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Błędy lekowe na Oddziałach Intensywnej Terapii
Drug errors in Intensive Care Units

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Streszczenie

Błędy ludzkie stanowią ogromne zagrożenie dla zdrowia i życia pacjentów hospitalizowanych. Często prowadzą one do nieumyślnego spowodowania śmierci albo znacznego uszczerbku na zdrowiu. Przyczyniają się do tego w głównej mierze błędy medyczne w zakresie podań leków, którym jak się okazuje w znacznym stopniu można by było zapobiec. Błędy takie zdarzają się wśród różnych grup pacjentów zarówno tych najmłodszych, jak i tych nieco starszych. Najbardziej narażone na błędy tego typu są Oddziały Intensywnej Terapii, gdzie podaje się bardzo silne leki, które mają zapewnić dogodne warunki do przeprowadzenia operacji w znieczuleniu ogólnym. Najczęściej takie leki podawane są w sposób dożylny, gdyż ta droga podania zapewnia najszybsze ich działanie. *Anestezjologia i Ratownictwo 2022; 16: 97-104. doi:10.53139/AIR.20221613*

Słowa kluczowe: błąd lekarski, oddział intensywnej terapii

Abstract

Human errors pose a huge threat to the health and life of hospitalized patients. They often lead to manslaughter or serious damage to health. This is mainly due to medical errors in administering drugs, which, as it turns out, could be prevented to a large extent. Such errors occur among various groups of patients, both the youngest and those slightly older. The most prone to errors of this type are Intensive Care Units, where very strong drugs are administered to ensure convenient conditions for surgery under general anesthesia. Most often, such drugs are administered intravenously, as this route of administration ensures their fastest action. *Anestezjologia i Ratownictwo 2022; 16: 97-104. doi:10.53139/AIR.20221613*

Keywords: medical error, intensive care unit

Introduction

Medical errors, especially in anesthetic practice, are quite frequent [1]. Generally speaking, a medical error is any procedure that deviates from the generally recognized precautionary principles. Human error is a high risk for hospitalized patients. It is estimated that approximately 100,000 to 400,000 deaths per year in the USA (United States of America) are due to medical malpractice [2]. This is due to medical errors, with errors occurring in about 5.3% of drug administrations during surgery [2]. This study considers that 70.3% of the errors could have been avoided [2]. Treatment errors are the main cause of morbidity and mortality in hospitalized patients [3]. Anesthesiology practice is particularly vulnerable to making a mistake due to the necessity to administer a wide range of very strong drugs [3]. In intensive care units, drugs with very different effects are often administered. Often, muscle relaxants, vasopressors and vasodilators are administered during one anesthesia, sometimes even simultaneously [3]. Due to the high potency, variety and frequency of drugs administered to patients under anesthesia, the risk of catastrophic errors seems not low [3]. The Institute of Medicine has announced that medication errors are the most common type of error encountered in healthcare [4]. They account for 19% of all adverse events and are responsible for over 7,000 deaths annually [4]. It is estimated that the frequency of medication errors in adult intensive care units may fluctuate around 947 per 1,000 patient-days, with a median of 105.9 per 1,000 patient-days [4]. Drug formulation is an important factor that may contribute to medication errors. The challenges associated with drug formulation are specific to different drug administration groups, although errors in the appearance and labeling of drugs appear in all forms and routes of drug administration [4]. Based on USA statistics, there are 1.5 million preventable ADEs (drug-related adverse events) each year, and hospitalized patients have at least 400,000 ADE per year. This number is equal to one patient treatment error per day [4,5]. Not all ADEs cause harm. On the other hand, those that result can be costly in terms of direct, indirect and opportunity costs. ADE-related costs that hospitals still face and that could be prevented amount to approximately $ 3.5 billion in the US [4,5]. In contrast, in outpatient settings, the annual cost of drug-related morbidity and mortality was estimated at approximately $ 177.4 billion in 2000, and this figure continues to grow [4,6].

