Identification of adverse events with the use of the black spots method – own example

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Abstract. 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. 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. The black spot method discussed in the paper is one of the most important and most widely used risk management method.

Introduction

The importance of the issues on this topic is especially important nowadays, with the very rapid development of medicine, universal and diverse medical and nursing care, demographic changes which cause an increase of the average life duration, which in consequence translates to the increase in the number of patients. A diverse scope of medical services unfortunately also causes an increased risk of occurrence of adverse events.

Risk management consists of appropriate implementation of appropriate procedures and the use of optimum methods of estimating and controlling the level of adverse events which may occur in specific conditions [11]. In the risk management process it is important to analyse and estimate significant risk groups, which occur in a hospital, and also the creation of
strategies and methods enabling for their management and minimisation. One should remember, that some risk groups are present in some medical entities regardless of specifics, other than in established conditions, since they are determined by the type of activity and the scope of provided services. It is thus impossible to create a universal list of adverse events\(^1\), which occur in a hospital. It is however possible to create their general list which will enable the ordering of individual events and assessment of their results. Risk areas present in a hospital may be classified in the following categories [3–4]:

I group: Human factor – causes threats and is subject to them. Hazardous events may be caused by medical errors, by making bad decisions. It should be added that interpersonal communication (patient – patient, personnel – patient, personnel – personnel) may also cause an increase of the risk level.

Risk factors:
- individual characteristics (such as sex, age, character) – influence the risk both on the risk increasing factors and the factors on which it depends whether a given person (both among the personnel and the patients) will be resistant to a given risk or not,
- medical errors
- making of incorrect decision (e.g. discharging oneself from the hospital may lead to an increase of a risk of illness and loss of health)
- improper communication between people, no understanding
- professional stress, stress of patients and visitors
- no will to cooperate between the personnel and patients.

II group: Hospital infections\(^2\) – both patients, personnel and persons with even a singular contact with the hospitals are susceptible. The period in which the infection has revealed itself is important (it was arbitrarily decided that it is 48 hours from signing into or out of a hospital, and in case of long incubation period (HBV, HCV, HIV, tuberculosis) a period no longer than its incubation period).

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\(^1\) In the article the term “adverse event” covers a wider scope than “medical events”, which in accordance with the amendment of the Patient Rights and Patient Rights Spokesman Act include the infection of a patient with a biological pathogenic factor, damage of the body, health disorder or death.

\(^2\) Hospital infection: “is an infection, which occurred as a result of provision of health services, when the illness: a) was not during its incubation period when the health services were provided, or b) occurred after the provision of health services during a period not exceeding its incubation period” (5 December 2008 Infection and Infectious Disease Prevention and Treatment Act; Dz. U. 2008 No, 234 item 1570).
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Risk factors:
- microorganisms present in a hospital environment,
- resistance of exposed persons,
- infection routes and entries
- sterilisation and disinfection technology.

III group: Occupational hazards
Risk factors:
- working time and discipline,
- OSH and ergonomics,
- working space,
- availability, freedom of movement,
- lighting,
- heating, ventilation,
- sanitary unit,
- access to drinking water,
- mess room.

IV group: Manually performed work
Risk factors:
- handling, transporting patients,
- procedures requiring long and precise use of tools,
- loads of joints.

V group: Dangerous substances – when identifying and analysing individual risk groups it should be noted, that in accordance with the 20 April 2004 Medical Products Act, there are four classes of medical products: I, IIa, IIb and III, which indicate a risk related with the use of a medical product. Classification was made, taking into account the criteria of invasiveness of the product, the place of contact and the place of use. The product class is established by the manufacturer, taking into account the anticipated use of the product\(^3\).

Risk factors:
- chemical compounds – lead, asbestos,
- reagents, drugs,
- bodily fluids,
- poisonous waste,
- compounds hazardous due to other reasons – flammable, chemical catalysts, explosives etc.

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\(^3\) 20 April 2003 Medical Products Act, chapter 3 – Classification and qualification of medical products (Dz. U. no. 93 of 30 April 2004).
VI group: Medical equipment and tools
   Risk factors:
   - life support equipment,
   - rehabilitation equipment,
   - diagnostics and prevention equipment,
   - imaging equipment,
   - sterilization and autoclaving equipment,
   - ionizing radiation,
   - the use of screens and displays,
   - vending machines,
   - devices connected to the current,
   - periodical inspections and maintenance.

VII group: Accidents
   Risk factors:
   - injuries requiring first aid,
   - fires,
   - hazardous spills,
   - choking on food, drugs,
   - cuts, damages to the skin.

VIII group: Other
   Risk factors:
   - violence, threats,
   - working in dangerous places,
   - noise,
   - stress influencing the mental condition.

In order to effectively manage the risk, individual risk groups should be not only precisely identified, but also a strategy should be created, enabling a systematic analysis and assessment of the risk.

