EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 12
Issue: 5
Year: 2025

# ASSESSMENT OF KNOWLEDGE, ATTITUDE, AND PRACTICE OF PHARMACOVIGILANCE AMONG PHARMACISTS AND HEALTH CARE PROFESSIONALS IN FOUR GOVERNMENT HOSPITALS AT SANA'A CITY, YEMEN

**Maged Alwan Noman[1], Mahmoud Mahyoob Alburyhi[1]*, Abdalwali Ahmed Saif[1] and Tawfeek A. A. Yahya[2]**

[1]Professor Dr. of Pharmaceutics and Industrial Pharmacy, Department Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.
[2]Professor Dr. of Medicinal Chemistry and Drug Design, Department of Medicinal Chemistry, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.

***Corresponding Author: Prof. Dr. Mahmoud Mahyoob Alburyhi**
Professor Dr. of Pharmaceutics and Industrial Pharmacy, Department Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.

**Article Received on 21/03/2024** **Article Revised on 10/04/2025** **Article Accepted on 01/05/2025**

## ABSTRACT

**Background**: Pharmacovigilance is now firmly based on sound scientific principles and is integral to effective clinical practice. **Aim**: To get an insight into the causes of under-reporting of ADRs. **Method**: This is a cross-sectional study that was carried out across four hospitals (Al-Jmhori, Al-Kuwait, Al-Sabeen, Al-Thawra) and pharmacies of capital secretariat using a survey-based questionnaire. Survey was conducted from December 2023 to February 2024, a self-administered questionnaire with mostly close-ended questions were distributed by study researchers to 130 physician, 160 pharmacists and 110 nurses working at different working places using convenience sampling technique. The statistical analysis was performed using the Statistical Package for Social Science (SPSS). **Results**: The result showed good knowledge, Attitude and practice of Pharmacovigilance among health care specialists in government hospitals and pharmacies, the Scoring of all General Knowledge was (65.6%), General Attitude was (78.5%), and all General Practice was (65.7%). **Conclusion**: In general, the study identified deficiencies in knowledge, attitude and practice towards the practical Pharmacovigilance, so this survey strongly suggests that there is a great, need for educational programs to increase awareness among health professionals.

**KEYWORDS:** Pharmacovigilance, Adverse drug reactions**,** Reporting.

## INTRODUCTION

### Pharmacovigilance Practice[1-150]

Patient safety is considered to be a major concern among healthcare systems around the world. Modern drug therapy has improved the way of managing and controlling diseases and is based on two essential factors: safety and effectiveness. The World Health Organization defines pharmacovigilance as "science and activities relating to detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

Because it is difficult to discover all adverse effects of drugs prior to drug approval, post-marketing monitoring and spontaneous reporting of serious and less common ADRs is important to achieve a safe use of medications and to understand risks of drugs. Recently, in Yemen has established its national pharmacovigilance center by Supreme Board of Drug and Medical Appliances (SBDMA) in the capital secretariat as a starting point to report the ADRs. Spontaneous voluntary adverse drug reaction (ADR) reporting is the backbone for the successful functioning of the Pharmacovigilance Programmer of Yemen. Pharmacovigilance program (PP) has played a major role in the detection of ADRs and banning of several drugs from the market. However, under-reporting of ADRs is one of the major problems associated with PP. Because of variation in drug response, individual prescribing habits, drug regulatory system, and availability of drugs, it has been recommended for every country to set up their own PP. Various methods of detecting an adverse event (AE) include spontaneous reporting, prescription event monitoring, and others.

Spontaneous voluntary adverse drug reaction (ADR) reporting is the backbone for the successful functioning of the Pharmacovigilance Programmer of Yemen. The aim of pharmacovigilance is to ensure safe and rational use of medicines, once they are released for general use

in the society**.** Doctors, nurses, Pharmacists and pharmacologists play an important role in the identification of such unseen ADRs.

The importance of pharmacovigilance practice lies in the study of drug design, preformulation of the drug raw materials, the formulation, the stability, the follow-up of the drug -drug interactions in medical prescriptions, and the stage after drug marketing. All manufacturing or clinical to use is among the studies that interested of pharmaceutical scientists in the world. [100-198]

The aim of pharmacovigilance is to ensure safe and rational use of medicines, once they are released for general use in the society**.** Doctors, nurses, Pharmacists and pharmacologists play an important role in the identification of such unseen ADRs.

## OBJECTIVES OF THE STUDY

Assess the knowledge, attitudes and practices (KAP) regarding pharmacovigilance and ADR reporting among healthcare professionals at various departments of government hospital and pharmacies in the capital secretariat to get an insight into the causes of under-reporting of ADRs and create conceptual knowledge with the importance of pharmacovigilance in improving the medical health of patient**.**

## MATERIALS AND METHODS

### Study Design

This is a cross-sectional study that was carried out across four hospitals (Al-Jmhori, Al-kuwait, Al-Sabeen, Al-Thawrah) and pharmacies of capital secretariat using a survey-based questionnaire. Survey was conducted from December 2023 to February 2024, a self-administered questionnaire with mostly close-ended questions were distributed by study researchers to 130 physician ,160 pharmacists and 110 nurses working at different working places using convenience sampling technique. The researchers explained the objective of the survey to all participants before their participation in the study; and after obtaining their agreement, they were handed a self-administered questionnaire to be filled. After that, the researchers came back later to collect the completed questionnaires and sent them for data entry process.

### Study Questionnaire

The questionnaire used in this study was based on a questionnaire from a similar survey conducted by the Australian Regulatory Authority (Therapeutic Goods Administration) and KAP questionnaire was designed to assess the demographic details of the healthcare professionals, their knowledge of pharmacovigilance, attitude towards pharmacovigilance, and their practice on ADR reporting. There were 22 questions in the questionnaire to assess the knowledge on ADR, attitude towards pharmacovigilance and their practice on reporting ADR.

