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The Importance of Pharmacovigilance and Ecopharmacovigilance in Nursing Education

Hemşirelik Eğitiminde Farmakovijilansın ve Ekofarmakovijilansın Önemi

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ÖZET

Tıptaki ilerlemelere yeni bilginin birikiminin eşlik etmesi yükseköğretim kurumlarını sağlık bakımı sağlayacak mezunlarını hazırlama şekillerini değiştirmeye zorlamaktadır. Bu makalede amaç, farmakovijilansın ve ekofarmakovijilansın önemi hakkında yükseköğretimdeki hemşirelik akademisyenleri arasında farkındalık yaratmak ve geleceğin hemşirelerinin eğitimindeki rollerinin altını çizmektir. Farmakovijilans farmasötiklerin insandaki advers etkilerini izler. Çevre için bir tür farmakovijilans olan ekofarmakovijilans ise, farmasötiklerin çevredeki ve ayrıca dolaylı yoldan insanlar üzerindeki terapötik olmayan düzeylerde farmasötiklere maruziyete bağlı advers etkilerini izler. Yükseköğretimdeki hemşirelik eğitimi uygulayıcıları mezuniyet öncesi ve sonrası hemşirelik öğrencilerinin akademik performanslarında ilerleme sağlayacak ders programlarını farmakovijilans ve ekofarmakovijilans alanlarında güncel duruma uygun hale getirmelidirler.

Anahtar Kelimeler: Farmakovijilans, ekofarmakovijilans, hemşirelik eğitimi.

ABSTRACT

Advancements in medicine accompanied by the accumulation of new knowledge force higher education institutions to change the way they prepare their graduates to deliver healthcare. The aim of this review is to raise the awareness of the importance of pharmacovigilance and ecopharmacovigilance among nursing academics in higher education and to underline their role in educating future nurses. Pharmacovigilance aims to monitor the adverse effects of pharmaceuticals on patients. Ecopharmacovigilance, as a kind of pharmacovigilance for the environmental, aims to monitor the adverse effects of pharmaceuticals both on the environment and on humans through indirect non-therapeutic exposure. Nursing education administrators in higher education should update their curricula in the fields of pharmacovigilance and ecopharmacovigilance that will yield the improvements in the academic performance of undergraduate and postgraduate nursing students.

Keywords: Pharmacovigilance, ecopharmacovigilance, nursing education.

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Introduction

Advancements in medical sciences and the increased number of nursing faculties have necessitated reminding the importance of the national undergraduate pharmacovigilance education, especially for nursing students. Pharmacovigilance was defined by the “World Health Organization” (WHO) as “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem”. One of the specific aims of pharmacovigilance as defined by the WHO is “to improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions” (WHO 2002; WHO 2004). “Adverse drug reaction (ADR)” was defined by the WHO as “a response to a drug which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function” (WHO 2002).

The history of the WHO Program for International Drug Monitoring begins as a worldwide response to the thalidomide tragedy in the mid-twentieth century. Safety monitoring systems were set up to prevent this tragedy ever happening again and thalidomide was taken off the market in many countries in 1961. The WHO created a collaborative system for international drug monitoring to collect individual reports of suspected ADRs in 1968 (WHO 2002; WHO 2004). The “WHO Collaborating Centre for International Drug Monitoring Uppsala Monitoring Centre (UMC)” was established in 1978 and began to provide technical support to countries to from their national pharmacovigilance centers (PVCs). National pharmacovigilance centers submit “individual case safety reports” (ICSRs) to the “WHO database” known as “Vigibase” (UMC 2004; WHO 2004).

The initiative of starting pharmacovigilance in Turkey was taken in 1985. The foundation of the “Turkish Adverse Drug Reaction Monitoring and Evaluation Center”

(TADMER) under the “General Directorate of Pharmaceuticals and Pharmacy” was the initial step and Turkey became connected to the network of national pharmacovigilance centers in the UMC as the 27th member in 1987 (Republic of Turkey Official Gazette 2005; Ozcan et al., 2016; TMMDA).

