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Metoda „czarnych punktów" metodą zarządzania ryzykiem na przykładzie szpitala klinicznego

Streszczenie

Wstęp. Szpitale są instytucjami, które ze względu na swoją specyfikę i charakter są szczególnie mocno narażone na różnego rodzaju zagrożenia. Jedną z najważniejszych i najczęściej stosowanych metod zarządzania ryzykiem jest metoda „czarnych punktów".

Cel. Celem badań było opracowanie podstaw tworzenia modelu procedur i interwencji medycznych w różnych oddziałach szpitala podlegających monitorowaniu w zakresie zarządzania ryzykiem.

Materiał i metody. Materiał badawczy pochodzi z jednego ze szpitali akademickich w województwie łódzkim. Zgromadzone informacje zebrane zostały w oparciu o 450 kompletnych historii chorób i inną dokumentację medyczną pacjentów leczonych w szpitalu w latach 2006-2007. Analizie poddano wybrane pobyty w stacji dializ oraz hospitalizacje w oddziale okulistyki, neurochirurgii i chirurgii plastycznej.

Wyniki. Zebrane dane pozwoliły określić nie tylko powikłania, które wystąpiły podczas udzielania w/w świadczeń medycznych, ale zaproponować ewentualne działania zapobiegawcze oraz korygujące. Jednocześnie na podstawie przeanalizowanej dokumentacji określono średni czas hospitalizacji (bez powikłań) dla każdej operacji/zabiegu, częstość poszczególnych zdarzeń niepożądanych, jak również średni czas pobytu dla konkretnego powikłania osobno. Oszacowano także, przybliżony koszt osobodnia w wybranych oddziałach.

Wnioski. Każdy niekorzystny skutek czy zdarzenie ma swoje określone przyczyny. Poznanie ich, a więc dokładne ustalenie etiologii jest rzeczą bardzo ważną i pierwszorzędną w całym procesie zarządzania ryzykiem. Analiza występujących powikłań czy zagrożeń, nawet tych wydawać by się mogło najmniej znaczących, to szansa na ich ograniczenie lub całkowite wyeliminowanie.

Słowa kluczowe: zarządzanie ryzykiem, metoda „czarnych punktów", identyfikacja zdarzeń niepożądanych, poziomy istotności czarnych punktów.

The method of "black spots" in risk management of adverse events – with the example of a research hospital

Abstract

Introduction. Health Care Centres are institutions which, because of their specificity and character, are particularly exposed to various kinds of risk. One of the most important and most frequently used methods of risk management is a method of "black spots".

Aim. The aim of this research was to develop the basis for creating a model of medical procedures and interventions which are subject to monitoring regarding risk management in various wards of a hospital.

Material and methods. Research material comes from one of the university hospitals in Łódź Province. The information was gathered basing on 450 complete medical histories and other medical documentation of patients treated in the hospital between 2006-2007. The analysis covered random chosen stays in the Dialysis Centre and hospitalization in the Ophthalmology Ward, Neurosurgery Ward and Plastic Surgery Ward.

Results. All gathered data made it possible not only to determine complications which occurred during the provision of the aforementioned medical benefits but also to propose possible preventive or corrective activities. Simultaneously, based on the analyzed documentation, the mean hospitalization time (with no complications) was determined for each surgery/treatment as well as the frequency of separate adverse events and the mean hospitalization time for each separate complication. The approximate cost of person-day was also estimated for chosen ward.

Conclusions. Each adverse effect or event has its specific causes. Recognizing them, i.e. precisely determining the aetiology, is a very important and primary aspect in the whole process of risk management. The analysis of occurring complications or hazards, even those that seem the least important, is a chance of limiting them or even completely eliminating them.

Keywords: risk management, method of "black spots", identify of adverse events, the significance levels of black spots.

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INTRODUCTION

The notion of risk management plays a crucial role in the correct functioning of each unit, including a health care unit. For hospitals, the possibility of identifying risk characteristic of them not only guarantees safety to patients and the whole hospital environment but also brings economic benefits. In the attempt to describe the method of "black spots" used in the study, it was assumed, that it is a complex of various methods (including event trees analysis and fault trees analysis) and fragmentary analyses (experts' analyses, epidemiological monitoring etc.) which often have various techniques and to which one may add other components, if necessary. It consists in identifying risk, building the hierarchy of hazards and proposing repair actions, such as tightening procedures or monitoring. It is cyclic and it has algorithm-block structure. This means that after the liquidation of the most dangerous and possible to remove black spots (in terms of economical and organizational situation of a unit), the next iteration on the next hierarchic level involves a new risk analysis, a new black spots selection etc.

