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Pharmacovigilance System in Georgia: A Study of Awareness, Behavior and Attitudes of Physicians and Pharmacists

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Abstract: Background: Improving public healthcare and its safety is important for the world healthcare system. Assessing the benefits, harms, efficacy, and risks of medications and their rational use increases patient care and safety index. The above–mentioned plays an important role in pharmacovigilance as well. It is clear from the practice of different countries that monitoring the side effects of drugs ensures their safe and effective use. The purpose of the study was to explore the level of awareness and behavior of pharmacists and physicians regarding pharmacovigilance. **Methods:** 370 pharmacists and 212 physicians participated in the survey exploring behaviors and attitudes regarding pharmacovigilance and pharmacosafety. **Results:** The physician awareness regarding "the order of information flow from the medical network about the side effects of the drugs" was as followed: 70% did not have knowledge about it, and 30% did. The data also revealed how frequently pharmacist would fill out the adverse effect reporting form if it was available: 67.3% of pharmacists indicated 1-3 times, 15.8% indicated 4-6 times, 6% indicated 7-10 times, and 10.9% indicated 10 times. Additionally, the survey explored how physicians would act when patients experience side effects. Data showed that 47.6% of physicians no longer prescribe the medicine, 32.4% of physicians prescribe another group of medicine that have less pronounced side effects, and 7.6% of physicians add another medicine to the prescription to remove the side effects. 12.4% of physicians diverted from the given choices and indicated the following results in the "other" field. **Conclusions**: Based on the result obtained, it seems like physicians and pharmacists play an important role in monitoring drug side effects and reporting drug related unexpected adverse events. Physicians and pharmacists have a positive attitude toward the pharmacovigilance system; however, their awareness is low.

Key words: Pharmacovigilance, pharmacosafety, adverse drug reaction, reporting form, physician, pharmacist.

1. Introduction

Pharmacovigilance as a medical discipline is crucial in preventing medicine-related adverse effects in humans, as well as promoting patient safety and the rational use of medicines [1]. Before a medicine is authorized for use, evidence of its safety and efficacy is limited to the results from clinical trials, where patients are selected carefully and followed up very closely under controlled conditions. After authorization, the medicine may be used in a large number of patients, for a long period of time, and along with other medicines. Certain side effects may emerge in such circumstances [2].

The history of Pharmacovigilance started on 29 January 1848, when a young girl (Hannah Greener) died after receiving chloroform anesthetic before the removal of an infected toenail. The case was published in *The Lancet* in 1893. In 1937, there were 107 deaths in the USA because of the use of sulfanilamide elixir, containing diethyl glycol as the solvent. This solvent was considered the cause of deaths, but the manufacturing companies were not aware of its toxicity at that time. Consequently, the Federal Food, Drug, and Cosmetic Act were established in 1938. In 1961, a big change of European Pharmacovigilance happened following the

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tragedy of Thalidomide [3]. In 1968, World Health Organization (WHO) established Programme for International Drug Monitoring, now coordinated by the Uppsala Monitoring Center in Uppsala, Sweden. The idea that pharmacovigilance centers are a luxury and affordable only in developed nations has been replaced by a realization, that a reliable system of pharmacovigilance is necessary for public healthcare and for the rational, safe, and cost-effective use of medicines in all countries [4].

Pharmacovigilance aims at the quickest possible identification of signals of medicinal product safety, which enables steps to minimize potential adverse reactions' consequences [5]. What constitutes an important part of pharmacovigilance is the collection and analysis of individual reports of adverse reactions [6]. The person reporting the adverse event is the source of data on the medical product; this could be a healthcare professional (HP), a person with medical qualifications (e.g., a physician, a dentist, a pharmacist, or a nurse), a consumer (non-healthcare professional; non-HP), or a patient's relative or caregiver). The purpose of this particular study is to explore the level of awareness and behavior of pharmacists and physicians regarding pharmacovigilance [7].

2. Methods

The survey was conducted from January 2022 to May 2022. Different questionnaires were created for pharmacists and physicians. 370 pharmacists and 212physicians participated in the survey. Physicians were found through various resources and face-to-face interviews at the eight hospitals. Pharmacists were found in different Pharmacies (PSP Pharma, Pharmadepot, Aversi Pharma, NeoPharm, and IMPEX Pharmacy).

The survey included questions regarding pharmacovigilance; the participants were presented with questions such as: "From which sources do you get the upgraded information about pharmacosafety?" and "If you had access to suspected adverse drug reaction reporting form, how many times a day would you fill it out?" The Research was quantitative and qualitative, and the survey was anonymous. The confidentiality of the personal data of physicians and pharmacists was fully protected.