In 2005, TADMER was reconstructed with a new name as “Turkish Pharmacovigilance Center” (TUFAM). This reconstruction chose the term pharmacovigilance for the name of the institution to emphasize the subject. Pharmacovigilance in the name of the institution may be interpreted as the global integration of TUFAM into the network of national pharmacovigilance centers; the collaborative system created by the WHO. The “Regulation on the Monitoring and Assessment of the Safety of Medicinal Products for Human Use” was put into effect as the first pharmacovigilance regulation. In 2014, it was updated as the “Regulation on Safety of Drugs” in the context of harmonizing regulation with the EU directives by the Turkish Republic Ministry of Health and the “Good Pharmacovigilance Practices Guidelines” were also published (Ozcan et al 2016; Republic of Turkey Official Gazette 2005; 2014; TMMDA 2014). Hospitals with fifty or more beds have been required to assign “a pharmacovigilance contact person (PCP)”, “a medical doctor, pharmacist, or, where these are not available, a dental practitioner” in the hospital since 2005 (Güner and Ekmekci 2019; TMMDA).

In 2012 “The General Directorate of Pharmaceuticals and Pharmacy” changed its name as the “Turkish Medicines and Medical Devices Agency” (TMMDA) (Ozcan et al., 2016; TMMDA)).

TMMDA, as a single national authority, is responsible for developing and implementing regulatory, supervisory, and steering policies for medicines, medical devices and cosmetics (Mashaki et al., 2018; TMMDA 2010; TMMDA 2016).

Pharmacovigilance, the monitoring of drug safety after marketing approval, can be determined by the proper reporting of ADRs.

Studies have shown that approximately 5% of all acute hospitalizations originated from ADRs (Angamo et al., 2016; Leendertse et al., 2008; Pirmohamed et al., 2004). National Pharmacovigilance Programme has been conducted by TUFAM, since 2005. Nationwide ADR reports are collected in TUFAM, these reports are submitted to TUFAM mostly by two vital sources: “healthcare professionals” and “marketing authorization holders” (MAHs). The “healthcare professionals” responsible for ADR reporting are described as “a physician, pharmacist, dental practitioner, nurse or midwife” in the “Regulation on the Safety of Medicinal Products” in Turkey (Ozcan et al., 2016; TMMDA). As it is described in the regulation in Turkey nursing educators should attach importance to the pharmacovigilance education of their students in both undergraduate and postgraduate programs to meet the demands of the regulation and to protect patient’s safety.

A study evaluating the ADR reports submitted to TUFAM from 2005 to 2014 showed that reporting rates gradually increased since 2005, the type of the ADR reporter and reporting rates determined in the study were as follows: practitioner 59.8%, other healthcare professionals 28.7% and pharmacists 9.1% (Ozcan et al., 2016). A study of nurses conducted in a state hospital in Turkey showed that only 8% of the nurses reported ADRs and only 8% of the nurses knew about TUFAM (Vural et al., 2015). According to a study carried out among practitioners and nurses in Turkey, it was determined that 35.5% of the participants were hearing the term “pharmacovigilance” for the first time (Güner and Ekmekci, 2019). Another analysis this time of community pharmacists, showed that only 17.2% of the pharmacists had any knowledge about “pharmacovigilance” (Toklu et al., 2008). The awareness of TUFAM among physicians and nurses was as low as 30% in a recent study conducted in a university hospital in Turkey (Ergun et al., 2018). Another study evaluating the awareness of pharmacovigilance

and how it was practiced by the nurses and midwives determined that only 23.3% of the participants could correctly define it (Alan et al., 2013). According to a study analyzing the knowledge and attitudes of nurses towards ADR reporting, it was found that 40% of nurses had never submitted ADRs to TUFAM (Şencan et al., 2010). Underreporting is a global problem, which creates health and ethical burden, and reporting rates in Turkey are low compared to those in developed countries (Aydıncarhaliloğlu et al., 2018; Guner and Ekmekci 2019; Usta et.al., 2012). Increasing the knowledge of recognition of ADRs by nurses will increase the quality of pharmacotherapy and vigilance towards unexpected ADRs and the avoidability of ADRs. We propose that nursing managers in hospitals should attach importance to the planning of pharmacovigilance education in collaboration with pharmacology departments in their professional programmes. This will decrease the underreporting originating from their own belief in having insufficient pharmacology knowledge to recognize an ADR and nurses’ limited awareness about their role in pharmacovigilance (Bigi and Bocci 2017). Supporting education in the field of patient safety with continuous pharmacovigilance education and increasing the participation of nurses in reporting ADRs will provide the safe use of medicines and will decrease the economic burden of ADRs on the health care delivery system (Pirmohamed et al., 2004).

