

Patient safety in the process of pharmacotherapy carried out by nurses – A Polish-Slovak prospective observational study

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Abstract

Aim

This study was aimed at the determination and comparison of safety levels at the nurse-managed stage of the pharmacotherapy process in Poland and Slovakia by identifying the key risk factors which directly affect patient safety.

Background/Introduction:

Pharmacotherapy, i.e. the use of medicines for combating a disease or its symptoms, is one of the crucial elements of patient care. Studies carried out with regard to nursing workloads in the pharmacotherapy process prove that nurses spend 40% of their work on the management of medications. Medicine administration is the most frequent task of all nursing activities, and there is a possibility of committing errors at this stage due to the complex and multifaceted nature of the pharmacotherapy process.

Methods

The study involved a group of 1774 nurses, of whom 1412 were from Poland and 362 from Slovakia. The original Nursing Risk in Pharmacotherapy (NURIPH) tool was used. The Cronbach alpha coefficient was 0.832.

Results

Nurses from Slovakia most often, i.e. for 6 out of 9 factors (items: 1, 5, 6, 7, 8, 9), assessed the risk factors as “significant risk (3)”, and Polish nurses most often, i.e. for as many as 8 out of 9 risk factors (items: 1, 2, 3, 4, 5, 6, 7, 9), assessed the risk factors as “very significant (5)”. Significant differences ($p < 0.05$) were demonstrated in 8 (out of 9) risk factors.

Conclusions

The pharmacotherapy process implemented by nurses, regardless of the country, is burdened with a considerable number of risk factors and it might negatively affect patient safety. It has been found that the safety of the pharmacotherapy process is assessed by Polish nurses as much lower than by Slovak ones. Training activities in the field of adverse events, adverse reactions to medications and appropriate and effective communication should be introduced for all members of the medical staff involved in the pharmacotherapy process.

Background/introduction

Pharmacotherapy, i.e. the use of medicines for combating a disease or its symptoms, is one of the crucial elements of patient care. The proper course of pharmacotherapy has an impact on patient recovery, alleviation of symptoms and improvement of the health and quality of life of patients. The administration of medications is of essential importance for patient safety, and medication administration errors (MAEs) are directly related to mortality and morbidity rates [1,2]. Studies on nursing workloads in the pharmacotherapy process prove that nurses spend 40% of their work on the management of medications [3]. Keohane et al. note that medicine administration is the most frequent task of all nursing activities, and there is a possibility of committing errors at this stage due to the complex and multifaceted nature of the pharmacotherapy process [4].

The dynamics of a safe medicine administration process can be disturbed by the number of patients per nurse, their clinical condition and comorbidities, fatigue and stress of the nursing staff, inadequate working conditions and disturbances in the communication in the interdisciplinary team involved in the medicine management process [5,6,7].

It has been revealed that the most frequent errors in the pharmacotherapy process are the prescription of medicines (46%) and medicine administration (41%) [8].

Dean BS et al. in their study aimed at the formulation of a definition of prescribing errors, made a distinction to cognitive errors (related to the decision-making by physicians, for example prescribing a medication for a patient for whom that medication is contraindicated) and technical errors, such as an illegible order, using abbreviated medication names, entering "milligrams" instead of "micrograms" etc [9].

Nurses can contribute to technical errors, and the prevention of such errors depends not only on the professionalism of nurses but also on organizational factors and the work environment. There are numerous alarming risk factors that contribute to the occurrence of errors in nursing practice. The most significant of them include burnout, understaffing and heavy workload [10,11,12]. In order to prevent errors in the pharmacotherapy process, nurses have to use strategies, such as the discrimination of high-risk medications, separating medications with similar names, error analyses and increasing the awareness of medication errors [13,14].

Aim of the study

This study was aimed at the determination and comparison of safety levels at the nurse-managed stage of the pharmacotherapy process in Poland and Slovakia by identifying the key risk factors which directly affect patient safety.