3. Results

The study found that among the physicians participating in the study, 36.8% were family doctors, 1% were cardiologists, 3% were neurologists, 3.5% were endocrinologists, and 55.7% were of other specialties. Their practice experience ranged from 1 year (1%), 1 to 5 years (3%), and 6 years or more (96%). Pharmacists' practice ranged from 1 year (10%), 1 to 5 years (27.5%), and 6 years or more years of practice experience (62.5%).

3% of physicians and 17.7% of pharmacists reported that patients refer to them for side effects every day. In the same domain, "once a week" was indicated by 7% of physicians and 23.8% of pharmacists, and "once or twice a week" was indicated by 71.9% of physicians and 46.4% of pharmacists. 18.1% of physicians and 12.1% of pharmacists reported that patients do not refer to them with complaints regarding side effects (Chart 1).

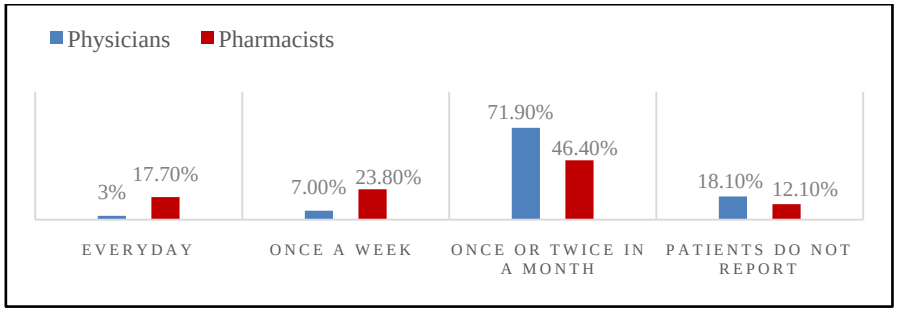

Chart 1 Frequency of referrals of patients to pharmacists and physicians in the event of side effects.

An important finding of the study was how physicians act when patients experience side effects; 47.6% of physicians no longer prescribe the medicine, 32.4% of physicians prescribe another group of medicine that have less pronounced side effects, and 7.6% of physicians add another medicine to the prescription to remove the side effects. 12.4% of physicians diverted from the given choices and indicated the following results in the "other" field: 14 of physicians noted that they never had a similar case, two of the physicians no longer prescribed the medicine and contacted the appropriate regulatory body of the healthcare system, and one physician included the side effect in the patient's history to explain the alternative of prescribing another medicine (Chart 2).

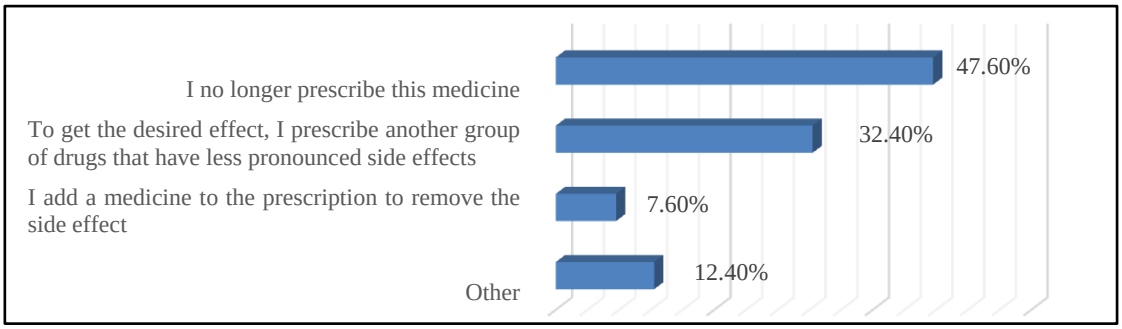

Chart 2 Actions of physicians in case of side effects.

One of the study's goals was to determine physicians' knowledge about the current regulation of pharmacovigilance in Georgia. 70% did not have knowledge about the current regulation of pharmacovigilance in Georgia, and 30% did (Chart 3).

Because the majority of physicians noted that they don't have knowledge regarding the current regulation of pharmacovigilance in Georgia, the following results were expected: 6% of physicians engage in the practice of completing the suspected adverse drug reaction reporting form, and 94% do not (Chart 4).

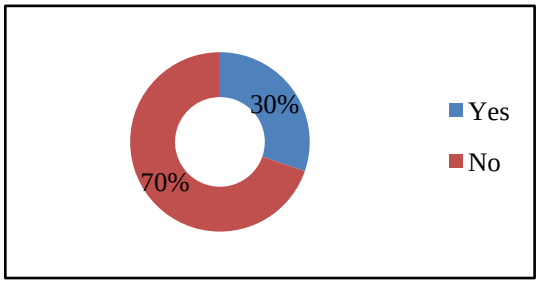

Chart 3 Physicians' awareness about the current regulation of pharmacovigilance in Georgia.

