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## Survey of pharmacist' opinion and knowledge on adverse drug reactions reporting in Poland

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### ABSTRACT

Reporting adverse drug reactions (ADRs) is an extremely important procedure that affects patient safety. ADR reporting is the responsibility of every medical professional, including pharmacists.

In the research, the aim of this study is to verify if pharmacists in Poland are ready to report adverse drug reactions. The research has been conducted via survey questionnaire within the tricity of Gdynia, Sopot and Gdańsk. The questionnaire consisted of thirteen questions, and every pharmacist with license to practice was allowed to participate in this study. The results indicate that Polish pharmacists assess their level of knowledge about reporting side effects at a moderate level. This may be due to the low popularity of training in this area. Moreover, the staff of community pharmacies have a lower perception of their level of knowledge about reporting ADR than do employees of hospital pharmacies and other related places ( $p < 0.001$ ). In addition, hospital pharmacists have more experience in ADR than those employed in community pharmacies, and pharmacists with a specialist title are more aware of the obligation to report ADR ( $p = 0.023$ ). Patients very rarely report side effects to pharmacists and this is indicated as the main reason for the lack of ADR reporting by this professional group. We conclude that pharmacists in Poland are not ready to report ADR, and more training is necessary.

### INTRODUCTION

Patient safety is a healthcare system issue that is critical to public health. Healthcare professionals are expected to collect information about adverse drug reactions (ADR) and report them. Pharmacists play an important role in this system and their spontaneous reporting of side effects helps assess the safety of a drug after it is placed on the market [1].

The Act of September 6, 2001 on Pharmaceutical Law states that the patient has the right to report all effects of medications that he or she feels are inappropriate. Notifications may be addressed, among others, to: the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (hereinafter referred to as: 'Office'), the responsible entity or a person practicing a medical profession [2]. The patient's right to report an adverse reaction is also included in Article 12a of the Act of November 6, 2008 on patient rights and the Patient Ombudsman, which specifies that an ADR report may be submitted by the patient, his/her guardian or legal representative to

a person practicing a medical profession or directly to the Office [3]. A pharmacist is a medical professional according to the article 2a. paragraph 1 of the act of the pharmaceutical law, which lists persons practicing a medical profession and includes: doctors, dentists, pharmacists, feldshers (senior feldshers), nurses, midwives, laboratory diagnosticians, paramedics and pharmaceutical technicians [2]. The Act of December 10, 2020 on the profession of pharmacist additionally emphasizes that this profession is an independent medical profession (Article 2).

This legal act once again states that receiving adverse reactions from patients and reporting adverse reactions to appropriate institutions is a professional obligation of a pharmacist (Article 33) [4]. Therefore, Polish law provides a basis for the pharmacist to fulfil the obligation to report adverse medicinal reactions in clients.

This obligation can be accomplished electronically via the URPL website or by using a physical form once called a 'yellow card', the term being still used in the UK [5]. The form must contain the name of the medicinal product, indication of at least one symptom of the drug's side effect,

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the full name and basic data of the patient: age, gender and body weight. The reporting person should provide his/her full name and contact method (e-mail, telephone). If this person does not have information about the patient at the time of the occurrence of an adverse reaction, he or she may send a report, but should complete it with the missing data as soon as possible. The form may be extended to include more detailed information on a given adverse reaction based on the knowledge held by the reporter.

The free Mobit Scanner mobile application can, as well, be used to report ADR, which can be downloaded to smartphone. After starting the application, the barcode on the packaging of the medicine should be scanned so as to be reported. After the application has correctly identified the medicine, the full name and basic data of the patient and the reporting person should be entered. After completing the necessary data, the report is sent to the Office.

Guardians, legal representatives and patients also have the opportunity to report adverse reactions by phone using the hotline of Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Under European regulations, the European Medicines Agency designates doctors, local pharmacies and the online form as the main ways to report side effects for patients. EMA provides information on each national institution that allows the reporting of side effects online [6,7].

There are six types of Adverse Drug Reactions:

- Type A – dose dependent;
  - Type B – dose independent;
  - Type C – dependent on long-term use;
  - Type D – time-delayed;
  - Type E – caused by drug withdrawal;
  - Type F – related to lack of effectiveness of therapy [8].
- Reporting side effects applies to every medicinal product, regardless of its availability category. The Office does not collect reports of adverse reactions related to the action of dietary supplements [9].

The Pharmaceutical Law Act of September 6, 2001 distinguishes and defines serious adverse drug reaction as actions causing, regardless of the dose used: the patient's death, or which are life-threatening, required the need for hospitalization or the need to extend this or result in such a reaction that the doctor, based on his/her knowledge and experience, considers too abnormal. Medical professionals according to the Art. 2a of the above-mentioned Act, are obliged to report this type of ADR within 15 days of receiving information about their occurrence [2].