In order to determine all black spots in a hospital, it is necessary to use experts' opinions (consultations with experts), which makes it possible to create appropriate assessment scales in the future. It is on the basis of those scales that specific hierarchic levels will be determined.

The assessment of influence of individual elements connected with a patient's stay in a hospital requires detailed examination. An attempt was made to model patients' safety measurements with the example of the analysis of surgeries performed during chosen hospitalizations. During the construction of the models, the following factors connected with a hospital environment and specificity of performed surgeries were taken into account: hospitalization time, number of infections, number of bedsores, resurgeries, complications, number of intravenous insertions, surgery time etc.

AIM

The aim of this research was to develop the basis for creating a model of medical procedures and interventions which are subject to monitoring regarding risk management in various wards of a hospital through:

- development of risk identification methods for the purposes of risk management (identification of adverse events associated with selected medical interventions)
- development of a model of selected procedures for effective (medical and economic) risk management
- development of a scale for assessing levels of hierarchical events.

Particular attention was paid to quantifiable safety indicators, such as:

- hospital infections
- postoperative complications
- reoperations
- re-hospitalizations
- bedsores
- other adverse events occurring during selected operations

This is to be the most secure system possible focused on the prevention of adverse events without attributing blame.

MATERIAL AND METHODS

The presented research material comes from one of the university hospitals in Łódzkie Province. The information was gathered basing on 450 complete medical histories and other medical documentation of patients treated in the hospital between 2006-2007. The analysis covered random chosen stays in the Dialysis Centre and hospitalization in the Ophthalmology Ward, Neurosurgery Ward and Plastic Surgery Ward. Because of a wide range of activities and diversity of surgeries performed in those wards, for the purposes of this study the authors analysed only the following surgeries: removal of cataract and glaucoma, brain tumour removal, rhinoplasty and haemodialysis. It occurred that consultations with numerous experts were necessary not only in order to deepen and verify the obtained information but also to determine (with a significant resistance of the environment) which of the incidents may be recognised as undesirable events.

RESULTS

All gathered data made it possible not only to determine complications which occurred during the provision of the aforementioned medical benefits but also to propose possible preventive or corrective activities. The obtained results are presented in the Table 1.

Based on the events presented above and their possible causes, preventive actions determined by specialists for individual surgeries/treatments include, above all, the following:

- For rhinoplasty:
  - detailed interview and the assessment of general health condition of patients,
  - increased precision during the treatment,
  - intensified nursing care of patients aiming at providing them with essential knowledge on dealing with the operated place,
  - providing patients with suitable conditions of hospitalization,
  - informing patients on the way of taking care of themselves after the treatment and on limiting physical activity.
- For haemodialysis [1,2]:
  - inspection of insertion places,
  - thorough preparation of patients to the treatment (determining dry body mass or blood pressure) and constant care of patients during their stay in dialysis centre,
  - using a device which controls the process of ultrafiltration,
  - avoiding significant increases in patients' body mass during periods in-between dialyses or performing short haemodialysis treatments,
  - correct regulation of medical apparatus (ultrafiltration speed, sodium levels in the solution, temperature of dialysis liquid, or dialyzer disinfection),
  - limiting tissue ischaemia during the dialysis,
  - recommending that patients limit the consumption of table salt,

TABLE 1. A kinds and causes of complications occurring during chosen hospitalizations [1-11].