### Study Population

The target population of this study were the physicians, pharmacists and nurses.

Inclusion criteria: were being a nurse, pharmacist or physicians and having answered of all items in the questionnaire.

Exclusion criteria: was that the professional category was not identified in the questionnaire.

### Statistical Analysis

The statistical analysis was performed using the Statistical Package for Social Science (SPSS).

For the calculation of each dimension, only participants who answered all the questions were included, whereas for the calculation of the total score all the answers of the three dimensions were used. In case a participant failed to answer a question from any dimension, the total score would not be calculated. Final data were expressed as frequency and percentages.

## RESULTS AND DISCUSSION

Spontaneous reporting is an important method in reporting an ADR in PV program and under-reporting is major challenge. Assessing the KAP of PV among the HCPs is thus very important specially in a Regional PV Centre as it will ensure the extent of correct knowledge, right attitude and proper practice of HCPs in reporting an ADR. In Yemen, few studies have been done so far. The current study was conducted in capital secretariat which included a total of 388 healthcare professionals in which 138 pharmacists, 132 physicians, and 118 nurses. All categories of professionals had good levels considering knowledge, practice and “attitude”. In Sana'a to the best of our knowledge, this is the first study conducted among health care specialists in government hospitals and pharmacies in the capital secretariat which aimed to assessment of knowledge, attitude, and practice of pharmacovigilance of both community pharmacies and government hospitals with regard to pharmacovigilance and ADRs reporting.

### According to the Knowledge-Based Questions

General knowledge of Pharmacovigilance among health care specialists in government hospitals and pharmacies are shown in Table 1.

**Table 1: Distribution of Generals Knowledge.**

| N | Variable | General Knowledge | | | |
|---|---|---|---|---|---|
| | | Good | | Poor | |
| | | Freq | % | Freq | % |
| 1 | Are you familiar with the concept pharmacovigilance? | 172 | 44.3% | 216 | 55.7% |
| 2 | Define Pharmacovigilance? | 241 | 62.1% | 147 | 37.8% |
| 3 | The important purpose of Pharmacovigilance is? | 195 | 50.2% | 193 | 49.7% |
| 4 | Are you aware of any drug that has been banned recently due to side effects of drugs? | 264 | 68% | 124 | 31.9% |
| 5 | Are you aware of suspected side effects of drugs reporting system? | 120 | 30.9% | 268 | 69.1% |
| 6 | Is there a pharmacovigilance committee in Capital Secretariat? | 46 | 11.9% | 342 | 88.1% |
| | **Total** | **44.57%** | **60.1%** | **55.38%** | **70.9%** |
| | **Scoring of General Knowledge** | **44.5%** | | | |

**Table 2: Comparison Between the Pharmacists, Nurses and Physicians Regarding Knowledge.**

| Knowledge | | | | | | |
|---|---|---|---|---|---|---|
| Question Number | Pharmacist n(138) | | Nurses n(118) | | Physician n(132) | |
| | Good | Poor | Good | Poor | Good | Poor |
| **1** | 67% | 33% | 44% | 56% | 20% | 80% |
| **2** | 73% | 27% | 50% | 50% | 62% | 38% |
| **3** | 54% | 46% | 40% | 60% | 55% | 45% |
| **4** | 80% | 20% | 58% | 42% | 64% | 36% |
| **5** | 42% | 58% | 40% | 60% | 11% | 89% |
| **6** | 14% | 86% | 14% | 86% | 7% | 93% |
| Average Score | **55%** | **45%** | **41%** | **59%** | **37%** | **63%** |
| **General knowledge Score** | **44.29%** | | | | | |

As shown in Table 2, the general score for knowledge is poor (44.29%) in (6) variable this result is the same as the study developed with health professionals from Nepal. The degree of knowledge was calculated based on the correct answers to the paragraphs related to knowledge, where each correct answer was given a degree, and the wrong degrees were not calculated, and the general percentage of knowledge was taken according to the average of the correct degrees.

**Table 3: Distribution of the Variables of the Knowledge Dimension Stratified by Professional Category.**

| Level of Knowledge (Adequacy) | Professional Category | | | | P. Value |
|---|---|---|---|---|---|
| | Nursing | Pharmacy | Physicians | Total | |
| | n(%) | n(%) | n(%) | n(%) | |
| **Are You Familiar with the Concept Pharmacovigilance** | | | | | |
| Know the concepts and apply them daily (Adequate) | 24 (6.2) | 58 (14.9) | 12 (3.1) | 94 (24.2) | <0.05 |
| Has advanced knowledge and apply it daily (Adequate) | 12 (3.1) | 18 (4.6) | 4 (1) | 34 (8.8) | |
| Know how to apply (Adequate) | 16 (4.1) | 17 (4.4) | 11 (2.8) | 44 (11.3) | |
| Do not know the concepts (Inadequate) | 66 (17) | 45 (11.6) | 105 (27.1) | 216 (55.7) | |
| **Define Pharmacovigilance** | | | | | |
| The science of monitoring effectiveness of drugs happening in a Hospital (Inadequate) | 36 (9.3) | 14 (3.6) | 35 (9) | 85 (21.9) | <0.05 |
| The process of improving the effectiveness of Drugs (Inadequate) | 13 (3.4) | 9 (2.3) | 2 (0.5) | 24 (6.2) | |
| The detection, assessment, | 59 | 100 | 82 | 241 | |