Methods

Design and settings

The survey was conducted in the period from May 2019 to September 2019 in cooperation with the Supreme Chamber of Nurses and Midwives in Poland and the Slovak Chamber of Nurses and Midwives.

In Poland messages were sent to the District Chambers of Nurses and Midwives with information about surveying pharmacovigilance safety among nurses. The invitation to participate in the study was accompanied by a link to the website where the questionnaire was placed. In Slovakia, the distribution of the test link was similar. The link to the questionnaire was sent by e-mail via the central register of nurses of the Slovak Chamber of Nurses and Midwives.

Study participants

The criterion for inclusion in the study was the possession of a valid licence to practice as a registered professional nurse and documented professional activity. The study involved 1774 participants from all over Poland and Slovakia, including 1412 nurses from Poland and 362 nurses from Slovakia. The survey excluded 467 subjects who did not complete the questionnaire; thus the results were not completed and, as such, rejected from further analysis.

Data collection

The NURIPH questionnaire was available on the website throughout the survey. In Poland, the link to the questionnaire has been published on the website of the Supreme Chamber of Nurses and Midwives and the website of the District Chambers of Nurses and Midwives. In Slovakia, the link was sent by e-mail via the central register of nurses of the Slovak Chamber of Nurses and Midwives. Also, the study was promoted during national conferences dedicated to nurses. Each participant completed an anonymous NURIPH questionnaire via the internet. After completing the questionnaire, participants validated and sent electronically the questionnaire to the platform where the data was collected.

Research tool

The original Nursing Risk in Pharmacotherapy (NURIPH) tool was used. NURIPH's proprietary tool consists of a metric on socio-demographic data and a risk matrix to evaluate selected ergonomic factors triggering risk in the pharmacotherapy process. Nine risk factors were considered in the matrix: 1 – **Poorly legible or illegible medical orders**; 2 – **Inappropriate communication** between physician, nurse, and midwife regarding changes in drug orders; 3 – **Time** pressure during nurse/medical supervision; 4 – **Inappropriate** work organization: preparation of medicines for patients combined with the simultaneous performance of other activities by a nurse/ midwife (for example, answering calls, execution of current diagnostic orders, etc.); 5 – **Lack of clarity** or illegibility of medical orders for nurses and midwives; 6 – **No physician's prescription** of a specific solvent for a particular medicine; 7 – **Shift work** causing psycho-physiological fatigue; 8 – **Limited availability of training** on the effects of medicines, side effects and adverse reactions to medicines used in patients; and 9 – **Preparation of personalized** sheets with the name and dosage of the medicine on the drug tray.

A five-step scale of risk assessment (from 1 to 5) was used to assess the above ergonomic factors: 1 – minor risk, 2 – little risk, 3 – significant risk, 4 – more significant risk, and 5 – very significant risk.

The relationship between the levels of risk in the pharmacovigilance brochure and the likelihood of adverse health effects on the patient and the likelihood of a nurse/ midwife being legally liable is shown in Table 1.

The NURIPH tool has been validated and the Cronbach alpha coefficient for the NURIPH tool is 0.832. Based on the obtained value of the Cronbach alpha coefficient, it should be concluded that the tool is reliable. All items have positive discrimination power (Witczak et al., 2020) [15].

Ethical considerations

The study was fully anonymous and voluntary. The research project was approved by the independent Bioethics Committee of the Wroclaw Medical University (No KB–610/2017). All participants granted their written informed consent after a thorough explanation of the procedures involved. The study was carried out in accordance with the tenets of the Declaration of Helsinki and guidelines of Good Clinical Practices (World Medical Association, 2013).

Statistical analysis

The chi-squared test (with Yates' correction for 2x2 tables) was used to compare qualitative variables among groups. In the case of low values in contingency tables, Fisher's exact test was used instead. The Mann-Whitney test was used to compare ordinal variables between two groups. Significance level for all statistical tests was set at 0.05. The analysis was performed in the R program, version 4.0.3 (R Core Team, 2020) [16].