Obstacles, challenges and difficulties in the intensive care unit

Intensive Care Units pose a particular challenge when it comes to errors in treatment [4,7]. They are a very dynamic environment with often critically ill patients who often require quick adaptation of the current procedure [4]. ICUs (Intensive Care Units) are facilities prone to errors where even minor adverse events may lead to serious disability [4,8,9,10]. It is assumed that medical errors may constitute up to 78% of all medical errors in ICU, with an average of 1.75 medical errors per patient per day [4,11]. Treatment errors in the ICU are not only more frequent, but also more serious, and cause greater damage [4,12]. Many factors contribute to the high frequency of errors in ICU treatment [4]. As ICU patients are usually elderly and with comorbidities, they are more prone to pharmacological errors. These patients require more care and receive relatively more medications that may weaken the body, in addition, such patients may be at greater risk of iatrogenic harm. Moreover, the pharmacokinetics of drugs may also change in critically ill patients, mainly due to changes in the volume of distribution and drug clearance [10]. The pharmacokinetics of many drugs are influenced by, among others, high volume resuscitation, positive pressure ventilation, surgery, systemic inflammatory response, and changes in protein binding that are characteristic of ICU patients. Drugs used in the ICU are more powerful, require dose calculation, and also interact with various drugs and are continuous infusions (they have a greater potential for error) [4,13].

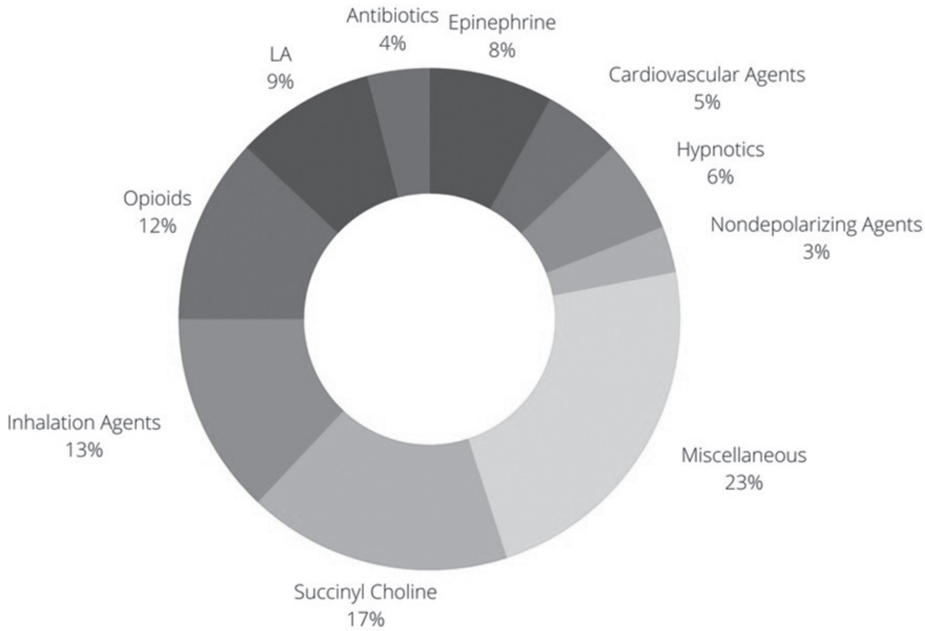
Medication errors in intensive care units

Drug-related medication errors accounted for 4% of claims in the ASA (American Society of Anesthesiologists) Project Report (2003).

