical events are presented in detail in Table II.

Of the 42 medical events ruled, 34 were related to surgical procedures and childbirth. The

most frequently ruled medical events concerned orthopedic procedures, and among those, the most common happened during repositioning of a fractured arm (55.5%) (Table III).

In the remaining eight cases of medical event rulings, there were no medical procedures involved. These concerned medical events in emergency and non-operative departments (Table IV).

**Table III.** Medical procedures for which a medical event was ruled by the Regional Commission for Evaluation of Medical Events in Szczecin in the years 2012-2017.

Procedures by medical speciality	N	%	Type of procedure	N	%
Orthopaedic	9	26.6	repositioning of a fractured arm	5	55.5
			knee puncture	1	11.1
			surgery on a fractured arm	1	11.1
			hip surgery	1	11.1
			repositioning of a fractured thigh	1	11.1
Surgical	8	23.5	laparoscopic cholecystectomy	4	50.0
			removal of mandibular tumour	1	12.5
			thyroidectomy	1	12.5
			small intestine surgery	1	12.5
			breast reduction	1	12.5
			colonoscopy	4	80.0
Gastroenterological	5	14.8	gastric surgery	1	20.0
			kidney transplant	1	33.3
Urological	3	8.8	renal pelvis endoscopy	1	33.3
			prostate surgery	1	33.3
Gynaecological	2	5.9	childbirth	1	50.0
			hysterectomy	1	50.0
General	2	5.9	PVC insertion	1	100.0
			blood pressure measurement	1	100.0
Cardiological	1	2.9	coronography	1	100.0
Neurological	1	2.9	neurolysis	1	100.0
Ophthalmic	1	2.9	cataract removal	1	100.0
Vascular Surgery	1	2.9	arterial decongestion	1	100.0
Otorhinolaryngological	1	2.9	microlaryngoscopy	1	100.0

The most common cause of medical events was failure to follow procedures and carelessness of the medical staff (66.7%). The root causes of medical events are shown in Figure 3.

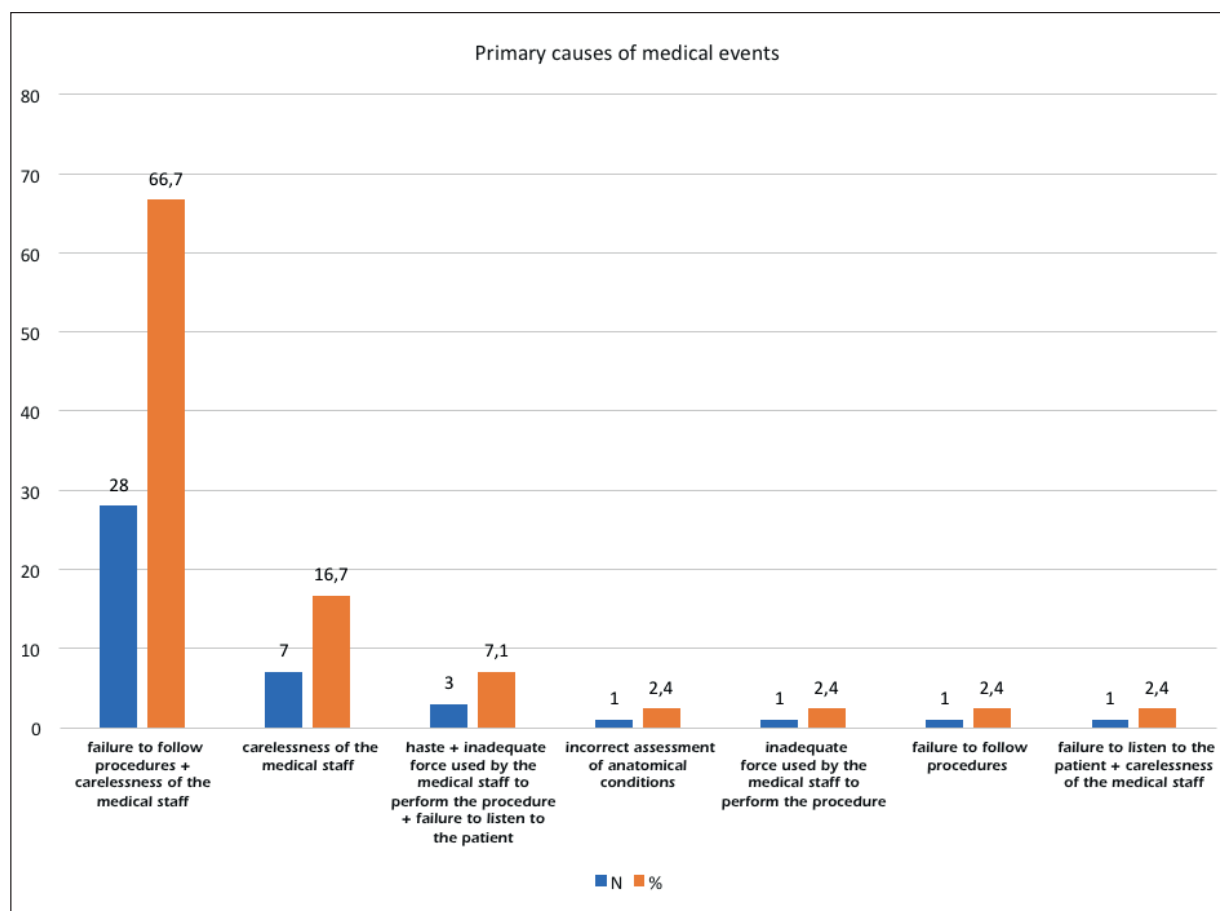
For medical event rulings, the time from the occurrence of the event to the submission of the application averaged 271.3 days. The time from the submission of the application to the first hearing averaged 72.6 days. The time from the submission of the application to the ruling averaged 168.4 days. The average number of Commission hearings was 2.9.