Results

The characteristics of the study group

The study involved 1774 nurses (1412 (79.6%) nurses from Poland and 362 (20.4%) nurses from Slovakia). Women prevail in the study group – they accounted for 94.9% and 96.4% of the Polish and Slovak groups respectively. Slovak nurses were younger – most of them, as much as 38.4%, were at the age of 40-49 years, and Polish nurses were predominantly (37.6%) at the age of 50-59 years. A noticeably higher percentage of Polish nurses were graduates of master-degree programs compared to Slovak nurses (54% of Polish, and 38.7% of Slovak nurses). With regard to professional experience of nurses in both countries, it has been found that the largest group of nurses have worked for more than 30 years (38.4% in Poland and 28.2% in Slovakia). Nurses from Poland most frequently carried out their work in large cities with more than 500 thousand population (30.3%), and nurses from Slovakia – in cities with less than 50 thousand population (36.5%). More than 60% of Polish nurses and nearly 75% of Slovak nurses declared that they work in no more than one place. The most numerous group of Polish nurses worked in medical treatment wards (27.8%), and most Slovak nurses worked in wards other than surgical and medical treatment wards (66.3%). The characteristics are presented in the Table 2.

Results of the NURIPH risk matrix

The results presented in Table 3 demonstrate that, in general, nurses in Poland assess the safety level of the pharmacotherapy process lower than nurses from Slovakia, i.e. they assess the existing risk factors as very significant. An analysis of individual elements of the risk matrix reveals that nurses from Slovakia most often, that is for 6 out of 9 risk factors (items: 1, 5, 6, 7, 8, 9) assessed them as “significant risk (3)”, whereas Polish nurses most often, that is for as many as 8 out of 9 risk factors (items: 1, 2, 3, 4, 5, 6, 7, 9) assessed risk factors as “very significant (5)”. Significant differences ($p < 0.05$) were demonstrated in 8 (out of 9) risk factors. Only one risk factor was assessed very similarly by both groups, namely the “limited availability of training on the effect of medicines, side effects and adverse reactions to medicines used in patients” – item 8, where $p = 0.399$. The mean score obtained in this case by Polish nurses was 3.62, and by Slovak nurses – 3.54, which means that they assess this factor between “significant risk (3)” and “more significant risk (4)”. A certain similarity can be observed in the assessment of items 2, 3 and 4. Most of both Polish and Slovak nurses assessed the above-mentioned risks as “very significant risk (5)” – namely inappropriate communication between doctors, nurses and midwives regarding changes in drug orders, pressure of time during nurse/medical supervision and inappropriate work organization.

Table 4 presents the results for questions from outside the NURIPH matrix. Values for p below 0.05 indicate significant differences between the groups of nurses from Poland and Slovakia. Nurses from Poland assigned lower ratings to the overall level of pharmacotherapy safety at their work ($p < 0.001$). Moreover, they more frequently claim to be at the highest risk of committing errors (53%), and they less frequently claim that all persons involved are equally responsible for such errors, while Slovak nurses predominantly claim that all persons involved are equally responsible for such errors (82.3%) ($p < 0.001$). Another aspect in the questionnaire was the influence of electronic medical records on the elimination of risk factors in the pharmacotherapy process – nurses from Poland (42.5%) and Slovakia (48%) claim that it will contribute to increasing the safety of pharmacotherapy, but only to a limited extent.

Both groups claim that in the event of incorrect administration of a medicine, the patient affected or his/her family should be informed about such an occurrence (75.6% of Polish nurses and 69.6% of Slovak nurses). There is also a consistency of responses to the question, who should inform the patients or their families about errors committed in the pharmacotherapy process – Polish (62.7%) and Slovak (75%) nurses claim that it is the attending physician or the doctor who issued the prescription who is responsible in this regard. Both in Poland and in Slovakia, the room where nurses prepare medications serves many purposes. Polish nurses as a rule inspect ward medicine stocks once or twice every six months (32.9%), Slovak nurses perform this task slightly more often, i.e. once or twice a month (28.2%). In both countries, regular training courses on the adverse effects of medications usually are provided in places other than the facilities in which nurses perform their work. They also have no possibility to have a consultation with a clinical pharmacologist. With regard to adverse events in the pharmacotherapy process related to the professional experience of nurses, an inverse correlation can be noted, i.e. nearly 70% Slovak nurses experienced them, and, on the other hand, 70% Polish nurses declared that they did not have such an experience ($p < 0.001$).