Due to the characteristics of the pharmacy profession, pharmacists are ideally prepared to collect, detect and prevent adverse reactions. In the healthcare system, pharmacists are specialists in the field of medicines and are particularly prepared for this role. For this reason, when discussing Pharmacovigilance systems, it is necessary to take a closer look at the everyday practice of masters of pharmacy. Optimal and effective pharmaceutical practices can improve the effects of pharmacotherapy, reduce the number of side effects and reduce the global cost of health care. Due to their extensive knowledge, pharmacists are able to support pharmacovigilance systems in monitoring drug effectiveness, side effects and predicting interactions,

hence reducing the cost of pharmacotherapy. It should be remembered that pharmacists in community pharmacies are statistically the most frequently visited group of medical professionals, which provides ideal circumstances for reporting ADR [10].

To ensure the highest effectiveness and safety of pharmacotherapy, cooperation between patient and medical specialist is required. In professional practice, pharmacists focus in particular on the risks that threaten optimal pharmacotherapy, such as low compliance (failure to systematically take medications) or low adherence (conduct inconsistent with medical recommendations). Pharmacists, in their daily activity, help patients/clients to identify and resolve (or avoid) problems. Although in most countries the prescription is issued by a doctor or nurse, pharmacists have a key role in informing patients about taking the right steps to ensure safety and effectiveness throughout the course of drug therapy.

On average, 55% of all pharmacists worldwide work in community pharmacies, 18% in hospitals, 10% in the pharmaceutical industry, 5% in clinical trials and 5% in regulatory institutions [11]. A total of 73% of all pharmacists work in environments that allow for direct and full knowledge of pharmacotherapy, patients and side effects. This shows how important is the role of pharmacists in the pharmacovigilance system. Pharmacists are highly educated and have a professional responsibility in the provision of pharmaceutical care which includes the identification, prevention, and resolution of drug-related problems (DRPs). It is one of their core jobs to ensure the safe use of medicine. Reporting ADRs is equally important [12].

## AIM

The aim of this study was to seek answers to the following research questions:

1. How much importance do pharmacists attach to having knowledge about the side effects of medications?
2. What is the subjective assessment of the level of knowledge of pharmacists about the side effects of drugs?
3. What is the level of knowledge of pharmacists about reporting drug side effects?
4. What barriers stop pharmacists from reporting adverse reactions?
5. What do pharmacists think of the process of reporting adverse drug reactions?

The main hypothesis was formulated as follows: Pharmacists in Poland are ready to report adverse drug reactions.

## MATERIAL AND METHODS

The survey method was used in the study. For this purpose, an original research tool was developed – a survey questionnaire. The content of the survey was assessed by experienced researchers of the Medical University of Gdańsk and then corrected taking into account all comments and recommendations.

The initial part of the survey included general questions examining respondents' knowledge and opinion about adverse events and the process of reporting them.

The first question was closed and was intended to assess the subjective assessment of pharmacists on their level of knowledge about drug side effects. The respondent could choose one of five possible answers on a five-point Likert scale, where “1” meant “very poor” and “5” meant “very good”. The next closed category question asked whether the participating pharmacist had ever received training on adverse drug reactions and their reporting? The surveyed person had to choose one of three answers: “yes”, “no”, “I don't remember”. The subsequent two questions were intended to determine how important pharmacists think is their knowledge about the side effects of the drugs they dispense and how important patients' knowledge in this area is. The questions again used a five-point Likert scale. The following question in this part of the questionnaire sought to determine whether pharmacists felt they had sufficient knowledge on how to report adverse reactions. The answer was verified in another open-ended question that tested this knowledge. Afterwards, participants were asked to comment on the obligation to report adverse reactions. Questions 9 to 13 concerned the participant's previous experience with reporting adverse events.

The questions were intended to estimate the frequency of reporting of adverse reactions and to assess this process from the pharmacist's point of view. Reasons for the lack of such reporting were also sought. The survey (translated into English) is attached to this article.

In undertaking this survey, a pilot study was first conducted on a small group of respondents ( $n=5$ ). As the outcome of this was successful, wider distribution of the questionnaire subsequently occurred. The article describes the results that showed statistical significance.

### Statistical calculations

The obtained research results were subjected to statistical analysis. Calculations were performed in IBM SPSS. The values of the analyzed variables were presented using absolute numbers ( $n$ ) and relative numbers (%). Contingency tables and  $\chi^2$  tests were used to assess the relationship between variables. In the work,  $p=0.05$  was assumed as the level of significance below which the results were considered statistically significant.