| | | | | | |
|---|---|---|---|---|---|
| understanding & prevention side effects of drug. (Adequate) | (15.2) | (25.8) | (21.1) | (62.1) | |
| The science that discovers the effectiveness of drugs after marketing them (Inadequate) | 10 (2.6) | 15 (3.9) | 13 (3.4) | 38 (9.8) | |
| **The Important Purpose of Pharmacovigilance** | | | | | |
| To identify safety of drugs. (Adequate) | 47 (12.1) | 75 (19.3) | 73 (18.8) | 195 (50.3) | |
| To Calculate the duration of drug effectiveness. (Inadequate) | 12 (3.1) | 7 (1.8) | 10 (2.6) | 29 (7.5) | |
| To identify predisposing factors to drug (Inadequate) | 33 (8.5) | 27 (7) | 16 (4.1) | 76 (19.6) | 0.161 |
| Determine the effectiveness of drugs that have not been previously identified. (Inadequate) | 26 (6.7) | 29 (7.5) | 33 (8.5) | 88 (22.7) | |
| **The Important awareness of Pharmacovigilance** | | | | | |
| Are you aware of any drug that has been banned recently due to side effects of drugs? (Adequate) | 68 (17.5) | 111 (28.6) | 85 (21.9) | 264 (68) | <0.05 |
| Are you aware of suspected side effects of drugs reporting system? (Adequate) | 47 (12.1) | 58 (14.9) | 15 (3.9) | 120 (30.9) | <0.05 |
| Is there a pharmacovigilance committee in Capital Secretariat? (Adequate) | 17 (4.4) | 19 (4.9) | 10 (2.6) | 46 (11.9) | 0.172 |

The general knowledge among physicians was poor (36.69%) from the (6) variable. The number of participants is 132 which were mostly undergraduate physicians. The sample obtained from four hospitals Al-Sabeen n (34) Al-Jomhory n (33) Al-Kuwit n (33) Al-Thawrah n (32).

**Distribution of The Variables of The Knowledge Dimension for Physicians n (132)**

As shown in Table 3. For the Q are you familiar with the concept pharmacovigilance

The number of participants which chose the correct answer were n 27 (20.45%) and the wrong answer were 105(79.54%) which was poor result this result shows that there is a need and scope for creating awareness among medical student for the Q define pharmacovigilance? Only 82 (62.1%) define pharmacovigilance in (the detection, assessment, understanding & prevention side effects of drug) which a good result comparing with the previous question.

For the Q the important purpose of pharmacovigilance? Only 73 participant (55.3%) answers adequately.

For the Q the are you aware of any drug that has been banned recently due to side effects of drugs? Only 85 participant (64.3%) answers adequately

For the Q are you aware of suspected side effects of drugs reporting system? Only 15 participant (11%) answers adequately which was poor result this result shows that there is a need and scope for creating awareness among medical students.

For the Q is there a pharmacovigilance committee in capital secretariat? Only 10 participant (7%) answers adequately which was poor result this result shows that there is a need and scope for creating awareness among medical students.

The general knowledge among nursing was poor (40.98%) but was better than physicians The number of participants is 118 which obtained from four hospitals Al-Sabeen n (33) Al-Jomhory n (33) Al-Kuwit n (26) Al-Thawrah hospital n (26).

**Distribution of the Variables of the Knowledge Dimension for Nurses n(118)**

As shown in Table 3**.** For the Q Are you familiar with the concept pharmacovigilance.

The number of participants who chose the correct answer were n 52(44.3%) which was poor result This result shows that there is a need and scope for creating awareness among medical students.

For the Q Define Pharmacovigilance ONLY 59 (50%) Define Pharmacovigilance in (The detection, assessment, understanding & prevention side effects of drug) which was a good result This result shows that there is a need and scope for creating awareness among medical students.

For the Q The important purpose of Pharmacovigilance ONLY 47 participant (39.8%) answers adequately which was poor result This result shows that there is a need and scope for creating awareness among medical students

For the Q the Are you aware of any drug that has been banned recently due to side effects of drugs only 68 participant (57.6%) answers adequately.

For the Q Are you aware of suspected side effects of drugs reporting system? Only 47 participant (39.8) answers adequately.

For the Q Is there a pharmacovigilance committee in Capital Secretariat? Only 17 participant (14.4%) answers adequately.
The general knowledge among pharmacists was good (55.2%) from the total participant. The number of participants was 138 obtained from random community pharmacies in Capital Secretariat.

**Distribution of the Variables of the Knowledge Dimension for Pharmacists**
As shown in Table 3. For the Q are you familiar with the concept pharmacovigilance.
The number of participants who chose the correct answer were n 93(67.3%)
For the Q define pharmacovigilance only 100(73.4%) define pharmacovigilance in (the detection, assessment, understanding & prevention side effects of drug) which was different from other articles in the same subject
For the Q the important purpose of pharmacovigilance only 75 participant (54.3%) answers adequately which was close from other articles in the same subject
For the Q the are you aware of any drug that has been banned recently due to side effects of drugs only 111 participant (80.4%) answers adequately
For the Q are you aware of suspected side effects of drugs reporting system? Only 58 participant (42%) answers adequately.
For the Q is there a pharmacovigilance committee in capital secretariat? Only 19 participant (13.7%) answers adequately.
In knowledge the present study show that the pharmacist has the highest score secondly nurses and thirdly physicians this lack of knowledge among physicians and nurses and also the male has the highest score may be because they don't have PV course in their college courses. and also, the males have higher score than females as shown in Table 4. Generally, there was a poor knowledge in the reporting system for ADR and the Is there a pharmacovigilance committee in Capital Secretariat which indicate the lack of training programs conducted by Yemen health administration in this topic.
To overcome the lack of knowledge among health care professionals' medical schools must conducted a continuing medical education program (CME) on this topic to encourage them to actively participate in reporting ADRs.