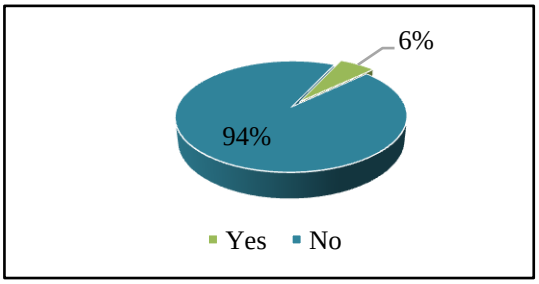

Chart 4 Physicians practice of completing the suspected adverse drug reaction reporting form.

Regarding the question "From which sources do you get the upgraded information about pharmacosafety", 47.3% of physicians indicated that they get the information from pharmaceutical companies, 2.5% do not get the information from anywhere, 28.10% get it from scientific journals, official scientific and medical websites, 5.1% get it from the Agency of Regulation of Medical and Pharmaceutical Activities, and 17% get the information from other sources (Chart 5).

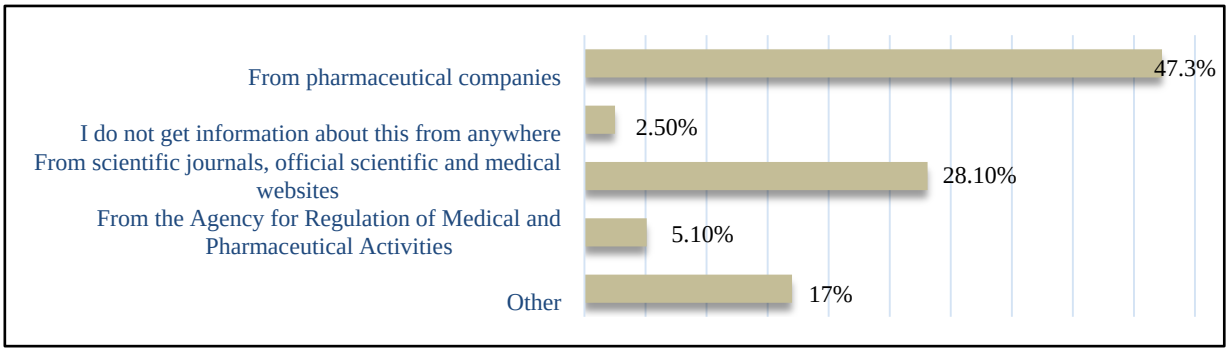

Chart 5 Awareness of physicians about pharmacosafety.

The study also looked at how pharmacists behave when patients experience side effects. The results showed that 1% of pharmacists suggested contacting the relevant department of the Ministry of Health (Pharmacovigilance Department); 12% of pharmacists recommend medication to relieve the identified adverse reaction; 21.4% of pharmacists suggested contacting the physician to discuss changing their medication with another group of drugs and 65.6% suggested consulting their doctor (Chart 6).

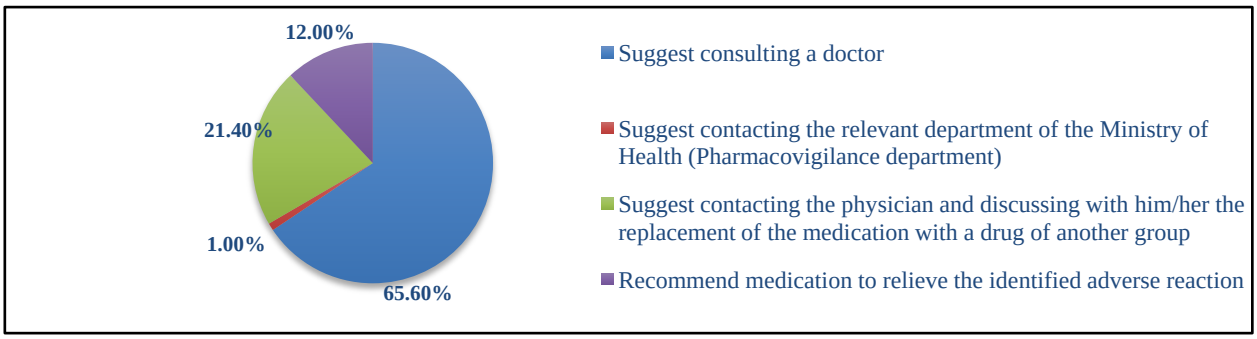

Chart 6 Actions of pharmacists in case of side effects.