### Study group

This study was fully anonymous and did not require the consent of the bioethics committee. The study group consisted of pharmacists licensed to practice in Poland. Having an active license to practice the profession was the only inclusion criterion in the study, which the respondents confirmed independently. The survey was completed by 404 masters of pharmacy. According to data from the Central Statistical Office, as of December 31, 2022, 25.8 thousand pharmacists worked in Poland's pharmacies. Taking this number as the size of the study population, the representative number of respondents was a minimum of 379 (with a confidence level of 95%, margin of error of 5%). This number was estimated using Roarsoft's Sample Size Calculator, available free online. It can therefore be concluded that the appropriate size of the study group was achieved. It was impossible for researchers to obtain information on the total

number of pharmacists listed in the Register of Pharmacists of the Republic of Poland.

The surveys were distributed both in paper version and in the form of an online form in the period from April 1, 2023 to May 24, 2023. In total, 350 paper questionnaires were printed and distributed in public pharmacies in the Tricity area and during the Reporting Meeting of Delegates of the Gdańsk District Pharmaceutical Chamber. The return rate of paper surveys was 198, which is 56% of all printed surveys. The form, which can be completed electronically, was actively shared in groups associating pharmacists on social media and by e-mail through the District Chambers of Pharmacy in Poland.

## RESULTS

### Demography

In total, 404 respondents participated in the study, including 106 men and 296 women, which constituted 26.2% and 73.3% of all respondents, respectively. Two people preferred not to declare their gender.

As the place of practicing their profession, 359 pharmacists indicated a community pharmacy (which constituted 88.9% of all respondents), 30 of the surveyed pharmacists worked in a hospital pharmacy (7.4%) and 15 respondents indicated a place of work other than a pharmacy, e.g. clinical trials, university or pharmaceutical company. Detailed data describing the demographics and characteristics of the study group are presented in Table 1.

Of the 404 respondents, 26 (6.5% of the study group) rated their level of knowledge about side effects as poor (2). The rating “3” or “moderate”, was chosen by 154 people, which constitutes 38.2% of all respondents. Option “4” (good) was selected by 149 respondents (37%). The highest subjective assessment of their own knowledge (“5”) was given by 74 people – 8.4% of the study group. The average assessment of own knowledge among respondents was 3.67 on a scale from 1 to 5.

Only 34.9% of respondents (141 people) declared participation in training on ADR and their reporting, despite the fact that as many as 68.5% of all respondents considered their knowledge on this subject to be “very important” and 32.7% assessed having this area of knowledge as “important”.

Statistically significant relationships between variables were also found ( $p<0.001$ ). Specifying participation in ADR reporting training and specialization, pharmacists with a specialist title participated in training more often (49.5%) than did people without specialization (29.6%). Moreover, it was shown that people with the longest work experience (over 22 years) were most likely to have participated in training on adverse drug reactions in the past (46.8%) ( $p=0.005$ ) (Table 2).

To the next question: “Do you think you have sufficient knowledge on how to report adverse drug reactions?”, 52 people (12.9%) chose the lowest rating of “1” – definitely not, The answer “no” (2) was chosen by 45 people (11.1%), and the intermediate option – “3” (I don't know) was chosen by 80 respondents – 19.8%. The most frequently chosen option was the number “4” (yes). This answer was given

**Table 1.** Detailed data describing the demographics and characteristics of the study group

|                                              | Number of responses       | % relative to the total                                 |
|----------------------------------------------|---------------------------|---------------------------------------------------------|
| Sex                                          |                           |                                                         |
| Male                                         | 106                       | 26.4                                                    |
| Female                                       | 296                       | 73.3                                                    |
| No answer                                    | 2                         | 0.5                                                     |
| Place of practicing as a pharmacist          |                           |                                                         |
| Community pharmacy                           | 360                       | 88.9                                                    |
| Hospital pharmacy                            | 30                        | 7.4                                                     |
| Pharmaceutical Company                       | 5                         | 1.23                                                    |
| Clinical Trials                              | 3                         | 0.74                                                    |
| University                                   | 2                         | 0.49                                                    |
| Pharmacy point                               | 1                         | 0.24                                                    |
| Location                                     |                           |                                                         |
| Big city (100 thousand of inhabitants)       | 303                       | 75.0                                                    |
| Medium city (20-100 thousand of inhabitants) | 56                        | 13.9                                                    |
| Small city (<20 thousand of inhabitants)     | 29                        | 7.2                                                     |
| Village                                      | 16                        | 4.0                                                     |
| Specialist title                             |                           |                                                         |
| Yes                                          | 107                       | 26.5                                                    |
| No                                           | 297                       | 73.5                                                    |
| Community pharmacist                         | 93                        | 22.7                                                    |
| Hospital pharmacist                          | 8                         | 2                                                       |
| Analytical pharmacist                        | 3                         | 0.7                                                     |
| Pharmacologist                               | 3                         | 0.7                                                     |
| Variable:                                    | Age (n=403)<br>(year old) | Length of professional<br>experience (n=403)<br>(years) |
| No data                                      | 2                         | 1                                                       |
| Average                                      | 40,02                     | 14.523                                                  |
| Median                                       | 39                        | 13                                                      |
| Standard deviation                           | 10,291                    | 10.041                                                  |
| Minimum                                      | 24                        | 0                                                       |
| Maksimum                                     | 75                        | 45                                                      |