**Table 4: Distribution of Knowledge Between Sex.**

| N | Male n196 (50.5%) | Female n192 (49.5%) |
|---|---|---|
| **1** | 117(59.6%) | 55(28.6%) |
| **2** | 132(67.3%) | 109(56.7%) |
| **3** | 101(51.5%) | 94(48.9%) |
| **4** | 147(76.5%) | 117(60.9%) |
| **5** | 75(38.2%) | 45(23%) |
| **6** | 27(13.6%) | 19 (9.8%) |
| **Average Score** | **50.9%** | **38.10%** |

These results obtained dividing the number of males who chose the correct answer by the total number of male and multiply it by 100. the same for the female results.

**In The Attitude-Based Questions**
**Table 5: Distribution of Generals Attitude.**

| N | Variable | General Attitude | | | |
|---|---|---|---|---|---|
| | | Good | | Poor | |
| | | Freq | % | Freq | % |
| 1 | The healthcare professionals responsible for reporting side effects of drugs is/are? | 192 | 49.5% | 196 | 50.5% |
| 2 | Which among the following factors discourage you from reporting side effects of drugs? | 169 | 43.6% | 219 | 56.4% |
| 3 | What is the main reason to notify an adverse drug event (side effects of drugs)? | 293 | 75.6% | 95 | 24.5% |
| 4 | Have you ever attended a tutoring session specified for pharmacovigilance? | 63 | 16.2% | 325 | 83.8% |
| 5 | Is there a need to include pharmacovigilance in undergraduate curriculum to create Awareness among the healthcare professionals? | 360 | 92.8% | 28 | 7.2% |
| 6 | Do you think Pharmacovigilance should be taught in detail to healthcare professionals? | 366 | 94.3% | 22 | 5.7% |

| | | | | | |
|---|---|---|---|---|---|
| 7 | Do you think side effects of drugs reporting is professional obligation for you? | 364 | 93.8% | 24 | 6.2% |
| 8 | Do you think reporting of adverse drug reaction is necessary? | 363 | 93.6% | 25 | 6.4% |
| **Total** | | **90%** | | **63.5%** | |
| **Scoring of General Attitude** | | **69.9%** | | | |

As illustrated in Table 5. The Attitude based questions the general score for attitude is good (69.9%) in (8) variable this result is the same as the study developed with health professionals from Brazil, Nepal and India.

**Table 6: Distribution of the Variables of the Attitude Dimension Stratified by Professional Category.**

| Attitude (Adequacy) | Professional Category | | | | P. Value |
|---|---|---|---|---|---|
| | Nursing | Pharmacy | Physicians | Total | |
| | n(%) | n(%) | n(%) | n(%) | |
| **The Healthcare Professionals Responsible for Reporting Side Effects of Drugs Is/Are?** | | | | | |
| Physicians s | 36 (9.3) | 17 (4.4) | 49 (12.6) | 102 (26.3) | < 0.05 |
| Pharmacists | 16 (4.1) | 24 (6.2) | 20 (5.2) | 60 (15.5) | |
| Nurses | 22 (5.7) | 7 (1.8) | 5 (1.3) | 34 (8.8) | |
| All of the above (Adequate) | 44 (17) | 90 (11.6) | 58 (27.1) | 192 (55.7) | |
| **Which Among the Following Factors Discourage You from Reporting Side Effects of Drugs?** | | | | | |
| Non-remuneration for reporting (Inadequate) | 40 (10.3) | 26 (6.7) | 51 (13.1) | 117 (30.2) | < 0.05 |
| Lack of time to report side effects of drugs (Inadequate) | 19 (4.9) | 24 (6.2) | 6 (1.5) | 49 (12.6) | |
| A single unreported case may not affect side effects of drugs database (Inadequate) | 23 (5.9) | 17 (4.4) | 13 (3.4) | 53 (13.7) | |
| Difficult to decide whether side effects of drugs have occurred or not (Adequate) | 36 (15.2) | 71 (25.8) | 62 (21.1) | 169 (62.1) | |
| **What Is the Main Reason to Notify an Adverse Drug Event (Side Effects of Drugs)?** | | | | | |
| It can lead to actions that reduce the risk associated to medicines (Adequate) | 36 (9.3) | 34 (8.8) | 47 (12.1) | 117 (30.2) | 0.274 |
| Reporting side effects of drugs is important to build drug safety profiles (Adequate) | 43 (11.1) | 78 (20.1) | 55 (14.2) | 176 (45.4) | |
| Mandatory policies to report side effects of drugs at workplace (Inadequate) | 12 (3.1) | 2 (0.5) | 9 (2.3) | 23 (5.9) | |
| Interest in obtaining scientific information about side effects of drugs (Inadequate) | 27 (17) | 24 (11.6) | 21 (27.1) | 72 (55.7) | |
| Have you ever attend a tutoring session specified for pharmacovigilance**?** (Adequate) | 24 (6.2) | 31 (8) | 8 (2.1) | 63 (16.2) | < 0.05 |
| Is there a need to include pharmacovigilance in undergraduate curriculum to create Awareness among the healthcare professionals**?** (Adequate) | 104 (26.8) | 133 (34.3) | 123 (31.7) | 360 (92.8) | < 0.05 |
| Do you think Pharmacovigilance should be taught in detail to healthcare professionals**?** (Adequate) | 103 (26.5) | 133 (34.3) | 130 (33.5) | 366 (94.3) | < 0.05 |
| Do you think side effects of drugs reporting is professional obligation for you**?** (Adequate) | 108 (27.8) | 134 (34.5) | 122 (31.4) | 364 (93.8) | 0.131 |
| Do you think reporting of adverse drug reaction is necessary? (Adequate) | 107 (27.6) | 129 (33.2) | 127 (32.7) | 363 (93.6) | 0.206 |

**Distribution of the Variables of the Attitude Dimension for Physicians n(132)**

As shown in Table 6. In the Q The healthcare professionals responsible for reporting side effects of drugs is/are? Only 58 (43.9%) participant answers adequately.

