

ADVERSE DRUG REACTIONS REPORTING: AWARENESS, KNOWLEDGE AND REASONS FOR UNDER-REPORTING AMONG HOPITAL PHARMACISTS IN THE REPUBLIC OF MACEDONIA

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Objective of the study

Assessment of the knowledge and awareness of adverse drug reactions (ADRs) reporting and pharmacovigilance system among hospital pharmacists in R. Macedonia and identification of the cause of under-reporting.

Materials and methods

• Study design and setting

Non-interventional, e-questionnaire based study was conducted for period of three months in order to evaluate hospital pharmacists' knowledge and attitude toward pharmacovigilance.

• The study population

Total of 54 hospital pharmacists from different healthcare organizations in Macedonia, different level of knowledge (Table 1) and working experience participated in the study (Table 2).

• The study instrument

Validated and predesigned e-questionnaire comprised of 19 questions that covered three main topics:

- Assessment of pharmacist awareness and knowledge regarding PV and ADRs reporting;
- Pharmacist's attitude, practice and reason for under-reporting; and
- Pharmacist's recommendations and suggestion to improve the PV.

Each pharmacist was asked to fill the e-questionnaire anonymously at their most convenient time

Table.1 Working place of pharmacists

Working place of participants (pharmacists)	N(%)
General hospital	18 (33.3%)
Clinical hospital	13 (24.1%)
University clinic	10 (18.5%)
Specialized hospital	8 (14.8%)
Other	5 (9.3%)

Table. 2 Experience in pharmacy practice

Working experience in pharmacy practice	N(%)
>20 years	32 (59.3%)
11-20 years	12 (22.2%)
6-10 years	6 (11.1%)
up to 5 years	4 (7.4%)