**Table 2.** A summary of the results of answers to the question regarding participation in ADR training and their reporting regarding variables

| Cross table                                                      |            |        |       |       |            |        |         |       |       |
|------------------------------------------------------------------|------------|--------|-------|-------|------------|--------|---------|-------|-------|
| Have you ever participated in training on ADR and its reporting? | Variable 1 |        |       | Total | Variable 2 |        |         |       | Total |
|                                                                  | Yes        | No     |       |       | <=6,0      | 6,1-13 | 13,1-22 | >22   |       |
| Yes                                                              | N          | 53     | 88    | 141   | 33         | 31     | 32      | 44    | 140   |
|                                                                  | %          | 49.5%  | 29.6% | 34.9% | 29.5%      | 31.3%  | 32.7%   | 46.8% | 34.7% |
| No                                                               | N          | 42     | 161   | 203   | 70         | 46     | 50      | 37    | 203   |
|                                                                  | %          | 39.3%  | 54.2% | 50.2% | 62.0%      | 46.5%  | 51.0%   | 39.4% | 50.4% |
| I don't remember                                                 | N          | 12     | 48    | 60    | 9          | 22     | 16      | 13    | 60    |
|                                                                  | %          | 11.2%  | 16.2% | 14.9% | 8.0%       | 22.2%  | 16.3%   | 13.8% | 14.9% |
| Total                                                            | N          | 107    | 297   | 404   | 112        | 99     | 98      | 94    | 403   |
|                                                                  | %          | 100%   | 100%  | 100%  | 100%       | 100%   | 100%    | 100%  | 100%  |
| Chi² tests                                                       |            |        |       |       |            |        |         |       |       |
| Pearson's Chi²                                                   | Value      | 13,726 |       |       | 18,453     |        |         |       |       |
|                                                                  | df         | 2      |       |       | 6          |        |         |       |       |
|                                                                  | p          | 0.001  |       |       | 0.005      |        |         |       |       |

Variable 1: Do you have a specialist title?

Variable 2: Length of professional experience expressed in years

by 143 respondents (35.4% of all pharmacists surveyed). According to the survey results, 84 pharmacists were most confident in their knowledge – 20.8% marked the answer “5” – definitely yes. Upon analyzing the answers to this question in relation to the place of practicing as a pharmacist, statistically significant relationships were found ( $p<0.001$ ), indicating that employees of community pharmacies have a lower perception of their level of knowledge about reporting ADR than do employees of hospital pharmacies and other places (Table 3).

**Table 3.** A summary of answers to the question regarding having the knowledge necessary to report ADR regarding to the place of practicing the profession

| Cross table                                                            |        |                                    |          |        |       |
|------------------------------------------------------------------------|--------|------------------------------------|----------|--------|-------|
| Do you think you have sufficient knowledge about how to report an ADR? |        | Place of practicing the profession |          |        | Total |
|                                                                        |        | Community pharmacy                 | Hospital | Other  |       |
| 1<br>“definitely not”                                                  | N      | 38                                 | 9        | 5      | 52    |
|                                                                        | %      | 10.6%                              | 30.0%    | 33.3%  | 12.9% |
| 2<br>„no”                                                              | N      | 41                                 | 3        | 1      | 45    |
|                                                                        | %      | 11.4%                              | 10.0%    | 6.7%   | 11.1% |
| 3<br>„i don’t know”                                                    | N      | 74                                 | 4        | 2      | 80    |
|                                                                        | %      | 20.6%                              | 13.3%    | 13.3%  | 19.8% |
| 4<br>„yes”                                                             | N      | 138                                | 4        | 1      | 143   |
|                                                                        | %      | 38.4%                              | 13.3%    | 6.7%   | 35.4% |
| 5<br>„definitely yes”                                                  | N      | 68                                 | 10       | 6      | 84    |
|                                                                        | %      | 18.9%                              | 33.3%    | 40.0%  | 20.8% |
| Total                                                                  | N      | 359                                | 30       | 15     | 404   |
|                                                                        | %      | 100%                               | 100%     | 100%   | 100%  |
|                                                                        |        |                                    |          |        |       |
| Pearson’s Chi²                                                         | Value  | df                                 |          | p      |       |
|                                                                        | 28,661 | 8                                  |          | <0.001 |       |