Which among the following factors discourage you from reporting side effects of drugs? Only 132 (100%)

participant answers adequately which the 4 variables are correct.
What is the main reason to notify an adverse drug event (side effects of drugs)? Only 102 (77.2%) participant answers adequately which is good result.
Have you ever attended a tutoring session specified for pharmacovigilance? Only 8 (6%) participant answers adequately.
Is there a need to include pharmacovigilance in undergraduate curriculum to create Awareness Among the healthcare professionals? Only 123 (93.1%) participant answers adequately.
Do you think Pharmacovigilance should be taught in detail to healthcare professionals? Only 130 (98.4%) participant answers adequately.
Do you think side effects of drugs reporting is professional obligation for you? Only 122 (92.4%) participant answers adequately.
Do you think reporting of adverse drug reaction is necessary? Only 127 (96.2%) participant answers adequately

**Distribution of the Variables of the Attitude Dimension for Nursing n (118)**

As shown in Table 6. In the Q The healthcare professionals responsible for reporting side effects of drugs is/are? Only 44(37.28%) participant answers adequately.
which among the following factors discourage you from reporting side effects of drugs? Only 118 (100%)
What is the main reason to notify an adverse drug event (side effects of drugs)? Only 79(66.9%) participant answers adequately.
Have you ever attended a tutoring session specified for pharmacovigilance? Only 24 (20%) participant answers adequately.
Is there a need to include pharmacovigilance in undergraduate curriculum to create Awareness among the healthcare professionals? Only 104 (88.1%) participant answers adequately.
Do you think Pharmacovigilance should be taught in detail to healthcare professionals? Only 103 (87.2%) participant answers adequately.
Do you think side effects of drugs reporting is professional obligation for you? Only 108 (91.5%) participant answers adequately.
Do you think reporting of adverse drug reaction is necessary? Only 107(90.6%) participant answers adequately.

**Distribution of The Variables of The Attitude Dimension for Pharmacists n (138)**

As shown in Table 6**.** In the Q The healthcare professionals responsible for reporting side effects of drugs is/are? Only 90(65.2%) participant answers adequately.
which among the following factors discourage you from reporting side effects of drugs? Only 138 (100%)
What is the main reason to notify an adverse drug event (side effects of drugs)? Only 112(81.1%) participant answers adequately.
Have you ever attended a tutoring session specified for pharmacovigilance? Only 31(22.4%) participant answers adequately.
Is there a need to include pharmacovigilance in undergraduate curriculum to create Awareness among the healthcare professionals? Only 133(96.3%) participant answers adequately.
Do you think Pharmacovigilance should be taught in detail to healthcare professionals? Only 133 (96.3%) participant answers adequately.
Do you think side effects of drugs reporting is professional obligation for you? Only 134(97.1%) participant answers adequately.
Do you think reporting of adverse drug reaction is necessary? Only 129 (93.4%) participant answers adequately.

**Table 7: Comparison Between the Pharmacists, Nurses and Physicians Regarding Attitude.**

| | Attitude | | | | | |
|---|---|---|---|---|---|---|
| | Pharmacist n(138) | | Nurses n(118) | | Physician n(132) | |
| | Good | Poor | Good | Poor | Good | Poor |
| 1 | 65% | 35% | 37% | 63% | 44% | 56% |
| 2 | 51% | 49% | 31% | 70% | 47% | 53% |
| 3 | 81% | 19% | 67% | 33% | 77% | 23% |
| 4 | 22% | 78% | 20% | 80% | 6% | 94% |
| 5 | 96% | 4% | 88% | 12% | 93% | 7% |
| 6 | 96% | 4% | 87% | 13% | 98% | 2% |
| 7 | 97% | 3% | 92% | 9% | 92% | 8% |
| 8 | 93% | 7% | 91% | 9% | 96% | 4% |
| **AVG Score** | **75%** | **25%** | **64%** | **36%** | **69%** | **31%** |
| **General Attitude Score** | **69.56%** | | | | | |

As shown in Table 7. The attitude in the present study show that the pharmacist has the highest score secondly nurses and thirdly physicians the present study shows a good attitude among health care professionals toward ADR reporting. In Which among the following factors discourage you from reporting side effects of drugs 30%

are discouraged by Non-remuneration for reporting , are discouraged by 12.6% Lack of time to report side effects of drugs, 13.7% A single unreported case may not affect side effects of drugs database and 62.1% are discouraged by difficult to decide whether side effects of drugs have occurred or not.to overcome this educating them that any suspected ADRs are to be reported even if one is not sure about it. 93.8% of the participant felt that ADR reporting is a professional obligation and 92.8% felt that PV should be taught in detail to health care professionals. which it reveals a positive attitude of the participants and this finding is almost similar to previous studies, also the average attitude score for female is higher than male in the dimension of attitude as shown in Table 8.

**Table (8): Distribution of Attitude Between Sex.**

| No | Male n196(%) | Female n192 (%) |
|---|---|---|
| **1** | 104(52.5%) | 88(45.8%) |
| **2** | 196(100%) | 192(100%) |
| **3** | 152(76.7%) | 141(73.4%) |
| **4** | 36 (18.1%) | 27(14.06%) |
| **5** | 182(92.8%) | 178(92.7%) |
| **6** | 184(93.8%) | 182(94.8%) |
| **7** | 183(93.3%) | 181(94.2%) |
| **8** | 182(92.8) | 181(94.2%) |
| **Average Score** | **77.70%** | **82.50%** |

This result obtained dividing the number of males who chose the correct answer by the total number of male and multiply it by 100. the same for the female result.

**In The Practice-Based Questions**

The General score for practice is poor (40.65%) in (8) variable, this result is the same as the study developed with health professionals from Nepal, India. Distribution of generals practice as shown in Table 9.