Ward	Kind of complication/event	Possible cause of the event
Ward of Plastic Surgery	reoperation/ repeated hospitalization	incorrect arrangement of nose bones or septum, incorrectly removed hump, need for shortening of the nose
	infection and temperature rise up to 39°C	wrong conditions in the ward (draughts, low temperature), lowered immunity of a patient, wrong behaviour of a patient
	plaster cast coming unstuck	plaster cast put badly or too loosely, carelessness of a patient
	local lesions within intravenous insertion	bad insertion, insufficient hygiene of the insertion place (disinfection)
	blood-stained vomit after the surgery	body reaction to anaesthetics
Dialysis Centre	sucking from the artery during HD	narrowing of arterial-venous fistula, decrease of arterial blood pressure, too fast ultrafiltration
	thrombus during HD	too slow blood flow, high speed of ultrafiltration, contact with air (as a result of insufficient rinsing or bad rinsing technique of a dialyzer), wrong administration of heparin
	considerable decrease of RR	excessive drop in the volume of circulating blood (e.g. as a result of incorrectly determined dry body mass or too low sodium levels in the dialysate), insufficient blood vessels contraction (e.g. too warm dialysate, neuropathies of autonomic nervous system, cardiac factors)
	pain in the chest during HD	air embolism
	pain in the spine during HD	air embolism
	leaking from the insertion	bad insertion, coagulation disorders
	the vessel breaks during HD	fragile vessels, long treatment with dialysis, clot in the discharging vessel
	severe itching of the skin	oversensitivity to a dialyzer or elements of blood line (e.g. heparin), disorders of Ca-P system
	muscle cramps	dehydrating a patient below dry body mass, using dialysates with too low sodium levels, accompanying hypotension
Ward of Ophthalmology – cataract	leaking wound	incorrect or too weak stich
	folded Descemet membrane	decrease of pressure inside an eyeball, too narrow incision, catching the membrane with a tip of a facoemulsifier during the entrance to the cavity, lengthened time of surgery
	dispersed blood in the vitreus humour cavity	damaging of choroid, changes in general pressure
	impossible to reduce intraocular pressure because of cells blocking the outflow of aqueous humour	the blockade of the internal opening and the resulting incorrect flow of vitreous humour
	corneal oedema	possible damage to cornea by touching endothelium with the tip of the phacoemulsifier, endothelium abrasion by nucleus or its fragments
	breaking of a lens capsule	too much aggression while lifting the lobule or inserting fluid to the eye, too sharp cannula edges
	iris odema	incorrectly made wound, cutting through with the head of the phacoemulsifier
Ward of Ophthalmology – glaucoma	massive blood leak to the front cavity or vitreus humour	damaging of choroid, changes in general pressure
	making the front cavity shallower	too large incision and the drop of the pressure in the eyeball, postsurgical wound not tight
	splitting apart of the stitch on the base of a flap	incorrect stitch
	folded Descemet membrane	decrease of pressure inside an eyeball, too narrow incision, catching the membrane with a tip of a facoemulsifier during the entrance to the cavity, lengthened time of surgery
	corneal oedema	precision in laser operation
	inflammation in the front cavity	chronic leak from filtering bleb,
	hypotony after the treatment	Lack of wound tightness, wrong incision, cutting too large number of stitches, choroidal detachment
	choroidal detachment	low intraocular pressure, inflammation
Ward of Neurosurgery	creation of epidural haematoma	incorrect or too lose stitches, the source of bleeding was not identified
	reddening between the buttocks	too rare changes of body position, insufficient nursing care (patting, compresses, anti-bedsore mattresses)
	postsurgical period with complications: left-side partial visual impairment	pressure of tumour on a nerve, dysfunction of visual nerve blood supply, damaging the nerve with tools
	postsurgical period with complications: left oculomotor nerve palsy	pressure of tumour on a nerve, dysfunction of visual nerve blood supply, damaging the nerve with tools
	vomit after the surgery	body reaction to anaesthetics
	local lesions within intravenous insertion	bad insertion, insufficient hygiene of the insertion place (disinfection)
	partial damage to right III nerve	damaging the nerve during the surgery
	paraplegia of an upper or lower limb	damaging the nerve during the surgery
	incidence of hydrocephalus – a patient required implantation of ventriculo-atrial shunt	increase in brain pressure

TABLE 1. continued

Ward of Neurosurgery	sliding down from the bed – bruises without fractures	insufficient care of a patient, no safety devices in a bed
	air in surgery site and ventricular system	diffusion of gases used to anaesthetization to air spaces
	hipokaliemia	disturbance of potassium metabolism
	hospital infection (cerebro-spinal meningitis)	incorrect sanitary-epidemiological conditions, no standards applied, low immunity of the organism
	death	insufficient haemostasis, unidentified source of bleeding, damaged arachnoidea, insufficient tightness and plasty of sella turcica

Source: the author's own study

- every-day administration of correct doses of drugs reducing arterial blood pressure after the dialysis treatment rather than before it,
- lengthy moisturization of the whole skin and applying softening agents to the whole skin.