Materials and methods

A team of specialists⁴, which undertook an innovative risk management enterprise, initially at a hospital in Swidnica, has created a map of “black spots” (areas with a significant concentration of adverse events), that is established “especially dangerous places, which correspond to a point event (...)” [1].

⁴ The team consists of: Director of the Swidnica hospital – Jacek Domejko, assistant professor Mariusz Piechota – anaesthesiologist from the University Clinical Hospital in Lodz, prof. Michal Marczak, Aleksandra Sierocka PhD.
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In the health care system medical entities, the following places are considered black spots [7]:

- especially dangerous, which are point events (ward, operational unit, central sterilisation point of the hospital, pharmacy etc.) or specific medical procedures which, when performed incorrectly, contribute to the occurrence of complications,
- special concentration of adverse events, the occurrence of which is more frequent than the average number of events aggregated in accordance with the accepted measurement scale.

The black spot method uses an event tree analysis and fault tree analysis method\(^5\) [10]. It qualifies an adverse event as a black spot, and then establishes its risk levels. This method is repeatable and has an algorithmic block structure, that is after eliminating previously specified and ordered black points (among these which may be removed), one “moves onto” another level of ordering, on which a repeated risk analysis is performed [10].

The method of black spots used for the research\(^6\) forms a whole in connection with other risk management methods (event tree analysis, fault tree analysis, expert analysis, epidemiological monitoring) [7]. Its first stage (initial results and conclusions will be analysed and presented in this article) is the identification of adverse events, which occurred during hospitalization. Subsequent stages will include detailed ordering (up to three levels), statistical analysis of medical events, and then presenting remedial actions [7].

Three departments of one of the Lodz clinical hospitals were included in the research (ophthalmology, cardiology and rheumatology and intensive care). Research material includes case histories and other medical documentation of patients treated in the period since 2011. Until today, 243 of complete case histories were analysed. Special care was paid to: type of stay at the ward (planned/emergency), basic and coexisting diagnosis, basic and additional procedures, injections/insertions of a needle (observation chart of peripheral intravenous needle insertions), presence of a fever and other

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5 Event tree analysis (ETA) and Fault tree analysis (FTA) methods form a graphical representation of causal dependencies, concerning accidental events. They are used as tools for the analysis of economic projects, organisational, business and manufacturing investments, and also for assessing hazards for personnel present at an area, at which the occurrence of hazards to their health and life is present. These methods take into account various adverse event results.

6 Empirical part of the studies and detailed description of the method will be presented in a PhD thesis under the direction of prof. Michal Marczak, entitled “Adverse event risk management using the example of Maria Konopnicka University Clinical Hospital in Lodz”. 
complications, data from the anaesthesiological protocol and survey, drugs taken).

Consultations were also made with specialists, in order to verify and establish which identified events should be qualified as adverse events.

Analysis of test results was performed by taking into account detailed description of adverse event risk factors, such as:

- cause of the event: character and complexity of the surgery, invasive diagnostics, nursing care, doctor actions, hospitalisation conditions: bed occupancy, number of hired medical personnel, existence of procedures and standards; environmental conditions: sanitary and epidemiological condition of the rooms, sterility of equipment and medical materials,
- human conditions: age and sex of the patient, health and coexisting illnesses, personnel qualifications, obeying the existing procedures and standards.

It is important that with every identified adverse event the cause of this event is analysed individually.

**Results**

After analysing 98 medical charts from the cardiological department, 5 medical events were noticed, of which the most frequent was nausea [Tab. 1].

**Tab. 1. Medical events at the cardiology ward**

<table>
<thead>
<tr>
<th>Type of medical event</th>
<th>Number of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>nausea</td>
<td>2</td>
</tr>
<tr>
<td>38.6° fever</td>
<td>1</td>
</tr>
<tr>
<td>infection</td>
<td>1</td>
</tr>
<tr>
<td>rash</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>5</strong></td>
</tr>
</tbody>
</table>

Source: own work on the basis of research material forming the empirical part of a PhD thesis

At the ophthalmology ward during the analysis of 98 case histories, 14 medical events were identified [Tab. 2].