**Table 9: Distribution of Generals Practice.**

| N | Variable | General Practice | | | |
|---|---|---|---|---|---|
| | | Good | | Poor | |
| | | Freq | % | Freq | % |
| 1 | In which circumstances do you consult the package leaflet medicines? | 275 | 70.8% | 113 | 29.2% |
| 2 | Have you ever experienced adverse drug reactions in your patient during your professional practice? | 247 | 63.7% | 141 | 36.3% |
| 3 | Have you ever read any article about preventing side effects of medications? | 256 | 66% | 132 | 34% |
| 4 | Have ever been trained on how to report adverse drug reaction? | 75 | 19.3% | 313 | 80.7% |
| 5 | Have you ever seen the adverse drug reaction reporting form? | 70 | 18% | 318 | 82% |
| 6 | Have you ever reported adverse drug reaction (side effects of drugs) to pharmacovigilance center? | 40 | 10.3% | 348 | 89.7% |
| 7 | Do you keep records of side effects of drugs? | 116 | 29.9% | 272 | 70.1% |
| 8 | Are you willing for side effects of drugs reporting? | 183 | 47.2% | 205 | 52.8% |
| **Total** | | **66.8%** | | **75%** | |
| **Scoring of General Practice** | | **40.2%** | | | |

**Table 10: Distribution of the Variables of the Practice Dimension Stratified by Professional Category.**

| Practice (Adequacy) | Professional Category | | | | P. Value |
|---|---|---|---|---|---|
| | Nursing | Pharmacy | Physicians | Total | |
| | n(%) | n(%) | n(%) | n (%) | |
| Prescribing a medicine for the first time (Adequate). | 43(11.1) | 40(10.3) | 69(17.8) | 152(39.2) | < 0.05 |
| Patient reports the occurrence of a side effects of drugs(Adequate). | 48(12.4) | 38(9.8) | 37(9.5) | 123(31.7) | |
| Patient asks for information about a medicine (Inadequate). | 13(3.4) | 28(7.2) | 21(5.4) | 62(16) | |
| Prescribing a medicine that is new to the | 14(3.6) | 32(8.2) | 5(1.3) | 51(13.1) | |

| | | | | | |
|---|---|---|---|---|---|
| patient (Inadequate). | | | | | |
| Have you ever experienced adverse drug reactions in your patient during your professional practice? (Adequate) | 75(19.3) | 89(22.9) | 83(21.4) | 247(63.7) | 0.962 |
| Have you ever read any article about preventing side effects of medications? (Adequate) | 81(20.9) | 104(26.8) | 71(18.3) | 256(66) | < 0.05 |
| Have ever been trained on how to report adverse drug reaction? (Adequate) | 35(9) | 31(8) | 9(2.3) | 75(19.3) | < 0.05 |
| Have you ever seen the adverse drug reaction reporting form? (Adequate) | 38(9.8) | 23(5.9) | 9(2.3) | 70(18) | < 0.05 |
| Have you ever reported adverse drug reaction (side effects of drugs) to pharmacovigilance center? (Adequate) | 25(6.4) | 10(2.6) | 5(1.3) | 40(10.3) | < 0.05 |
| Do you keep records of side effects of drugs? (Adequate) | 45(11.6) | 30(7.7) | 41(10.6) | 116(29.9) | < 0.05 |
| Are you willing for side effects of drugs reporting? (Adequate) | 55(14.2) | 96(24.7) | 32(8.2) | 183(47.2) | < 0.05 |

**Distribution of The Variables of The Practice Dimension Physicians n (132)**

As shown in Table 10**.** In the Q In which circumstances do you consult the package leaflet medicines? Only 106(80.3%) participant answers adequately.

In the Q Have you ever experienced adverse drug reactions in your patient during your Professional practice? Only 83 (62.8%) participant answers adequately.

In the Q Have you ever read any article about preventing side effects of medications? Only 71(53.7%) participant answers adequately.

In the Q Have ever been trained on how to report adverse drug reaction? Only 9(6.8%) participant answers adequately.

In the Q Have you ever seen the adverse drug reaction reporting form? Only 9(6.8%) participant answers adequately.

In the Q Have you ever reported adverse drug reaction (side effects of drugs) to Pharmacovigilance center? Only 5 (3.7%) participant answers adequately.

In the Q Do you keep records of side effects of drugs? Only 41(31%) participant answers adequately.

In the Q Are you willing for side effects of drugs reporting? Only 32 (24.2%) participant answers adequately.

**Distribution of The Variables Of The Practice Dimension Nursing n(118)**

As shown in Table 10. In the Q In which circumstances do you consult the package leaflet medicines? Only 91(77.1%) participant answers adequately.

In the Q Have you ever experienced adverse drug reactions in your patient during your Professional practice? Only 75(56%) participant answers adequately.

In the Q Have you ever read any article about preventing side effects of medications? Only 81(68.6%) participant answers adequately.

In the Q Have ever been trained on how to report adverse drug reaction? Only 35(29.6%) participant answers adequately.

In the Q Have you ever seen the adverse drug reaction reporting form? Only 35(29.6%) participant answers adequately.

In the Q Have you ever reported adverse drug reaction (side effects of drugs) to Pharmacovigilance center? Only 38 (32.2%) participant answers adequately.

In the Q Do you keep records of side effects of drugs Only 45(38.1%) participant answers adequately.

In the Q Are you willing for side effects of drugs reporting? Only 55(46.6%) participant answers adequately.

**Distribution of The Variables of The Practice Dimension Pharmacists n (138)**

As shown in Table 10**.** In the Q In which circumstances do you consult the package leaflet medicines? Only 78(56.5%) participant answers adequately.

In the Q Have you ever experienced adverse drug reactions in your patient during your Professional practice? Only 89(64.4%) participant answers adequately.