We also agree in this review that nurses should have the opportunity to update their knowledge through continuous professional education which may be conducted as servicetraining in the workplaces (bigi and Bocci, 2017; Pirmohamed et al., 2004; Van Eekeren et al., 2018).

Another important issue that must not be forgotten is the afterlife of drugs and the environmental footprints of the healthcare industry due to the active pharmaceutical

ingredients (APIs) in medications and their continued existence as environmental pollutants (Daughton and Ruhoy 2008). The initial steps to protect the environment were taken in the European Parliament's 2010 adoption of amendments to the existing pharmacovigilance legislation that would serve to extend the realm of conventional pharmacovigilance to encompass environmental concerns (Daughton and Ruhoy 2011; Directive 2001/83/EC). In 2010, the term ecopharmacovigilance, first coined by Velo, was defined as "the science and activities concerning detection, assessment, understanding and prevention of adverse effects or other problems related to the presence of pharmaceuticals in the environment, which affect both human and the other animal species" (Holm et al., 2013; Velo and Moretti, 2010). Pharmacovigilance works in the field of adverse effects of pharmaceuticals on patients and ecopharmacovigilance, which can be interpreted as a form of pharmacovigilance focusing on the environmental concerns, aims to monitor the adverse effects of pharmaceuticals both on the environment and on humans through indirect non-therapeutic exposure (Holm et al., 2013). In the literature, there is not a consensus on which term to use, and it features as ecopharmacology (Kummerer and Velo, 2006), environmental pharmacology (Rahman and Khan, 2006), pharmacoenvironmentology (Rahman et al., 2007), pharma Ecovigilance (Daughton 2010; Daughton and Ruhoy 2011), eco-pharmacostewardship (Taylor 2010) and finally ecopharmacovigilance. This latter term ecopharmacovigilance reflects the approach quoted at "The International Society of Pharmacovigilance (ISoP) annual meeting in Ghana in November 2010" (Murray-Smith, 2013) and that endorsed by Velo and Moretti (Velo and Moretti, 2010). The ISoP communicates with the "Environment

Committee of the European Parliament" and "Working Party on Pharmaceuticals and Medical Devices" and works up "to have ecopharmacovigilance as an integral part of pharmacovigilance" (Velo and Moretti, 2010). Accumulated unused, and leftover medications, ultimately becoming chemical waste, represent wasted health-care resources and failures in the administration of health care and are the leading cause of the increasing public health crises of drug diversion and nontherapeutic use. They also contribute to accidental or self-inflicted poisonings (Daughton 2014; Daughton and Ruhoy 2013). There is, therefore, a need to raise nurses' awareness of pharmacovigilance and ecopharmacovigilance and encourage them to adopt proper ADR reporting and safe disposal practices for pharmaceuticals and personal care products (PPCPs). Another aim of this review is to raise the awareness of ecopharmacovigilance among public health nursing educators in higher education, who focus on the relationship between the health of the population and the environment and who provide care directed at the populations with extra interest in more vulnerable populations such as pediatric and geriatric populations, rather than individuals. Another important aspect of the role of the public health nurses in the field of pharmacovigilance and ecopharmacovigilance originates from their oriented practice towards preventive health in diverse settings such as; "community nursing centers, local and state health departments, home health agencies, schools, and neighborhood centers". They may give education on the methods of ADR reporting, drug safety, safe drug disposal in their working areas such as public health facilities departments or schools and contribute to lowering both the risk for patients and costs for treating ADRs (Bigi and Bocci, 2017).

Ecopharmacovigilance is a new concept and a newly emerging science (Holm et al., 2013). The literature related to ecopharmacovigilance

is scarce in Turkey. Interdependence and interconnectedness of living things with the natural environment conceptualized in nursing.