Tabela I. Najczęstsze błędy w podawaniu leków
Table I. Common medication errors

Omission	No drug was given
Repeating	Additional dose of the intended drug
Substitution	Wrong drug instead of desired drug: switch
Insertion	A drug that is not to be administered at a specific time or at any time
Incorrect dose	Inappropriate dose of the intended drug
Invalid route	Inappropriate route of the intended drug
Another	Usually a more complex event that does not fit into the above categories

According to the reports of the Closed Claims Project (2003), out of 205 claims relating to a drug-related error case, there were only two “omissions”, four “wrong route” cases and no “duplications” [3]. There were also reported 50 cases of “substitution” (24%), 35 cases of “insertion” (17%), 64 cases of “incorrect dose” (31%) and 50 cases of “other” (24%) [3]. Drug infusions included 30 cases (15%). The most



Rycina 1. Grupy leków najczęściej powodujących błędy w farmakoterapii na OIT
Figure 1. The groups of drugs most often causing errors in pharmacotherapy in the ICU

frequently administered drug was succinylcholine [3]. Medication errors often had very serious consequences. There were 50 deaths (24%) and 70 cases showing significant morbidity. Many different drugs have been involved in errors [3]. In particular, they concerned two drugs: succinylcholine and epinephrine. Succinylcholine was involved in 35 cases (17%), and epinephrine in 17 cases (8%) [3].

The main cause of a drug error is misidentification of the ampoules or vials of the drug. Labels drawn up in a misleading, inaccurate or incomplete manner accounted for 21% of actual or potential medication errors reported to the US Pharmacopoeia Physician Network over a period of one year (1999) [3,14]. The following factors influence the recognition and identification of an object: shape, color, brightness and contrast. As these elements become more and more characteristic, drug identification becomes simpler and is burdened with a lower risk of error [15-17]. The American Society of Anesthesiologists has expressed its approval of the manufacture and use of pharmaceuticals with labels that meet the following standards that conform to the standards established by the American Society for Testing and Materials (ASTM) [3]. A fundamental change to the drug's label is the introduction of a critical information panel or field. The label shows the general name of the drug, total amount per total volume, and drug concentration in black text against a white background [3]. In addition, the label should also include the proprietary name of the drug, manufacturer, batch number, manufacturing date, and expiration date. There are recommendations that the text on the label should be designed in such a way as to increase the recognition of the name and concentration of the drug, in accordance with the recommendations of the international ASTM standards [3]. There are nine classes of drugs used in anesthetic practice. They have the standard background color established for user-use syringe labels in accordance with the international ASTM standards. In addition to the visual aspect, the basic information including the generic name of the drug, concentration and volume of the vial or ampoule should be marked with a barcode in an appropriate, not interfering with legibility of the labels, place on the vial or ampoule. There is another risk associated with the use of color-coded syringes. Namely, commercially available color-coded syringes have different, easily recognizable colors for different classes of pharmacological drugs, however, there are often many drugs in a class, each of which generally has different properties. All these drugs are available in the same color coding and, additionally, probably in the same syringe size [3,18]. Unlike in anesthesia practice, where one drug in each class is usually used, commercial systems fully provide access to many different agents in a class that are marked with the same syringe color, which may lead to errors in drug selection [3]. For example, morphine, fentanyl and pentazocine, three drugs of different strength, each contained in a blue syringe. Mixing these drugs can cause great harm.

In addition, there are many other causes of medication errors, for example combining drugs in one syringe or a bottle of infusion fluid, if the summary of product characteristics contains information on the contraindication to such combinations [19]. This may lead to a change in pharmacological parameters, may reduce efficacy and may increase the risk of potential complications [19]. In addition, the use of an inappropriate solvent or the wrong amount of solvent, incorrect duration of intravenous drug infusion, inappropriate drug administration in relation to food or enteral nutrition, which may change the benefit-risk balance of drug administration [19].