In the Q Have ever been trained on how to report adverse drug reaction? Only 31(26.2%) participant answers adequately.

In the Q Have you ever read any article about preventing side effects of medications? Only 104(75.3%) participant answers adequately.

In the Q Have you ever seen the adverse drug reaction reporting form? Only 23(16%) participant answers adequately.

In the Q Have you ever reported adverse drug reaction (side effects of drugs) to Pharmacovigilance center? Only 5(3.6%) participant answers adequately.

In the Q Do you keep records of side effects of drugs? Only 96(69.5%) participant answers adequately.

In the practice the present study shown in Table 11, that the pharmacist has the highest score secondly nurses and thirdly physicians the present study shows a good practice among health care professionals toward ADR reporting. Despite the good score there are a deficient in

the Q Have you ever seen the adverse drug reaction reporting form, in the Q Have you ever reported adverse drug reaction (side effects of drugs) to pharmacovigilance center and in the Q Have ever been trained on how to report adverse drug reaction which is concerning also this study result shows that the male has a greater score than female as shown in Table12.

**Table 11: Comparison Between the Pharmacists, Nurses and Physicians Regarding Practice.**

| | Practice | | | | | |
|---|---|---|---|---|---|---|
| | Pharmacists n(138) | | Nurses n(118) | | Physicians n(132) | |
| | Good | Poor | Good | Poor | Good | Poor |
| 1 | 56.50% | 43.50% | 77.10% | 22.90% | 80.30% | 19.70% |
| 2 | 64.40% | 36% | 64% | 36.00% | 62.80% | 37.20% |
| 3 | 75.36% | 24.640% | 68.64% | 31.36% | 53.78% | 46.22% |
| 4 | 75.30% | 24.70% | 29.66% | 70.34% | 6.80% | 93.20% |
| 5 | 22.40% | 77.60% | 29.60% | 70.40% | 6.80% | 93.20% |
| 6 | 7.24% | 92.76% | 32.20% | 67.80% | 3.70% | 96.30% |
| 7 | 21.70% | 78.30% | 38.10% | 63% | 31% | 69% |
| 8 | 69.50% | 30.50% | 46.60% | 53.40% | 24.20% | 75.80% |
| **Average Score** | **49.05%** | **50.95%** | **48.18%** | **51.89%** | **33.67%** | **66.33%** |
| **General Practice Score** | **43.75%** | | | | | |

**Table 12: Distribution of Practice Between Sex.**

| | Male n196 (%) | Female n192 (%) |
|---|---|---|
| 1 | 128 (65.36%) | 120 (62.5%) |
| 2 | 133 (67.8%) | 114 (59.3%) |
| 3 | 139 (70.9%) | 117 (60.93%) |
| 4 | 46 (23.4%) | 29 (15.1%) |
| 5 | 37 (18.8%) | 33 (17.1%) |
| 6 | 21 (10.7%) | 19 (9.8%) |
| 7 | 45 (22.9%) | 71 (36.9%) |
| 8 | 124 (63.2%) | 59 (30.7%) |
| **Average Score** | **42.9%** | **36.5%** |

This result obtained dividing the number of males who chose the correct answer by the total number of male and multiply it by 100. the same for the female result.

## CONCLUSION

It was observed that health care professionals have “poor level” for knowledge and practice toward pharmacovigilance and were considered as “a good level” regarding attitude. It was observed that pharmacists have better knowledge, attitude and practice toward pharmacovigilance than physicians and nurses. The study also show that male is better in knowledge, attitude and practice toward pharmacovigilance. In general, the study also identified deficiencies in "knowledge, practice and attitude" towards the practical pharmacovigilance, which makes it possible to guide better planning to face the challenges involved in strengthening the Yemen's Pharmacovigilance.

## REFERENCES


1. Sharma HL, Sharma KK. Drug Discovery and Clinical Evaluation of New Drugs. Hyderabad: Paras Medical Publisher., 2010.
2. Agarwal R, Aqil Mohamed Daher, Nafeeza MohdIsmail. Knowledge, Practices, and Attitudes Towards Adverse Drug Reaction Reporting by Private Practitioners from Klang Valley in Malaysia. Malays J Med Sci., 2012; 20(1): 52.
3. Alshakka M, Jha N, Algefri S, Ibrahim MI, Hassali MA, Abdorabbo A, Shankar PR. Problems and Challenges Faced in Consumer Reporting of Adverse Drug Reactions in Developing Countries – A Case Study of Yemen, Nepal and Malaysia. Indian J Pharm. Biol Res., 2014; 2(3): 37-43.
4. Hazell L, Cornelius V, Hannaford P, Shakir S, Avery AJ. How Do Patients Contribute to Signal Detection? A Retrospective Analysis of Spontaneous Reporting of Adverse Drug Reactions in The UK's Yellow Card Scheme. Drug Saf. 2013; 36(3): 199-206.
5. Subish P, Mohamed I, Mishra P. Pattern of Adverse Drug Reaction Reported by Community Pharmacist in Nepal. Phar. Pract., 2010; 8 (3): 201-207.
6. Upadhyaya HB, Vora MB, Nagar JG, Patel PB. Knowledge, Attitude and Practices Toward Pharmacovigilance and Adverse Drug Reactions in