In 2017, the “International Council of Nursing (ICN)” has focused on the theme of: “Nurses: A Voice to Lead, Achieving Sustainable Development Goals (SDGs)”. 17 SDGs were adopted in 2015 by the United Nations (UN) and “191 UN Member States had agreed to achieve these new goals by 2030”. Four of these SDGs containing titles related to the environment were as follows: “Goal 12: Responsible consumption and production, Goal 13: Climate action, Goal 14: Life below water, Goal 15: Life on the land” (ICN, 2017). The drug environment relationship is an inevitable cycle of the afterlife of drugs. Drugs pass to water, some of them may not be entirely removed by the sewage treatment process. Traces of them may be found in water in the environment. When entering the environment and the food chain through various routes, they may cause harmful effects to the ecosystem (Avinash 2015; Joss 2006). Education on ecopharmacovigilance is vital for maintaining a healthy society and biodiversity. This understanding will provide higher awareness of ecopharmacovigilance and safe drug disposal practices and these actions’ added value to the environment, indirectly to every individual (Avinash 2015). Raising a healthy generation will serve the outcomes of public health nursing programmes Nursing educators in public health nursing programmes should incorporate these aforementioned areas into their curriculum in order to prepare the next generation of public health nurses to be able to respond to the demands of society and of the heavily polluted planet.

Since no relevant international standard exists on teaching pharmacovigilance at universities for undergraduate nursing, medical, dentistry and pharmacy students, pharmacology academics tasked with teaching pharmacovigilance may struggle to select which topics they should cover in their courses (Van Eekeren et al., 2018). Therefore, they should refer to the appropriate international

standardizing bodies of guidance and recommendations for a core curriculum on pharmacovigilance for university education. In 2016, “a stakeholder’s meeting was initiated on behalf of the WHO” that was organized by the “LAREB WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting”. LAREB indicated and agreed on “the competencies in the field of pharmacovigilance” that undergraduate students should develop and “the key aspects that should be taught” (Van Eekeren et al., 2018). We also agree and propose that the WHO Pharmacovigilance core curriculum can be incorporated into the education programme of undergraduate and postgraduate nursing students (Van Eekeren et al., 2018). This may result in updating the key aspects of the curricula for nursing educators in higher education. Educators seeking materials to incorporate into their courses can access LAREB’s web-portal which provides a platform of educational materials to be shared (LAREB 2017). They can also refer to the “Good pharmacovigilance practice” and the new guideline in paediatric populations.

“Guideline on good pharmacovigilance practices: Product-or Population-Specific Considerations IV: Paediatric population” published by the “European Medicines Agency (EMA)” (GVP 2018).

According to the demands of developing professional training, we also want to emphasize in this review that pharmacology educators in nursing should attach particular importance to medication errors, rational drug use and drug use in special populations, which are also relevant to pharmacovigilance and ecopharmacovigilance, in their curriculum with continuous updates on these topics. Furthermore, pharmacology educators in nursing higher education should attach special importance to fostering a health culture bonding physicians and nurses, increasing the communication, sharing information and practice in the field of pharmacovigilance for finding an effective way to provide patient-centered care and rapid intervention in adverse drug reactions.

Conclusion

With this review, we hope that academics working in nursing higher education will recognize their key role in the national and globally integrated pharmacovigilance system and that they will join forces to strengthen their contribution to raising awareness of the necessity and legal importance of pharmacovigilance and ecopharmacovigilance and communication skills in pharmacovigilance in undergraduate nursing education. Teaching pharmacovigilance and ecopharmacovigilance should not, however, be limited to undergraduate nursing education.

Curricular updates in the training of undergraduate and postgraduate nursing students tailored to the developments in medicine and to national requirements yielding the greatest improvement in student's academic performance constitute an important basis for the internationalization of pharmacovigilance education and for raising awareness of pharmacovigilance, ecopharmacovigilance, and safe medication disposal practices in order to reduce antibiotic resistance and environmental footprint of healthcare professionals for maintaining or improving the quality of healthcare delivery and the pharmacovigilance system and for improving this newly emerging science ecopharmacovigilance.

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The literature used was shown in the references.

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What did the study add to the literature?

- Global pharmacovigilance system and regulation of pharmacovigilance in Turkey.
- Raising awareness of nursing academics of pharmacovigilance and ecopharmacovigilance.
- Pharmacovigilance and ecopharmacovigilance education in undergraduate and postgraduate nursing education should be developed.

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