Results

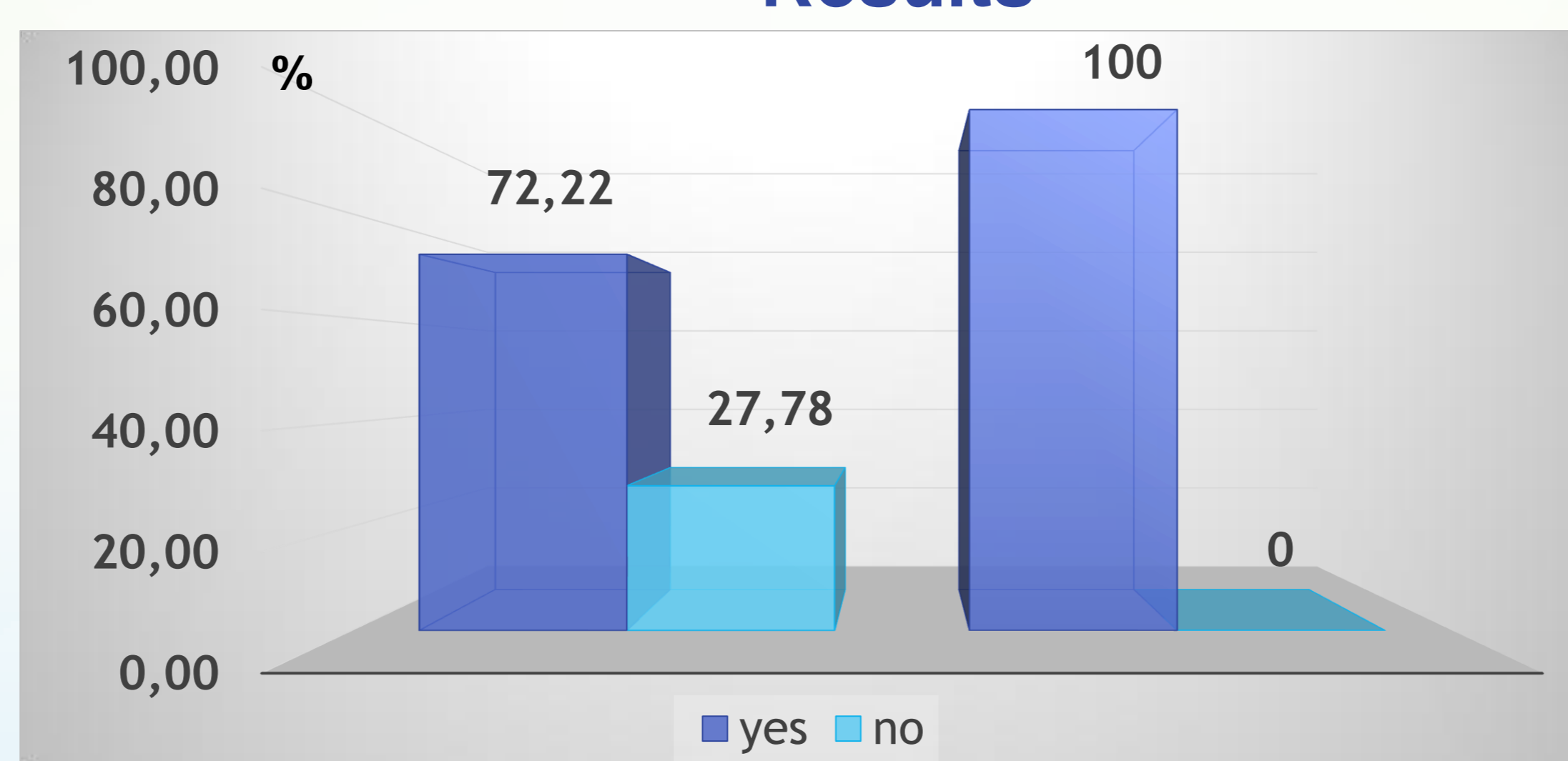


Figure 1. Attendance of education for ADR reporting and need for additional education for appropriate of ADRs reporting