Discussion

Patient safety is a relatively new research trend; it nonetheless arouses great interest of researchers. The World Health Organization (WHO) for nearly a decade has undertaken numerous actions to promote patient safety, including the promotion of medication without harm. In 2020, WHO declared their Flagship Initiative “A Decade of Patient Safety 2020-2030”. All the more so, the research area explored by the authors of this article proves immensely important taking into account the scarcity of publications on the detailed analysis of risk factors in the pharmacotherapy process. The tools that could be used for this purpose are also scarce.

Undoubtedly, in contemporary healthcare systems, there is a multitude of negative stressors that affect the safety of the pharmacotherapy process. They are related to such factors as nurse understaffing, population aging and the change of patient profile, patients with multiple morbidities and state-of-the-art medical technologies, not infrequently with complex interfaces. These stressors place the frontline medical staff, such as nurses, in a situation in which they can fall short of their standards and be unable to provide the highest quality of care [17].

Authors' own study has revealed that contemporary nurses are working under substantial time pressure (item 3). This could result from the said shortages of personnel and excessive workloads. The consequences could affect the ability to ensure patient safety. Performing work under considerable pressure can be conducive to errors which might entail serious consequences in the pharmacotherapy process. Both Polish and Slovak nurses paid attention to this fact and most of them, in both groups, considered working under time pressure as “very significant risk (5)”.

El-Bannaat et al. emphasize in their work that nurses should be supported in their provision of patient safety and also in their belief that errors in this process are predisposed by a great number of internal factors, such as shift pattern, and external ones, such as demographic or epidemiologic situation, and they should not, in the long run, entail the liability of nurses for incorrect pharmacotherapy [18].

A majority of both Polish and Slovak nurses assessed inappropriate work organization (item 4) as a factor characterized by “very significant risk (5)”. In many medical facilities, the nurse who prepares medications for patients also performs other tasks, such as answering phone calls in the meantime, talking to another person who enters the room in which medications are prepared, etc. The pharmacotherapy process requires intense concentration, and the above-mentioned situations conduce to medical errors. Moreover, it is rarely that separate rooms are assigned for medication preparation with access exclusively for the nurse appointed for that specific task. As demonstrated by research results, both in Poland and Slovakia, medicine preparation rooms serve many purposes. Preparation of personalized sheets with the name and dosage of the medicine on the drug tray poses an additional problem which has been assessed by Polish nurses as “very significant risk (5)”, and by Slovak nurses as “significant risk (3)”.

Studies conducted in Iran on errors in the pharmacotherapy process in teaching hospitals have revealed that the majority of factors are related to the work of nurses, for example, insufficient care of patient medical records, dissatisfaction with work and errors in the calculation of medication doses [19]. These studies are noteworthy, as in 2007 the frequency of errors in pharmacotherapy in Iran was around 2.4–5.6 times higher than in the United States [20].

Polish nurses also paid attention to the legibility of medical documentation as far as medical orders are concerned (item 1). They assessed this factor as “very significant risk (5)”. In Slovakia, in turn, it was assessed as “significant risk (3)”. This might result, among other reasons, from the fact that medical documents in Slovakia is already in the electronic format, while in Poland, not all medical institutions have implemented this solution by the time of conducting this study. Legibility of documentation (especially of medical orders) and medical order deficiencies are other factors that play a significant role in ensuring patient safety. Not infrequently, medical orders fail to provide information on the specific solvent for a particular medicine (item 6). Polish nurses consider it as “very significant risk (5)”, and Slovak nurses - as “significant risk (3)”.