On the question "if you had access to suspected adverse drug reaction reporting form, how many times a day would you fill it out", 67.3% pharmacists indicated 1-3 times, 15.8% indicated 4-6 times, 6% indicated 7-10 times, and 10.9% indicated 10 times or more (Chart 7).

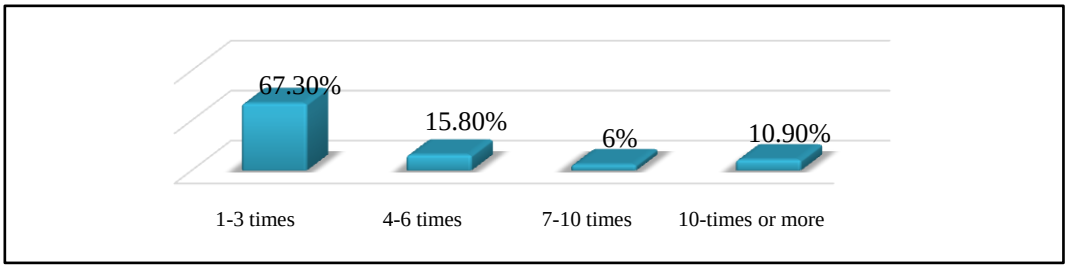

Chart 7 Frequency of activity of pharmacists in the presence of adverse drug reaction reporting form.

On the question "In your opinion, what benefits establishing a pharmacovigilance system in Georgia will have", 42.9% of pharmacists and 47.9% of physicians indicated that it would improve the evaluation of drug harm-benefit analysis. 19.7% of pharmacists and 37% of physicians indicated that it would cause improvements in the field of public health and safety related to the use of drugs. Lastly, 37.4% of pharmacists and 15.1% of physicians stated that it would improve the safety of patients and health

care indexes in regard to the use of drugs and all medical interventions (Chart 8).

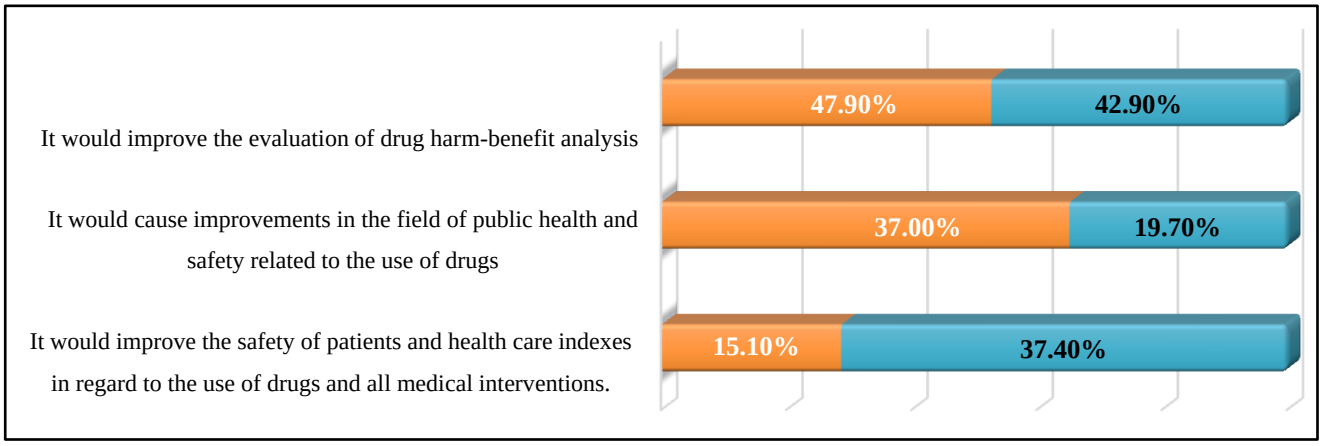

Chart 8 The attitude of pharmacists and physicians to the pharmacovigilance system in Georgia

4. Discussion

Based on the result obtained, we can conclude that the physicians and pharmacists play an important role in monitoring drug side effects and reporting unexpected drug-related adverse events. Another important finding was regarding physicians' low awareness of national legislation, the "flow of information from the medical network, the rules of information (which has been in force since 2003).

The received data also showed the desire of pharmacists to be actively involved in the pharmacovigilance system, which indicates that pharmacists are willing to provide regular information about drug side effects to relevant services in the health care system. Hence, establishing new standards of the pharmacovigilance system and further monitoring the current legislation would ensure more active involvement of healthcare professionals in pharmacosafety and pharmacovigilance, taking in mind their already existing positive attitude and willingness to address the issue.

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