In 42 cases that ended with a ruling of a medical event, the average amount of money demanded in the application was 89,857.14 PLN. The lowest sum

demanded was 29,000 PLN, and the highest was 300,000 PLN. In 39 cases out of these 42, medical facilities submitted a proposal for compensation for medical events. The average amount of the proposal was 10,113.04 PLN. The lowest amount proposed by hospitals was 100 PLN, and the highest was 83,500 PLN. In 61.6% of the cases, the amount of compensation/redress proposed by hospitals was no more than 10% of the amounts demanded by the applicants. The lowest amount of compensation paid was 2,500 PLN, and the highest was 100,000 PLN paid in enforcement proceedings. In 62.9% of the cases, the applicants did not accept the proposal of the medical facility.

**Table IV.** Rulings of the Regional Commission for Evaluation of Medical Events in Szczecin concerning medical events where no procedures took place.

Department	Long-term effect of the event	Commission's ruling	N	%
Emergency	dysfunction of an organ or a body part	health disorder	2	66.6
	chronic pain + depression, despondency + dysfunction of an organ or a body part	health disorder	1	33.3
Internal Medicine	death	death	1	50.0
	lack of earning capacity	bodily injury, health disorder	1	50.0
Nephrology	chronic pain + depression, despondency	infection	1	100.0
Emergency room	dysfunction of an organ or a body part	health disorder	1	100.0
Orthopaedics	dysfunction of an organ or a body part	health disorder	1	100.0



**Figure 3.** Primary causes of medical events from the rulings of the Regional Commission for Evaluation of Medical Events in Szczecin in the years 2012-2017.

## Discussion

Medical events and adverse events happen in hospitals all over the world. The occurrence of adverse events poses very serious medical and economic problems for healthcare providers. Paradoxically, with the development of medical science, medical technology and treatment methods, the occurrence of medical errors resulting in adverse events has increased. Both in Europe and around the world, government programs are developed to improve patient safety in hospitals. Various measures have also been taken to facilitate and accelerate the process of seeking compensation or redress for patients harmed in healthcare facilities. In Poland, an out-of-court system of pursuing claims for harmed patients has been in place since the 1<sup>st</sup> of January 2012. Regional Commissions for Evaluation of Medi-

cal Events have also been established. They are functionally and organizationally independent from the judiciary system and the public administration system<sup>30</sup>.

Although it is not possible to completely eliminate adverse events from hospitals, awareness of their occurrence and causes has a positive impact on controlling and minimizing their effects, which has a direct impact on increasing patient safety in healthcare facilities. The increasing demands of patients, their families, and taxpayers make it challenging for healthcare providers to guarantee the best possible quality of treatment, nursing and care for patients as well as to continuously improve safety for patients and healthcare professionals.