Adverse drug interactions in the ICU

The most important of the analgesic drugs used in ICUs are opioid analgesics, which may cause side effects in clinical practice. This applies to patients taking morphine, oxycodone and fentanyl [20]. Morphine shows a synergistic effect with opioid analgesics, inhalation and intravenous anesthetics and sedatives [20]. Their combination may result in a drop in blood pressure, excessive sedation, coma and apnea [20]. B-blockers and antihistamines, in particular hydroxyzine, increase the depressant effect of morphine on the central nervous system (CNS) [20]. Concomitant use with MAO inhibitors (monoamine oxidase) may result in the stimulation or inhibition of CNS function associated with hypertension or hypotension [20]. The combination of morphine and diclofenac is also not recommended, as it may inhibit the glucuronidation of morphine and increase its effect, which may translate into a greater risk of side effects [20]. Fentanyl has a synergistic effect in relation to drugs that depress the CNS [20]. Speaking of drugs that depress the CNS, I mean first of all barbiturates, benzodiazepine derivatives, neuroleptics, halogen anesthetics, drugs blocking neuromuscular conduction, opioids, antihistamines with sedative effect [20]. If fentanyl is combined with these drugs, the dose of fentanyl should be reduced and caution should be exercised due to its depressant effects on the respiratory center [20]. Strong inhibitors of cytochrome P450 CYP3A4, including ritonavir, itraconazole, and clarithromycin, may increase blood fentanyl [20]. Concomitant use of beta-blockers and fentanyl increases the risk of bradycardia. Remifentanil enhances the effects of anesthetics and benzodiazepine derivatives [20]. Remifentanil must not be combined in one solution with propofol, lactated Ringer's solution or a mixture of 5% glucose and lactate-buffered Ringer's solution [20]. Concomitant administration of sufentanil and ranitidine should not be carried out as ranitidine prolongs its metabolism. MAO inhibitors exacerbate respiratory depression following sufentanil. Concomitant administration of a derived benzodiazepine may result in a decrease in mean arterial pressure and a decrease in peripheral resistance. They may also cause bradycardia in patients taking calcium beta-blockers, verapamil and diltiazem. Moreover, itraconazole and ritonavir may inhibit the metabolism of sufentanil [20].

Dobutamine increases myocardial contractility through strong stimulation of B1R (B1 receptor for bradykinin) with mild to moderate B2R agonism (B2 receptor for bradykinin) and mild A1R agonism (A1 receptor for adenosine) [21]. The combination of dopamine and dobutamine at a dose of 7.5 μg/kg/min improved haemodynamics more than any of these drugs at a dose of 15 μg/kg/min in cardiogenic shock [21]. This shows the role of low-dose combination therapy in patients with hypotension requiring inotropic support [21]. Dobutamine may cause sub-additive inotropic effects in combination with epinephrine [21]. Some sources indicate a competition in B1R that mimics a partial agonist [21]. β-blockers weaken the effect of dobutamine [20]. Similarly, dobutamine and furosemide should not be combined with other alkaline substances, as it causes the inactivation of dobutamine [20]. Dobutamine should not be used simultaneously with salbutamol and MAO inhibitors [20]. Particular care should be taken with noradrenaline, especially when administered with MAO inhibitors and amitriptyline, as it may increase the risk of long-term hypertension [20].

The efficacy of sedative drugs may be modified by pharmacokinetic and pharmacodynamic interactions induced by other drugs. As a result of the interaction, there may be a reduction in effectiveness, and this may indirectly correlate with the phenomenon of "too shallow" analgosedation, which is usually responsible for an increased response to stressful situations, hypoxemia, myocardial ischemia, prolongation of ICU stay, increased treatment costs and the appearance of anxiety attacks. Drugs used in the ICU may cause mental disorders in patients, for example the occurrence of anxiety reactions or sleep disorders, which may consequently affect the effectiveness of drugs used in sedation protocols [20].

Non-steroidal anti-inflammatory drugs (NSAIDs) may shorten the duration of sleep and may additionally reduce sleep.

Catecholamines (dopamine, norarenaline and adrenaline) may induce sleep depletion and sedation. The effects on the receptors of the adrenergic system as well as the agonistic effect of dopamine in relation to the D2 receptors are described here [20,22-24]. β-blocker character With large volumes of distribution, such as propanolol, betaxolol, for example, may be responsible for insomnia and nightmares. Nightmares and, in some cases, reduction of sedation may also be caused by amiodarone, which has been classified into the third group of antiarrhythmic drugs according to Vaughan Wiliams [20,22-25]. Glucocorticoids (glucocorticoids) may be responsible for reducing melatonin secretion, which may cause delirium in the patient, especially in the elderly.