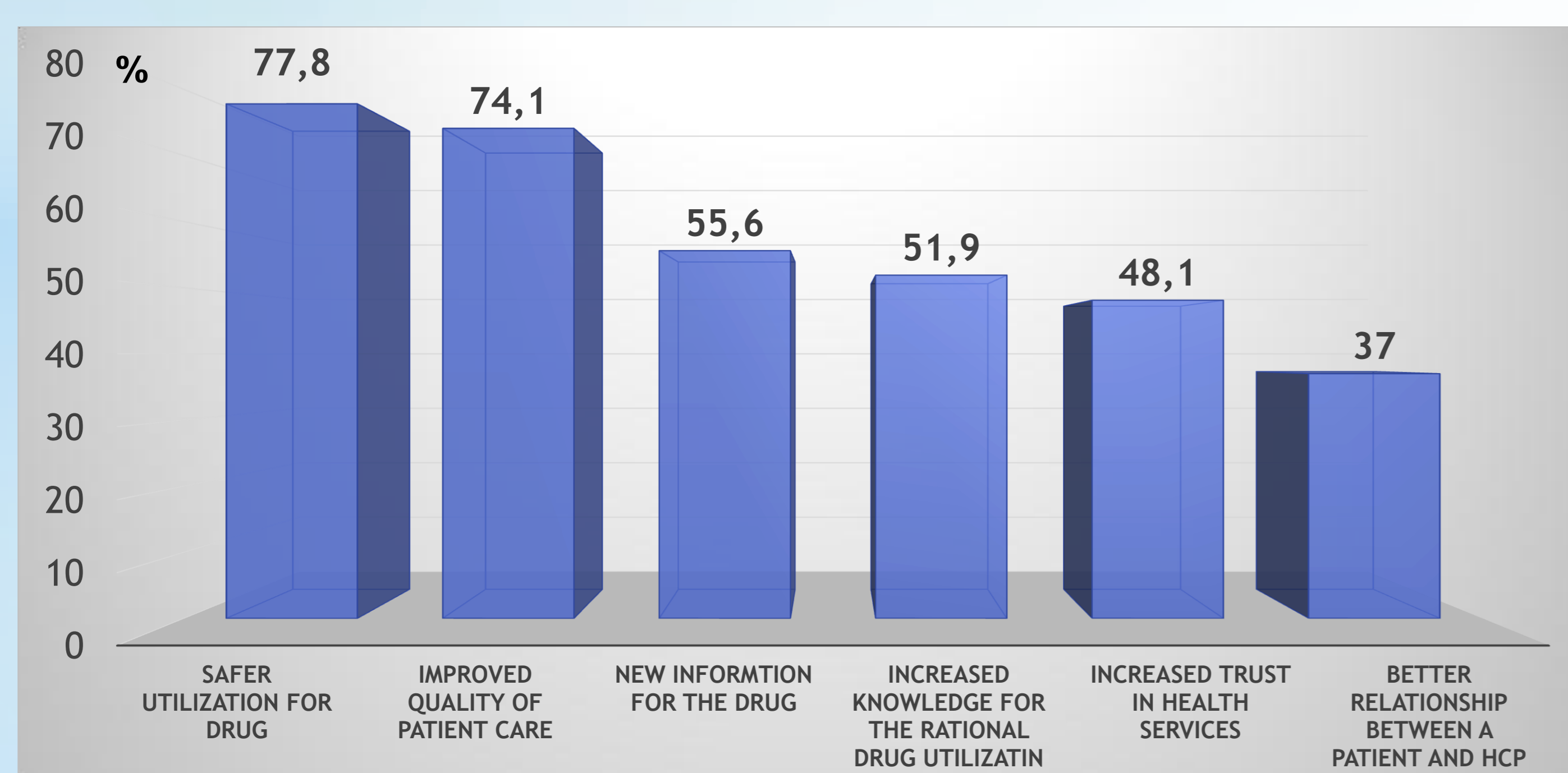


Figure 2. Benefits of ADRs reporting

Results are presented in %
* Explained in discussion

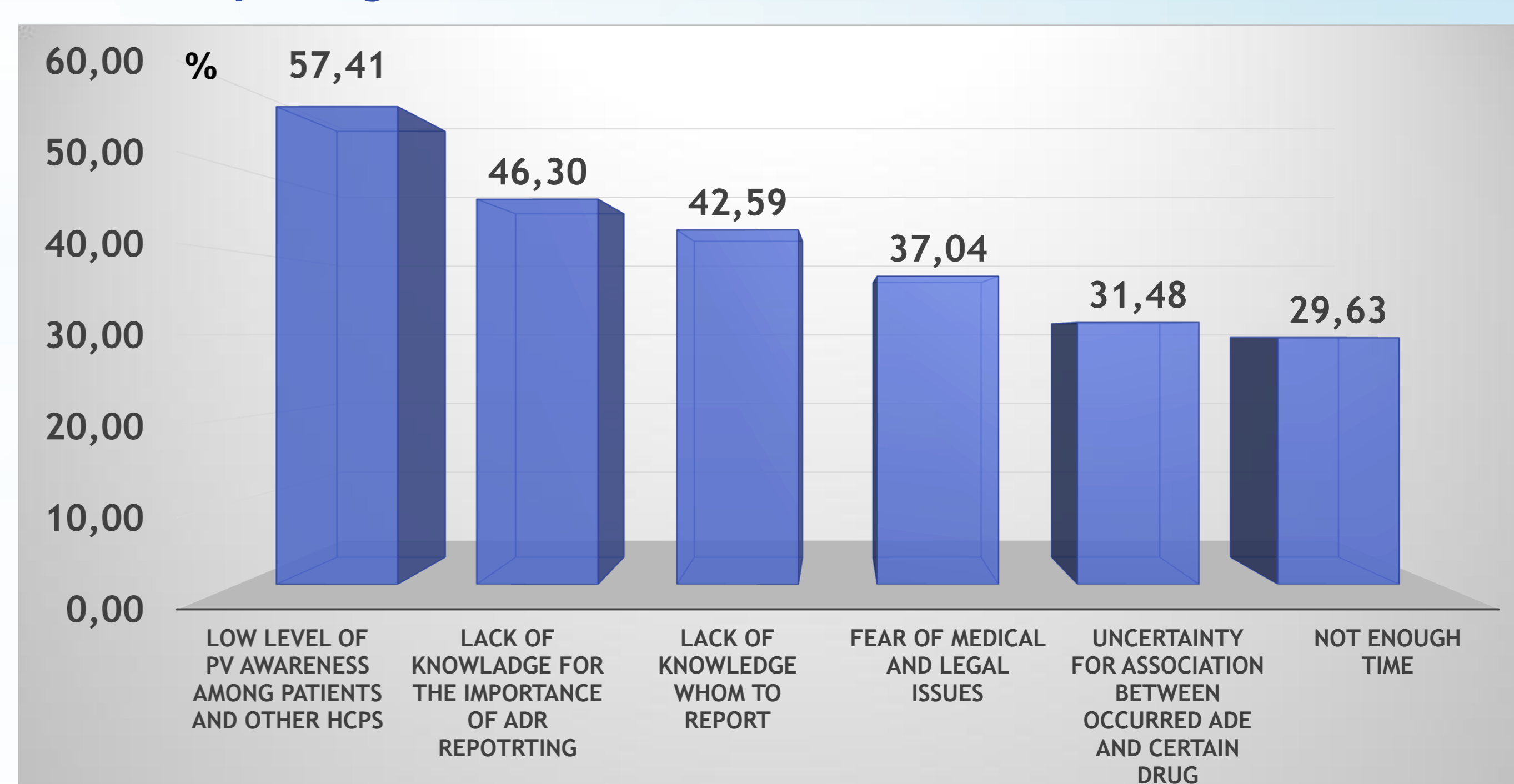


Figure 3. Key limiting factors for under-reporting of ADRs

Discussion

This was the first study conducted among hospital pharmacists evaluating the awareness, knowledge and reasons for underreporting observed in the hospitals in the Republic of Macedonia. High level of awareness (95%) for the importance of good pharmacovigilance (PV) practice and necessity of the adverse drug reactions (ADR) reporting was observed among the hospital pharmacist that participated in the study. Although 72.2% of 54 participants have attended an education for PV, all of the study participants specified the need of additional education in order to improve the practical implementation ADRs reporting in everyday clinical practice in hospitals in the Republic of Macedonia (Fig 1).

The results obtained from knowledge based questions confirmed good theoretical understanding for pharmacovigilance and presented a positive attitude towards ADR reporting. Almost 78% of the participants considered that ADRs reporting is contributing to utilization of safer drugs in clinical practice and they highlight it as the major benefit from implementation of good PV practice. 74.1% suggested that ADR reporting is associated with improvement of the quality of patient care, 54% of hospital pharmacists consider the new information for the drugs as uppermost benefit from good PV practice and almost 52% think that with ADR reporting the rational use of drugs will increase. 48.1% of the participants marked that increased trust in the health service as one of the benefits and 37% think that it will help in improvement of the relationship between patients and health care professionals (HCPs). All perceived benefits are presented in Figure 2.