Regarding the open question "Where should ADR be reported?", more than half of the respondents (62.5%) correctly answered that such notifications should be sent to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Another 14.3% of the respondents answered that this information should be provided to the drug manufacturer or the responsible entity (5%).

The vast majority – 340 pharmacists (84.2%) – also answered that reporting adverse drug reactions is the pharmacist's responsibility. Ten respondents (2.5%), however, selected the negative answer, while thirty people (7.4%) believed that it was only required in certain cases. The remaining respondents (24 people, 5.9%) admitted ignorance on this subject. People with a specialist title more often than others gave a correct answer ( $p=0.023$ ) (Table 4).

The survey results indicated that patients do not have the habit of informing their pharmacist about the observed side effects of the drugs they use. When asked how often the patient provides information about observed side effects in the pharmacy, 124 people (30.7%) marked the lowest answer – “1” – very rarely, while another 147 pharmacists (36.4%) answered that patients seldom provide this information (“2”). Therefore, in practice,

only 92 respondents (22.8%) had real opportunity to report adverse events to the appropriate institution. Most often, these were people working in hospital pharmacies ( $p<0.001$ ) and pharmacists with specialization ( $p=0.005$ ) (Table 5).

**Table 4.** A summary of answers to the question whether ADR reporting is the pharmacist's obligation to hold the specialist title

| Cross table                                       |       |                                 |       |       |
|---------------------------------------------------|-------|---------------------------------|-------|-------|
| Is ADR reporting the pharmacist's responsibility? |       | Do you have a specialist title? |       | Total |
|                                                   |       | Yes                             | No    |       |
| Yes                                               | N     | 99                              | 241   | 340   |
|                                                   | %     | 92.5%                           | 81.1% | 84.2% |
| No                                                | N     | 0                               | 10    | 10    |
|                                                   | %     | 0%                              | 3.4%  | 2.5%  |
| Only in certain cases                             | N     | 6                               | 24    | 30    |
|                                                   | %     | 5.6%                            | 8.1%  | 7.4%  |
| I don't know                                      | N     | 2                               | 22    | 24    |
|                                                   | %     | 1.9%                            | 7.4%  | 5.9%  |
| Total                                             | N     | 107                             | 297   | 404   |
|                                                   | %     | 100%                            | 100%  | 100%  |
| Chi <sup>2</sup> Tests (n=404)                    |       |                                 |       |       |
|                                                   | Value | df                              | p     |       |
| Pearson's Chi <sup>2</sup>                        | 9,522 | 3                               | 0.023 |       |

**Table 5.** Summary of answers to the question: "Have you ever reported ADR" regarding to the variables: place of practicing your profession and specialization

| Cross table                                       |   |                                    |                   |       |       |                                 |       |       |
|---------------------------------------------------|---|------------------------------------|-------------------|-------|-------|---------------------------------|-------|-------|
| Have you ever reported ADR provided by a patient? |   | Place of practicing the profession |                   |       | Total | Do you have a specialist title? |       | Total |
|                                                   |   | Community pharmacy                 | Hospital pharmacy | Other |       | Yes                             | No    |       |
|                                                   |   |                                    |                   |       |       |                                 |       |       |
| Yes                                               | N | 63                                 | 20                | 9     | 92    | 36                              | 56    | 92    |
|                                                   | % | 17.5%                              | 66.7%             | 60.0% | 22.8% | 33.6%                           | 19.9% | 22.8% |
| No                                                | N | 284                                | 10                | 6     | 300   | 67                              | 233   | 300   |
|                                                   | % | 79.1%                              | 33.3%             | 40.0% | 74.3% | 62.6%                           | 78.5% | 74.3% |
| I don't remember                                  | N | 12                                 | 0                 | 0     | 12    | 4                               | 8     | 12    |
|                                                   | % | 3.3%                               | 0%                | 0%    | 3%    | 3.7%                            | 2.7%  | 3.0%  |
| Total                                             | N | 359                                | 30                | 15    | 404   | 107                             | 297   | 404   |
|                                                   | % | 100%                               | 100%              | 100%  | 100%  | 100%                            | 100%  | 100%  |

If a pharmacist has never reported an adverse drug reaction, he/she had a choice of seven proposed answers explaining the reason for this situation of affairs, as well as the possibility to provide further information. Multiple answers or reasons could also be selected, therefore  $n=511$ . The respondents' answers are listed in Table 6.