Providing medical services is inevitably associated with the possibility of unexpected events, such as medical events. In the era of high medi-

cal standards, an open debate concerning the factors that determine the occurrence of violations in the field of law, diagnostics and therapy should be pursued. The results of studies<sup>31-33</sup> conducted by many authors justify the use of guidelines and maintaining bias when discussing the issues related to the reporting of adverse events. Such a belief may increase positive attitudes towards providing information on adverse events, thus counteracting the phenomenon of not publishing such important data<sup>34</sup>.

In the years 2012-2017, the Commission for Evaluation of Medical Events in Szczecin received 279 applications to evaluate a medical event. Information on the size of this phenomenon can also be found in other studies across Poland. A study published by Krzych et al<sup>35</sup>, which aimed at analyzing the activities of Regional Commissions for Evaluation of Medical Events from the beginning of 2012 to April 2013, showed 791 applications submitted in all voivodeships. A report on the activities of the Regional Commission for Evaluation of Medical Events in Gdańsk in 2012-2015 recorded 245 applications<sup>36</sup>. Collecting and analyzing such important data should be reflected in Polish health policy.

In the analyzed period of 2012-2017, the Commission received 279 applications and initiated 214 proceedings to evaluate a medical event. Until the completion of the study, a ruling was made on the occurrence of a medical event in 42 (25.9%) cases and on the absence of a medical event in 120 (74.1%) cases. In a study by the Supreme Audit Office, the ratio of rulings on the occurrence of a medical event to rulings on the absence of a medical event was slightly different, i.e., 431 (32.1%) to 910 (67.9%), respectively<sup>37,38</sup>. In a study by Budzowska et al<sup>37</sup>, the ratio was 23.67% to 76.33%.

In our study, the majority of applicants were not assisted by a professional representative. At the same time, quite a large number of applications (65) were returned. This result may indicate the need for more attention to education in the field of submitting applications for evaluation of a medical event.

The most frequent medical events were health disorders (33.3%) and bodily injuries (30.9%). Of the 42 medical event rulings, 34 (80.9%) were for surgical procedures and childbirth. The most common procedures were orthopedic (26.6%) and surgical (23.5%).

In 92.6% of the cases, the medical facilities submitted a compensation/redress proposal, and in the remaining cases (7.4%) the applicants ob-

tained an executory entitlement to initiate enforcement proceedings. In the study by Budzowska et al<sup>37</sup>, slightly fewer medical facilities (88.29%) offered the applicants a compensation/redress, thus 11.71% of the applicants issued an executory entitlement. In our study, in 62.9% of the cases, the applicants did not accept the proposal of the medical facility, and in the study by Budzowska et al<sup>37</sup>, the percentage was 59.18%.

According to the results of the study, failure to follow procedures and carelessness of the medical staff were the primary causes of medical events (66.7%). It is worth noting the resources of medical staff in the region under analysis. The number of medical staff working in hospitals in the West Pomeranian Voivodeship per 1,000 inhabitants in 2017 was: 2.46 for doctors, 4.21 for nurses, 0.53 for midwives<sup>39,40</sup>. The obtained data clearly indicate a moderate number of medical staff performing medical services in Poland. Such a perspective may contribute to an increased tendency to commit medical errors. Factors such as failure to follow procedures or carelessness of the medical staff may result from haste caused by insufficient staffing during the performance of health services. The occurrence of medical errors as well as medical and adverse events may result from extended working hours<sup>41</sup> and professional burnout<sup>42</sup>.

The limitation of this study is the inclusion of complaints from only one of the Polish voivodeships, which makes it difficult to assess the problem in the entire territory of Poland. At the same time, medical events include only hospital treatment, which limits the possibility of inferring the number of medical errors in the region.

## Conclusions

1. The vast majority of the rulings of the Regional Commission for Evaluation of Medical Events in Szczecin were decisions on the absence of a medical event.
2. Medical events have not been eliminated in hospitals in North-Western Poland.
3. Medical events occur most frequently in surgical departments.
4. The root causes of medical events were factors implying medical errors, i.e., failure to follow procedures, failure to exercise due diligence and haste on the part of the medical staff.
5. The results of the analysis of the research material indicate that medical events and adverse



events should be reported so that they can be analyzed, conclusions can be drawn and remedial measures can be introduced.

6. Patient safety in medical facilities can be increased by taking preventive measures resulting from the analysis of medical events and adverse events, e.g., by supplementing staff shortages.

### Conflict of Interest

The authors declare that they have no conflicts of interest.

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