57.4% of hospital pharmacists considered low awareness for importance of pharmacovigilance among patients and other health care professionals as key factor for underreporting of ADR. Almost 46% of participants notified that not sufficient information for the importance of ADR reporting as key reason for underreporting whereas the lack of knowledge whom to report was noticed as leading factor for underreporting for 42.6% of evaluated participants. 37% of hospital pharmacists mentioned the inappropriate fear of medical and legal issues as key factor for underreporting. Additionally the lack of time was addressed as the main limitation factor for implementation of appropriate PV practice, followed by the uncertainty for association between occurred adverse drug event (ADE) and utilization of certain drug. The discussed limiting factors accountable for underreporting are presented in Figure 3. These results point out the needs for implementation of proper infrastructure and legal framework as major determinants for improvement of PV practice in the future.

Conclusion

- * This is the first study conducted among hospital pharmacies in the Republic of Macedonia considering the knowledge, awareness and pharmacovigilance practice.
- * A satisfactory level of knowledge and awareness of PV and ADRs reporting was confirmed among hospitals pharmacists but the study provides important data for existence of the real gap between the knowledge and everyday PV practice in our country
- * This study addresses the need for implementation of educational and training programs for the hospital pharmacists, patients and other HCPs in order to encourage them for active participation in ADR reporting and arising patient safety of drug therapies in Republic of Macedonia .
- * The poor ADR reporting practice emphasized the urgent need for implementation of the appropriate strategies for improvement the awareness of pharmacovigilance practices in hospitals and on the national level.

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