Of those who reported an ADR in the past, 70% of these or 76.92% of all people who declared the experience of reporting an adverse reaction, said the process of reporting was simple and easy. A negative answer was given by 11 people or 12.08% of all respondents who reported an ADR (2.7% of the entire study group), while 10 people said they had no opinion on this matter. In particular, hospital-based pharmacists found ADR reporting to be easy. Accordingly,

60% of the indicated group answered this way ( $p<0.001$ ) (Table 7).

**Table 6.** List of reasons for pharmacists not reporting ADRs

| What are the reasons for not reporting ADR?                | Number of responses | %     |
|------------------------------------------------------------|---------------------|-------|
| No information from the patient                            | 212                 | 41.5  |
| not applicable answer                                      | 114                 | 24.2  |
| Insufficiently complete information from the patient       | 115                 | 20.54 |
| No time                                                    | 27                  | 5.3   |
| Lack of knowledge about the process of reporting ADR       | 23                  | 4.5   |
| Bad experiences in the past with the ADR reporting process | 4                   | 0.8   |
| Total                                                      | 511                 | 100.0 |

**Table 7.** A summary of answers to the question: "Do you think the ADR reporting process is easy?" in relation to the variable: place of practicing the profession of pharmacist

| Cross table                                     |        |                                    |                   |        |       |
|-------------------------------------------------|--------|------------------------------------|-------------------|--------|-------|
| Do you think the ADR reporting process is easy? |        | Place of practicing the profession |                   |        | Total |
|                                                 |        | Community pharmacy                 | Hospital pharmacy | Other  |       |
| Yes                                             | N      | 44                                 | 18                | 8      | 70    |
|                                                 | %      | 12.3%                              | 60.0%             | 53.3%  | 17.3% |
| No                                              | N      | 10                                 | 1                 | 0      | 11    |
|                                                 | %      | 2.8%                               | 3.3%              | 0.0%   | 2.7%  |
| I have no opinion                               | N      | 9                                  | 0                 | 1      | 10    |
|                                                 | %      | 2.5%                               | 0.0%              | 6.7%   | 2.5%  |
| Not applicable                                  | N      | 296                                | 11                | 6      | 313   |
|                                                 | %      | 82.5%                              | 36.7%             | 40.0%  | 77.5% |
| Total                                           | N      | 359                                | 30                | 15     | 404   |
|                                                 | %      | 100%                               | 100%              | 100%   | 100%  |
| Chi <sup>2</sup> tests (n=404)                  |        |                                    |                   |        |       |
| Pearson's Chi <sup>2</sup>                      | Value  | df                                 |                   | p      |       |
|                                                 | 60,658 | 6                                  |                   | <0.001 |       |

Hospital pharmacy employees also stood out from other respondents in response to the question "Do you agree that reporting an adverse reaction requires a lot of time and energy from the pharmacist?" Here, 68.4% of their answers were negative (57.9% – "no", 10.5% – "definitely not"), which clearly contrasted with the answers given by employees of other places ( $p=0.018$ ) (Table 8).

Similar differences in the answers given to the same question were observed when analyzing them in relation to the specialist title held by the surveyed pharmacists. People with specialization more often answered negatively ( $p=0.032$ ) (Table 8).

## DISCUSSION

This work is the first study on the issue of reporting adverse reactions among pharmacists in Poland and is pioneering in this area. The obtained results indicate that pharmacists moderately assess their level of knowledge about ADR and their reporting. The average rating on a scale of 1-5 was 3.67. However, all respondents agreed that knowledge on this topic is important or very important.