Fluoroquinolones and antidepressants from the group of serotonin reuptake inhibitors (SSRIs) cause insomnia and the reduction of sedation. The combination of fluoroquinolones with SSRIs may reduce the effectiveness of sedatives, including benzodiazepines. Phenytoin may be responsible for side effects in the form of interrupted sleep [20,24,25].

There are two drugs that cause particularly unfavorable interactions in ICU patients - midazolam and haloperidol. Midazolam is a drug that enhances the central effect of analgesics and anesthetics [20]. When taken simultaneously with opioid analgesics, it increases the sedative effect and, at the same time, may lead to cardio-respiratory depression. Blood pressure may drop significantly when a high dose of fentanyl is combined with midazolam. Intravenous midazolam reduces the need for halothane used to maintain general anesthesia [20]. In addition, the drug reduces the risk of tachycardia, as well as limits the increase in blood pressure, which is caused by ketamine. Rifampicin reduces the concentration of midazolam in the blood. Cycloserine, amiodarone and classic neuroleptics are responsible for inhibiting midazolam hydroxylation. The second drug, haloperidol, administered simultaneously with drugs prolonging the QT interval, such as procainamide, amiodarone, sotalol, moxifloxacin or intravenous erythromycin, increases the risk of ventricular arrhythmias [20]. Such combinations in pharmacotherapy are not recommended. It is also not allowed to combine haloperidol with drugs disturbing the electrolyte balance, for example with loop diuretics [20]. This combination may result in ventricular arrhythmias. Drugs such as carbamazepine, phenobarbital and rifampicin can lower the plasma concentration of haloperidol [20]. Haloperidol enhances the action of CNS depressants and, at the same time, may weaken the effect of adrenomimetics, as well as reverse the action of agents lowering blood pressure that block adrenergic receptors [20].

Among the unfavorable interactions with antibacterial and antifungal drugs, various types of combinations are distinguished, including clindamycin, fluoroquinolones, as well as azole antifungal drugs [20]. Erythromycin in combination with clindamycin may reduce the antibacterial effect of clindamycin [20]. Erythromycin inhibits the metabolism of fluconazole and itraconazole, which may increase the risk of hepatotoxicity [20]. Blood creatinine levels may increase when ciprofloxacin, levofloxacin and cycloserine are administered simultaneously. Therefore, it is important to control this parameter in hospitalized patients [20]. The combination of omeprazole and ciprofloxacin may reduce the activity of ciprofloxacin [20]. It is also noteworthy that fluoroquinolones, due to their affinity to the picrotoxin site in the GABA receptor complex, result in a significant reduction of the seizure threshold [20]. This risk increases after the age of seventy, after injuries, after CNS procedures, and as a result of taking medications that lower the seizure threshold [20].

Studies indicate that relatively frequent interactions in ICUs occurred with the use of linezolid [20]. Linezolid should not be used concurrently with rifampicin, as it may reduce the effectiveness of linezolid [20]. Due to its serotonergic effect, linezolid may lead to an increased risk of serotonin syndrome when polytherapy is used with other serotonergic drugs.

Medication errors under pediatric anesthesia

Studies have been conducted in which events related to medication errors were analyzed [26]. Drug errors are classified by: drug category; type of error by phase of administration: prescribing, preparing, or serving; bolus or infusion error; type of organizer and level of training; harm as defined by the National Coordination Council for the Reporting and Prevention of Medicines Errors; and the perceived possibility of prevention [26]. A total of 276 treatment errors were reported, which constitute the third most common event category after cardiac and respiratory events [26]. In the case of pediatric anaesthesiology, errors in treatment most often concerned opioids and sedatives / hypnotics [26]. In line with the treatment phase classification, 30 events were recorded during preparation, 67 during prescription, and 179 during administration. Undoubtedly, the most frequent mistakes were administering the wrong dose and then changing the syringe [26]. In 57 events, treatment errors were reported for drugs prepared as infusions, as opposed to single bolus administrations [26]. All anesthetists made mistakes in medication use. Most often, these incidents happened during visits. Studies have shown that more than 80% of the errors reported have affected patients and more than half of these cases have resulted in harm to patients. Fifteen cases (5%) required a life-saving intervention. It is extremely important that almost all of these errors (97%) could be prevented.