At the intensive care ward after an analysis of 47 case histories, 62 medical events were identified. It should be noted that with one patient multiple events may occur simultaneously [Tab. 3].
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Tab. 2. Medical events at the ophthalmology ward

<table>
<thead>
<tr>
<th>Type of medical event</th>
<th>Number of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>inflammatory reaction after intravenous insertion of a needle</td>
<td>4</td>
</tr>
<tr>
<td>eyelid oedema</td>
<td>1</td>
</tr>
<tr>
<td>inflammatory reaction in the vicinity of the eye</td>
<td>1</td>
</tr>
<tr>
<td>vomiting</td>
<td>5</td>
</tr>
<tr>
<td>raised temperature</td>
<td>1</td>
</tr>
<tr>
<td>infection of upper respiratory tract</td>
<td>1</td>
</tr>
<tr>
<td>allergic rash in the vicinity of wrists</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>14</strong></td>
</tr>
</tbody>
</table>

Source: own work on the basis of research material forming the empirical part of a PhD thesis

Tab. 3. Medical events at the intensive care ward

<table>
<thead>
<tr>
<th>Type of medical event</th>
<th>Number of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>bradycardia</td>
<td>14</td>
</tr>
<tr>
<td>apnoea episodes</td>
<td>7</td>
</tr>
<tr>
<td>enlarged, distended stomach</td>
<td>5</td>
</tr>
<tr>
<td>retention of mucus in the respiratory tract</td>
<td>5</td>
</tr>
<tr>
<td>vomiting</td>
<td>4</td>
</tr>
<tr>
<td>tachycardia</td>
<td>4</td>
</tr>
<tr>
<td>green stool</td>
<td>2</td>
</tr>
<tr>
<td>blood leaks, erosion around the probe pipe</td>
<td>2</td>
</tr>
<tr>
<td>skin allergy after giving paracetamol</td>
<td>1</td>
</tr>
<tr>
<td>desaturation at the pressure of: 115/80</td>
<td>1</td>
</tr>
<tr>
<td>a lot of thick secretion in the intubation tube</td>
<td>2</td>
</tr>
<tr>
<td>suppurative discharge from the wound</td>
<td>1</td>
</tr>
<tr>
<td>hiccups</td>
<td>1</td>
</tr>
<tr>
<td>metabolic acidosis</td>
<td>1</td>
</tr>
<tr>
<td>presence of fluid in the pleura</td>
<td>1</td>
</tr>
<tr>
<td>difficulty in wound healing</td>
<td>1</td>
</tr>
<tr>
<td>serum and blood contents of the wound</td>
<td>3</td>
</tr>
<tr>
<td>large amount of partially digested food discharges through a fistula</td>
<td>1</td>
</tr>
<tr>
<td>probe in the duodenum and in the stomach drains brownish-bloody contents</td>
<td>1</td>
</tr>
<tr>
<td>rash over the entire body</td>
<td>1</td>
</tr>
<tr>
<td>allergic rash, mainly on the face</td>
<td>1</td>
</tr>
<tr>
<td>serum and blood contents of the drainage tube</td>
<td>1</td>
</tr>
<tr>
<td>redness and oedema at the needle insertion site</td>
<td>1</td>
</tr>
<tr>
<td>dysplastic and inflammatory changes of the lungs</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>62</strong></td>
</tr>
</tbody>
</table>

Source: own work on the basis of research material forming the empirical part of a PhD thesis
Discussions and conclusions

The actions described above were intended to identify adverse events, in order to enable further analysis using the black spots method. The initial isolation and grouping of the events, after the analysis of documentation from three wards of a Lodz clinical hospital, it shows that from 81 events, which could have an adverse influence on the course of patient’s hospitalisation, the lengthening of the hospital stay, worsening of health, 76.5% of all events are incidents which occurred at the intensive care ward (62). It is related mainly to the profile of the ward (i.e. a higher probability of hospital infections, complications, more specialised procedures), patient’s health (resistance), longer hospitalisation stay (average duration of patient’s stay at the intensive care ward – 9.8 day, at cardiology – 3.8 day, ophthalmology – 2.7). The most frequently occurring medical events included: bradycardia (14 times – the probable reason may be: congenital heart defect, drugs provided, heart surgery complications, electrolyte imbalance and other), apnoea episodes (7) and vomiting (5).

When constructing risk management and hospital safety improvement programmes (not only for patients) using the black spots method, it is possible not only to lower the costs borne by a given medical entity, but what’s most important, to reduce the amount of deaths [6–7].

The method described above has high efficiency, on the condition, that the remedial procedures will be created on the basis of specific medical events existing at individual wards – the individual approach enables to increase the effectiveness of the described method.

Effective identification, classification and assessment of adverse event sources, establishing their range and influence on the conducted activity, and then undertaking actions to minimise their influence reduces the level of risk at the institution.

Every medical entity should introduce a risk management system or at least should use effective tools enabling the minimisation of the amount of adverse events, including medical ones, not only to improve patient’s safety but to reduce the costs or improve logistics. The main goal should be to reduce the amount of complications and patient mortality [1]. When creating safety improvement and risk management programmes in medical entities the specifics of a given institution and ward should be taken into account and a plan of action should be created, adapted to its needs and possibilities.

It should be remembered that the entire personnel working at the facility should be involved in this process. The ability to reduce and manage
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the risk will reduce the amount of adverse risks, improve patient’s treatment quality and even reduce the costs of the hospital.

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