Bryant R. et al. emphasize that the education of nurses by pharmacists/ clinical pharmacologists on the use of some groups of medications, in particular of those from the high-risk group, i.e. narcotics, medications used in cancer treatment, medications for heart diseases, etc., could contribute to reducing errors in the pharmacotherapy process [21].

Unfortunately, the authors’ own research has demonstrated that neither in Poland nor in Slovakia, is there any possibility for nurses to consult a hospital pharmacist/ clinical pharmacologist. What is more, nurses from Poland draw attention to the fact that they are not familiar with the list of generic medications and assess this factor (item 5) as “very significant risk (5)”, and Slovak nurses assess it as “significant risk (3)”. Knowledge deficiencies in safe pharmacotherapy could be eliminated by staff training courses. At the same time, nurses from Poland and Slovakia state that they are not trained on a regular basis, and most of them assess the factor of the availability of training (item 8) as “significant risk (4)”.

The absence of consultation possibilities is a symptom of lacking communication. Communication in a therapeutic team, as emphasized by Soodabeh et al., is of crucial importance [22]. Both Polish and Slovak nurses stated that inappropriate communication in the therapeutic team is a significant risk factor (item 2).

Keers R.N. et al. in their systematic review of literature on medication administration errors (MAEs) in hospital note that many system-related factors contribute to errors in the pharmacotherapy process. It is important not only to differentiate between the types of these factors but also to analyze how they are generated and how they combine to ultimately result in harm to patients. It is therefore of special importance that research on the safety of pharmacotherapy is conducted at both national and international scales with regard to particular healthcare systems [23].

The research project aimed at determining the safety level of the pharmacotherapy process in two neighboring European countries revealed substantial differences between them. It was found that in the Polish healthcare system, the safety level of pharmacotherapy, as assessed by nurses, is lower than that in Slovakia. It constitutes an important impulse for continuing research in this area and providing staff training on an ongoing basis.

Ensuring patient safety is an immensely difficult task, as demonstrated both by the authors' own study and studies conducted by other researchers. Nevertheless, it is an important task not only for medical staff but also for healthcare managers.

Study limitations

Based on the survey and the analysis of the results, the method of data collection should be approached critically. The use of electronic survey available at the link is undoubtedly a very convenient solution – on the one hand, it allows us to quickly reach people who live on the other side of the country and quickly aggregates collected data, which saves time spent on entering data and reduces the risk of error during this process. On the other hand, this solution raises some concerns among the respondents, namely whether this method is entirely anonymous. It was found that a significant proportion of the respondents did not complete their investigation, i.e. did not send a reply to the server because they were afraid that it could be identified.

Implications for nursing management

Based on the results of this study, it should be noted that the proprietary NURIPH tool can be used to identify risk factors in the pharmacotherapy process in hospitals worldwide. A diagnosis based on the results obtained can contribute to the development of new procedures, to the improvement of their quality and safety of the patient, and preventive action. It should be concluded, taking into account the conclusions of the literature review, that the NURIPH tool can be a universal tool for the rapid diagnosis of risks in inpatient medicine worldwide. Moreover, medical and management staff should be trained on patient safety.

Conclusions

Literature review, authors' professional experiences and the results of authors' own study demonstrate that the pharmacotherapy process implemented by nurses, regardless of the country, is subject to numerous risk factors and can adversely affect patient safety. Staff deficiencies, working under time pressure, excessive responsibilities, inadequate work organization, or disturbed interpersonal communication in a medical team can lead to medication errors which can ultimately result even in patient death. It has been found that the safety level of pharmacotherapy is assessed by Polish nurses much lower than by Slovak nurses. The needs for work reorganization continue to be ignored, and they include, at the least, assigning a room to be used exclusively to carry out medical orders, and accessible only to those involved in the pharmacotherapy process. In summary, educational activities dedicated to

the entire medical staff involved in the pharmacotherapy process should be implemented in the field of adverse events, adverse effects of medications and appropriate and effective communication. Managers, in turn, should be made aware that changing work organization, improving work conditions and avoiding accusations and search for persons to blame in a situation of an adverse event can considerably improve patient safety in their organizations.

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