- For cataract surgery [3]:
  - detailed interview and the assessment of the general health condition of patients,
  - paying special attention to the precision of the incision and "manoeuvring" with the tip of the phacoemulsifier,
  - inspection of stitches and wound tightness,
  - using suitable technique and tools,
  - correct use of viscoelastic,
  - informing patients on the way of taking care of themselves after the treatment and on limiting physical activity.
- For the glaucoma surgery [4]:
  - detailed interview and the assessment of the general health condition of patients,
  - paying special attention to the precision of the incision in conjunctiva and "manoeuvring" with the tip of the phacoemulsifier,
  - closing the wound precisely and making stitches,
  - inspection of the stitches and wound tightness (Seidel test),
  - regular measurements of intraocular pressure before the surgery and afterwards,
  - covering the eye,
  - informing patients on the way of taking care of themselves after the treatment and on limiting physical activity.
- For the brain tumour surgery [5,6]:
  - detailed interview and the assessment of the general health condition of patients,
  - intensified inspection of insertion places,
  - intensified anti-bedsore measures (not only in lying patients),
  - paying special attention to precision during the tumour surgery,
  - correct stitches and, if necessary, additional sealing of the wound,
  - correct haemostasis,
  - choice of an appropriate method of anaesthetization (e.g. qualification to the application of nitrous oxide),
  - administration of nitrous oxide with other anaesthetics.

Simultaneously, based on the analyzed documentation, the mean hospitalization time (with no complications) was determined for each surgery/treatment (see tab.1) as well as the frequency of separate adverse events and the mean hospitalization time for each separate complication. The approximate cost of person-day was also estimated for chosen clinics. This cost includes not only expenses incurred by wards (e.g. consumption of materials and energy, including medicines, medical materials and devices; equipment; external services, e.g. renovations, transport, tests, security; taxes and charges; salaries; depreciation) but also payments resulting from the maintenance of the operating suit and related to treatments performed in it (e.g. anaesthetics, spare parts for medical devices, stitches, implants, prostheses etc.).

The exemplary information are presented in the Table 2.

With the use of the data presented above, the attempt has been made to identify and assess black spots. The adoption of the three basic predictor variables in the method of "black spots", i.e. risk level in medical category, average costs, and extraordinary costs (related to complications), resulted naturally from research assumptions (analysis of adverse effects) and from the possibility of obtaining relevant data in the analyzed hospital (cost analysis, expert risk analyses, and proportions of corrective and preventive measures). The form of the model was proposed based on the few-years' research of the team led by prof. Michał Marczak concerning the measurement of health, functioning and disability (ICF) and, particularly, concerning scales (assessment aggregates) used in rheumatology, such as DAS or DAS 28. Significant knowledge has been obtained on the construction of suitable econometric models for the needs of health care, the technique and criteria of identifying parameters for these models and the assessment of their structure. As a consequence, for the construction of the model the additive form of the risk assessment function was adopted (W1 formula); the power relationship between exogenous variables and the endogenous variable was adopted as the basic one. Model parameters were determined with the identification method basing on the minimization of loss function. In the calculation construction, optimization consisted in viewing and selecting parameters from four-dimensional matrix, what was performed with the method of computer simulation with computation reduction consisting in using the method of gradients exceeding threshold values.

The following procedure was adopted (3 levels of procedure), which made it possible to determine critical places which could simultaneously pose considerable risk to patients (Figure 1).

TABLE 2. Data for Ophthalmology Ward – for cataract.

Kind of complication/event	Frequency (%)	Approximate cost of person-day	The average length of stay without complications (days)	The average stay with complications (days)	Approximate ordinary cost (without complications) (PLN)	Time with complications (days)	Approximate extraordinary cost (with complications) (PLN)	Approximate extraordinary, mean cost of complications
leaking wound	2.86					10	2,745	
folded Descemet membrane	1.43					8	1,647	
dispersed blood in the vitreus humour cavity	1.43					4	0	
impossible to reduce intraocular pressure because of cells blocking the outflow of aqueous humour	2.86	549.0	5.7	5.9	2,745.0	9,5	2,470.5	1,647.0
corneal oedema	1.43					11	3,294	
breaking of a lens capsule	1.43					10	2,745	
iris odema	1.43					8	1,647	
leaking wound	2.86					4,5	0	