**Table 8.** A summary of answers to the question “Do you agree with the statement that reporting ADR requires a lot of time and energy?” relative to variables:

Variable 1: Place of practicing the profession of pharmacist

Variable 2: Having a specialist title

| Cross table                                                                              |       |                    |                   |       |        |            |       |       |
|------------------------------------------------------------------------------------------|-------|--------------------|-------------------|-------|--------|------------|-------|-------|
| Do you agree with the statement that reporting an ADR requires a lot of time and energy? |       | Variable 1         |                   |       | Total  | Variable 2 |       | Total |
|                                                                                          |       | Community pharmacy | Hospital pharmacy | Other |        | Yes        | No    |       |
| Definitely no                                                                            | N     | 1                  | 2                 | 2     | 5      | 3          | 2     | 5     |
|                                                                                          | %     | 1.9%               | 10.5%             | 20.0% | 6.0%   | 8.6%       | 4.2%  | 6.0%  |
| No                                                                                       | N     | 20                 | 11                | 1     | 32     | 18         | 14    | 32    |
|                                                                                          | %     | 37.0%              | 57.9%             | 10.0% | 38.6%  | 51.4%      | 29.2% | 38.6% |
| I have no opinion                                                                        | N     | 8                  | 1                 | 2     | 11     | 6          | 5     | 11    |
|                                                                                          | %     | 14.8%              | 5.3%              | 20%   | 13.3%  | 17.1%      | 10.4% | 13.3% |
| Yes                                                                                      | N     | 14                 | 5                 | 5     | 24     | 7          | 17    | 24    |
|                                                                                          | %     | 25.9%              | 26.3%             | 50.0% | 28.9%  | 20%        | 35.4% | 28.9% |
| Definitely yes                                                                           | N     | 11                 | 0                 | 0     | 11     | 1          | 10    | 11    |
|                                                                                          | %     | 20.4%              | 0%                | 0%    | 13.3%  | 2.9%       | 20.8% | 13.3% |
| Total                                                                                    | N     | 54                 | 19                | 10    | 83     | 35         | 48    | 83    |
|                                                                                          | %     | 100%               | 100%              | 100%  | 100%   | 100%       | 100%  | 100%  |
| Chi <sup>2</sup> tests                                                                   |       |                    |                   |       |        |            |       |       |
| Pearson's Chi <sup>2</sup>                                                               | Value | 18,447             |                   |       | 10,544 |            |       |       |
|                                                                                          | df    | 8                  |                   |       | 4      |            |       |       |
|                                                                                          | p     | 0.018              |                   |       | 0.032  |            |       |       |

A study on a similar topic was conducted in Liverpool among randomly selected hospital pharmacists associated with the Royal Pharmaceutical Society of Great Britain. It showed that only 16.2% of all respondents declared a lack of self-confidence when talking about ADR with doctors, but as many as 33.7% felt afraid of sending a report on an inappropriate form, and 32.3% of all respondents in the UK believed that their level of knowledge about ADR is insufficient, and over 40% of all pharmacists are not convinced that they have recognized ADR correctly [13]. However, in Iran, only 4.5% of all pharmacists declare that they do not have sufficient knowledge about reporting adverse reactions [13].

The low subjective level of knowledge in this area among Poland's pharmacists and the lack of confidence are undoubtedly related to the fact that only one third of the respondents have ever participated in training on ADR reporting. The study showed that people with specialization were more likely to participate in such courses. The results obtained in this study correspond to data from a study conducted by researchers from Liverpool, where a similar percentage of 37.9% of surveyed pharmacists declared participation in ADR training [14]. A significantly lower percentage of educated pharmacists was observed in Iran, where only 20% of respondents took part in a course on ADR [13]. A trend was noticed that people with a specialist title were more likely to participate in additional training.

Despite the low assessment of their level of knowledge and the lack of completed training and courses, over half of the respondents stated that they knew how to report an adverse reaction. Unfortunately, community pharmacy

pharmacists more often responded negatively, pointing to the uncertainty of their skills in this area.

Many studies conducted so far document that lack of knowledge about the ADR reporting process is a common problem among pharmacists. It is often pointed out that pharmacists do not know what types of ADR should be reported [15-17].

Nevertheless, the results were confirmed in the knowledge verification question, where more than half of the respondents correctly answered that ADR notifications should be sent to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Unfortunately, however, a large group of pharmacists were still unable to correctly indicate the place of reporting. In order to reliably understand the true level of knowledge of pharmacists about ADR, more detailed studies are needed, because one basic question in this area does not give a complete picture. Taking into account the results of a study conducted in India in 2020, where the increase in the level of knowledge before and after educational intervention was very clear, the need for constant access to training for pharmacists can be noted. In the mentioned study, over 90% of all participants were aware of the definition of an adverse drug reaction before the training, but it turned out that only 58.6% of all participants were able to correctly answer all more detailed questions. It can be concluded that knowledge on this topic had improved thanks to the educational intervention to a statistically significant extent [18].

The vast majority of respondents are aware that reporting adverse drug reactions is a responsibility that pharmacists hold. In particular, people with a specialist title gave a correct answer more often than did other participants. This result is also similar to the data obtained in a study in the UK, where 86.1% of surveyed pharmacists agreed that ADR reporting is a professional obligation, (14) as well as to the results of a study conducted in Iran, where 90.6% of all surveyed pharmacists considered ADR reporting to be an obligation [13]. In turn, in a study conducted in Ethiopia in 2021, 93% of all surveyed pharmacists agreed that ADR reporting is part of the professional responsibilities of all medical professionals [19].