Discussion

ICU errors are quite common. However, as previously mentioned, the vast majority of ICU errors were preventable. There are several ways to help reduce medication errors in medication. One of them is special attention and concentration during the shift. Particular attention should be paid to the risks associated with each patient's drug management, especially drugs that are taken by patients on a long-term basis and those at high risk. Human and organizational factors are also extremely important. Simulators or e-learning tools and scenario-based learning activities that mimic specific situations can be of great help [27]. Cooperation between doctors of various specialties is also very important, not only before the procedure, but also during the usual daily treatment of the patient. Physicians should also use the expertise of pharmacists to the extent possible in order to ensure the best pharmacological supply for their patients [27]. Before the procedure, doctors should know and be aware of the chosen organizational system. Also, attention should be paid to establishing the roles of all people potentially involved in the process of agreeing drugs for patients, not only doctors, but also nurses and pharmacists. It would be extremely valuable to provide specialists in the areas of patient care with interdisciplinary lifelong learning in the field of risk management and the proper use of management devices. It is also important to prevent mistakes made in the preparation, reconstruction and administration of drugs. Training could include the handling of pumps and injectors, infusion lines and their accessories, undesirable mechanical events, human-machine interface, and the ergonomics of inappropriate equipment [27]. When it comes to avoiding errors in administering drugs to patients, there are several rules that should be followed in this regard. These include reading labels carefully before administering them, applying the five laws principle, which covers the right drug, in the right dose, at the right time, in the right way, to the right patient [27]. In addition, devices that reduce errors can be used, as well as barcode readers, establishing drug preparation and administration protocols, limiting drug delivery lists and avoiding similarities in color and name, and reporting and analyzing drug errors. In addition, you should consult a pharmacist on a regular basis on the ward. It is also helpful to have programmable feed syringes connected to the computer. You also need to be very vigilant about the sedatives and vasoactive drugs involved in most ICU treatment errors. The first and foremost prevention of preparation errors is to proactively check the information on medicine packs, which you should read carefully. Additionally, the storage system should be transparent, formally defined and common to all facilities, including emergency supplies. The specialists who are responsible for the preparation of drugs should be clearly identified, and their verification must be carried out at specified intervals, and should be recorded. It is important not to prepare your medication in advance and you should also take measures to avoid medication confusion. These include, for example, the availability of only those drugs that are absolutely necessary in treatment. In addition, drugs should be available in doses and concentrations that are routinely used. If there is a similarity in the color, shape or name of the drugs, the dispensers should be informed to increase their alertness. Storage of high--risk drugs is not recommended [27]. However, if there is such a need, these drugs should be properly secured. The personnel should also be informed about possible dangers. The identification of administrative routes is also very important [27]. The route of administration should be indicated on each label. It is also important to remember that certain procedures and protocols must be validated in order to prescribe, prepare and administer ICU medications. In particular, the dilution, solvent, duration, speed and route of administration must be determined. In the event of an actual or potential treatment error, the event should be analyzed using a validated method [27]. Feedback about the event should be shared with the team involved and, under certain circumstances, with other departments.

Summary

Mistakes happen in all age groups, both in adults and children. The vast majority of them are quite easily preventable. The key to success is to use pre-filled drug syringes to avoid accidental ampoule swapping. Drugs should be appropriately labeled, for example with barcodes at the site of drug administration, in order to avoid changing the syringes and confirming the correct dose, and to control the infusion of drugs by two people to obtain more accurate administration of the drug. Generally speaking, medication errors are a consequence of the human condition. Even the most qualified and conscientious doctors can make such a mistake. Over the past two decades, anesthesiology has made many strides in improving patient safety, resulting in reduced morbidity and mortality.

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