Source: the author's own study

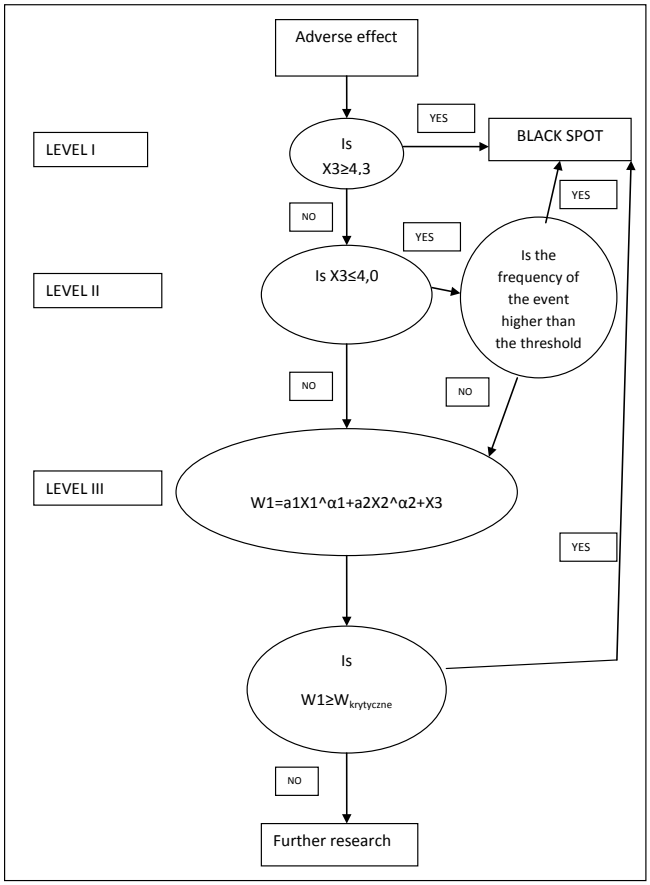

FIGURE 1. Procedure model for the determination of black spots [7].

Simultaneously, for the needs of the study, the aforementioned formula of (W1=a1X1^α1+a2X2^α2+X3) was used on the third level of the model (see Figure 1), which takes into consideration many elements, such as [7]:

X1 – ordinary cost
X2 – cost of complications*frequency
X3 – expert assessment

Indexes used in the formula are as follows:

- for all surgeries (except for the treatment of haemodialysis)
  a1=0.011
  a2=0.0004
  α1=0.50675
  α2=1.3155
- for the treatment of haemodialysis:
  a1=0.009
  a2=0.0006
  α1=0.42675
  α2=1.4423

Information obtained based on the model and formula presented above made it possible to determine "black spots", simultaneously taking into account three proposed hierarchic levels (Table 3).

Therefore, it can be noticed that the highest risk for a patient is posed by those events which not only obtained the highest number of points in expert assessment but also were the most frequent, i.e. deaths, occurrence of epidural haematoma, or blood in the chamber of the vitreous body. Next, the events were placed such as, e.g., lesions within local insertion, oedema, or muscle cramps; these are events which have not been qualified as "black spots" by the procedure presented above. It should be noted that the expert assessment is a mean value calculated from the assessments performed by three independent experts and the frequency of complications has been determined based on the analyzed documentation. This study is the example of an analysis of adverse effects accompanied by proposals of preventive measures, i.e. techniques of risk management.

DISCUSSION

Due to the specificity and nature of the enterprise, the many factors affecting its operations, and the multitude of existing definitions, the approach to this issue is undergo-

TABLE 3. Rank of adverse events.