However, patients do not have the habit of informing their pharmacist about the observed side effects of the drugs they use. Therefore, in practice, few pharmacists had real opportunity to report adverse reactions to the appropriate institution. Most often, these were people working in hospital pharmacies and pharmacists with specialization. Employees of public pharmacies had such experience the least often. It is worth paying attention to a possible problem that was observed in Iran during the study, where as many as 42% of all surveyed pharmacists did not report side effects, despite having received information about ADR. Ultimately, as many as 25% of all pharmacists have never had the opportunity to report adverse reactions to appropriate institutions [13]. Among Ethiopian pharmacists, more than half of all respondents encountered patient-clients in their pharmacy describing adverse drug effects. Most often, this amounted to an average of two cases annually. However, as many as 75% of all respondents participating in this study declared that they reported ADRs to appropriate institutions at least once during their professional career [19].

In Malaysia, a study was conducted to examine the attitude and experience of pharmacists in reporting ADR in 2010 and the same study in 2020. The results of this study confirm greater involvement in reporting ADR among pharmacists working in hospitals compared to those practicing in community pharmacies. Among pharmacists who reported an adverse reaction in their patients in the last 6 months, 88% of all hospital pharmacists in 2010 and 81% in 2020 reported ADRs. In the group of pharmacists and general pharmacies, it was 14% in 2010 and 40% in 2020, respectively [12].

The main barriers to reporting adverse events were missing or incomplete patient information. The same reason was one of the most frequently mentioned by Iranian pharmacists, but it accounted for only 13.6% of all responses [13]. In a study carried out in Ethiopia, pharmacists most often did not report ADRs because they were not sure whether the symptom described by the patient was a consequence of taking a specific drug [19].

Of those who reported a side effect in the past, most said the process for reporting such was simple. This was mainly the opinion of pharmacists working in hospitals. They also believed that reporting an adverse reaction did not require much time and energy from the pharmacist. Specialized pharmacists had a similar opinion, which distinguished them from other respondents. In a survey conducted among hospital pharmacists in the UK, only 9.5% of all respondents believed that ADR reporting was a complicated process [14]. However, only 3% of all Iranian pharmacy graduates felt the same way [13]. In addition, the majority of Ethiopian pharmacists stated that ADR reporting did not require much additional work [19].

The available literature on the subject includes proposals that have the potential to improve ADR reporting and include:

- increasing access to training and education in the indicated area;
- spending more time on contact with patients in the hospital ward (in the case of hospital pharmacists);
- providing more encouragement, reminders and awareness-raising from superiors;
- increasing access to applications enabling easy online reporting;
- providing benefits from reporting (remuneration for performing additional duties for the system) [14].

Survey research provides evidence of the practice, opinion and knowledge of respondents. The purpose of such activity is to collect information on the occurrence of a given phenomenon and to group the results in relation to the scale and intensity level. This permits the results to be extrapolated to a large population group. Subsequently, this enables us to draw conclusions about the causes and effects, which allows us to propose new solutions to the examined problem. A big advantage of this study was the partial possibility of conducting it online. The added value of online survey research is that it provides the ability to create complex questions, as well as access a wider array of survey distribution, and do so with low production and distribution costs. Online surveying also gives the ability to quickly obtain and analyze data.

## CONCLUSIONS

We conclude that pharmacists in Poland are not prepared to report adverse drug reactions because they most often assess their level of knowledge in this area as “moderate”. Upon analyzing the available literature in this area, it can be stated that this is a common and global problem. Training on ADRs and their reporting are not popular among pharmacists, even though they consider this area of knowledge important and are aware of the obligation of pharmacists to report ADRs. In fact, only slightly more than half of all respondents knew how to make such a report.

Pharmacists working in hospital pharmacies rate their knowledge of ADRs higher than others and believe that the process of reporting them is simple and does not require much time and energy. The same opinion is also held by pharmacists with a specialist title, who more often declared participation in training on ADRs and who stated that they were more aware of the obligation to comply with them. Of note, pharmacists employed in community pharmacies reported adverse reactions less frequently than did other respondents.

Summarizing the above conclusions, it can be underlined that the main hypothesis of the study was refuted. Based on the results obtained and conclusions drawn, it can be noted that there is a need for greater education of pharmacists in reporting adverse reactions, especially those employed in community pharmacies.

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