Adverse event	Rank
reoperation/ repeated hospitalization	1
blood-stained vomit after the surgery	2
infection and temperature rise up to 39°C	3
local lesions within intravenous insertion	4
plaster cast coming unstuck	5
dispersed blood in the vitreus humour cavity	1
impossible to reduce intraocular pressure because of cells blocking the outflow of aqueous humour	2
iris odema	3
breaking of a lens capsule	4
leaking wound	5
corneal oedema	6
folded Descemet membrane	7
massive blood leak to the front cavity or vitreus humour	1
making the front cavity shallower	2
corneal oedema	3
inflammation in the front cavity	4
folded Descemet membrane	5
choroidal detachment	6
splitting apart of the stitch on the base of a flap	7
hypotony after the treatment	8
death	1
creation of epidural haematoma	2
air in surgery site and ventricular system	3
postsurgical period with complications: left-side partial visual impairment	4
paraplegia of an upper or lower limb	5
hospital infection (cerebro-spinal meningitis)	6
local lesions within intravenous insertion	7
vomit after the surgery	8
partial damage to right III nerve	9
incidence of hydrocephalus – a patient required implantation of ventriculo-atrial shunt	10
postsurgical period with complications: left oculomotor nerve palsy	11
hipokaliemia	12
sliding down from the bed – bruises without fractures	13
reddening between the buttocks	14
considerable decrease of RR	1
pain in the chest during HD	2
the vessel breaks during HD	2
sucking from the artery during HD	3
thrombus during HD	4
pain in the spine during HD	5
leaking from the injection site	5
muscle cramps	5
severe itching of the skin	6

Source: the author's own study

ing constant transformations. To gain a thorough understanding of all the stages that make up the risk management process one needs to not only have substantial knowledge about the systemic organization of the company, its structure, and its environment, but also collect information about possible risks and significant changes to safety levels and their consequences. At the same time, more and more companies and institutions, including those in the health care sector, are taking the effort to implement risk management.

For hospitals, which provide medical services, the opportunity to identify their specific risks would not only be beneficial for the patients and personnel, but would also help ensure smooth operations of the hospitals themselves. It must be remembered that we are all constantly accompanied by some risk, and it is not possible to conduct any activity with no hazards whatsoever.

It should also be emphasized that the level of acceptable risk in the Polish health care system is too high. Neither the government nor local governments pursue any policies in this field, information policy included. No measures have been taken to determine the extent of the problem in question [7].

The specification of adverse events and various errors and their classification makes one realize how many factors and elements may affect their incidence. Errors may be caused not only by inadequate qualifications of specialists, by a lack of cooperation between the staff taking direct part in the diagnostic and therapeutic processes (e.g. doctors, nurses, technicians, laboratory technicians, etc.), or by the head of the facility, but also by the medical equipment used in the facility.

Gaining a full understanding of adverse events is a necessary and indispensable part of the process of identifying the sources of possible risks and indicating those that cause the most damage and are important for the proper functioning of the entire healthcare facility, and also for the safety of the patient.

It is a difficult and tedious task to collect all the necessary information; one has to have both relevant experience and knowledge of the organizational structure of the facility and its characteristics.

The black spot method discussed in the paper is one of the most important and most widely used risk management methods. However, the method has not been applied in the health care system until now. Therefore, the present state of knowledge and the potential of specialists who deal with the problem are small.

The authors of the study assume that the proposed method will optimize the performance of health facilities in many respects, including their economic, medical, and even logistical efficiency. Furthermore, a change in risk management at the level of organizational units will allow for changes in a wider range of subsystems and the entire health system.

The study has shown that the method presented above is applicable and leads to reduced risk [8].

CONCLUSIONS

1. Based on the collected materials, we successfully identified "black points" posing a risk both to patients and to the entire hospital environment (e.g. non-compliance with the rules, standards, and sanitary and hygienic procedures increases the number of hospital-acquired infections; inadequate history-taking or assessment the patient's health status; lack of precision during surgery in terms of making incisions or placing sutures).
2. The "black points" were hierarchized indicating the first three levels of their significance and assigning ranks to them (the higher the rank, the greater the risk the event carries).
3. Possible causes of the identified events were determined with the help of specialist physicians, and a number of suggestions were made for preventive efforts to reduce or eliminate the complications in the future.
4. It was found that adverse events, including nosocomial infections, contribute to the prolonged hospitalizations because quite often it is necessary to conduct non-routine tests or use intensive antibiotic therapy.
5. The hospital unit in which additional adverse events occur often bears considerable costs of non-routine procedures (e.g., the occurrence of nosocomial infections such as hospital-acquired meningitis at a neurosurgery unit resulted in average hospitalizations of up to 38 days and additional costs of hospital stay and treatment of the order of PLN 21,000).
6. The great practical utility of the procedures presented in the paper and of the proposed model and mathematical equation may become the basis for the development of an algorithm for minimizing adverse effects.

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