Postgraduate Students of Tertiary Care Hospital in Gujarat. J Pharma Tech Res., 2015; 6(1): 29-34.
7. Sivadasan S, Sellappan M. A study on The Awarness and Attitude Towards Pharmacovigilance and Adverse Drug Reaction Reporting Among Nursing Students in A Private University, Malaysia. International Journal of Current Pharmaceutical Research., 2015; 7(1): 84-89.
8. Ganesan S, Vikneswaran G, Reddy KC, Subrahmanyam DK, Adithan C. A Survey on Knowledge, Attitude and Practice of Pharmacovigilance towards Adverse drug reactions reporting among Physicians and Nurses in a Tertiary Care Hospital in South India. J Young Pharm.; 2016; 8 (4): 471-6.
9. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspectives in Clinical research.; 2011; 2(4): 129.
10. Gupta SK, Nayak RP, Shivaranjani R, Vidyarthi SK. A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India. Perspectives in clinical research., 2015; 6(1) : 45.
11. Ravindra S. Beedimani, Sameer Uz Zaman, Subrahmanyam Darbha,Sharat Chandra Potturi. An evaluation of knowledge, attitude and practice of pharmacovigilance among medical students and doctors at a tertiary care hospital. Int J Basic Clin Pharmacol., 2018; 7 (2): 324-332.
12. Campbell JE, Gossell-Williams M, Lee MG. A Review of Pharmacovigilance. West Indian Med J. 2014; 63(7): 771.
13. Beninger P. Pharmacovigilance: An Overview. Clin Ther. c2018; Jul 18.
14. Soni R, Kesari B. A Review on Pharmacovigilance. Int J Pharm Sci Rev Res., c2014 May-Jun; 26(2): 237-241.
15. Garashi HY, Steinke DT, Schafheutle EI. A Systematic Review of Pharmacovigilance Systems in Developing Countries Using the WHO Pharmacovigilance Indicators. Ther. Innov. Regul. Sci. 2022; 56: 717-743.
16. Sarker A, Ginn R, Nikfarjam A, O'Connor K, Smith K, Jayaraman S, et al. Utilizing social media data for pharmacovigilance: A review. J Biomed Inform. 2015; 54: 202-212.
17. Bihana K, Lebrun-Vignes B, Funck-Brentano C, Salem JE. Uses of pharmacovigilance databases: An overview. Therapies; c2020.
18. Inácio P, Cavaco A, Airaksinen M. The value of patient reporting to the pharmacovigilance system: A systematic review. Br J Clin. Pharmacol. 2017; 83: 227- 246.
19. Moore N, Berdaï D, Blin P, Droz C. The next chapter in pharmacovigilance. Therapies. 2019; 74: 557-567.
20. Shaw D, Ladds G, Duez P, Williamson E, Chan K. Pharmacovigilance of herbal medicine. J Ethnopharmacol, 2012; 140: 513-518.
21. Mammì M, Citraro R, Torcasio G, Cusato G, Palleria C, Di Paola ED. Pharmacovigilance in pharmaceutical companies: An overview. J Pharmacol. Pharmacother., 2013; 4(1).
22. Hauben M, Madigan D, Gerrits CM, Walsh L, Van Puijenbroek EP. The role of data mining in pharmacovigilance. Therapies, 2010; 65: 929-948.
23. Pitts PJ, Le Louet H, Moride Y, Conti RM. 21st century pharmacovigilance: Efforts, roles, and responsibilities. Drug Saf., 2002; 25(1): e486-e492.
24. Wilson AM, Thabane L, Holbrook A. Application of data mining techniques in pharmacovigilance. Br J Clin Pharmacol, 2004; 57(2): 127-134.
25. Jeetu G, Anusha G. Pharmacovigilance: A WorldwideMaster Key for Drug Safety Monitoring. J Young Pharm, 2010; 2(3): 315-320.
26. Biswas P. Pharmacovigilance in Asia. J Pharmacol Pharmacother, 2013; 4(1): S7-S19.
27. Laporte JR. Fifty years of pharmacovigilance - Medicines safety and public health. Pharmacoepidemiol Drug Saf. 2016; 25: 725-732.
28. Alhat BRA. Pharmacovigilance: An Overview. IJRPC., 2011; 1(4): 968-974.
29. Renard TL, Buclin T. Pharmacovigilance. Rev Med Suisse; c2012; 117-119.
30. Saleh HA, Fourrier-Réglat A, Diogène E. Patientcentered pharmacovigilance: A review. Trop J Pharm Res. 2018; 17(1): 179-188.
31. Rohilla A, Singh N, Kumar V, Sharma MK, Dahiya A, Kushnoor A. Pharmacovigilance: Needs and Objectives. J Adv. Pharm. Educ. Res. 2012; 2(4): 201- 205.
32. Casadevall N, Edwards IR, Felix T, Graze PR, Litten JB, Strober BE, et al. Pharmacovigilance and biosimilars: Considerations, needs and challenges. Expert Opin. Biol. Ther., 2013; 13(7).
33. Shuka SS, Gidwani B, Pandey R, Rao SP, Singh V, Vyas A, Importance pharmacovigilance in Indian Pharmaceutical Industry, Asian Journal of Research in Pharmaceutical Science. 2012; (2): 04-08.
34. WHO, Pharmacovigilance, ensuring the safe use of medicines, Geneva WHO.2004.
35. Mann RD, Andrews EB, eds. John Wiley & Sons Ltd, Pharmacovigilance, Chichester. 2002.
36. Jadhav Sudhakar and Chakraborthy Guno, "Pharmacovigilance in India: Need of Hour", Journal of Advances in Pharmacy and Healthcare Research (JAPHR). 2011; 1: 01-03.
37. Kesharwani V, Farooqui MA, Kushwaha N, Singh RK, Jaiswal PK, An overview on pharmacovigilance: a key for drug safety and monitoring, Journal of Drug Delivery and Therapeutics. 2018; 8(5): 130-135.
38. The importance of pharmacovigilance-safety monitoring of medicinal products. Geneva: World Health Organization; 2002. Available at: https:

//apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf. Accessed on 01 July 2020.
39. WHO cc in Uppsala (UMC). Available at: https: //www.who.int/medicines/areas/quality_safety/safety efficacy/PV_fast_facts/en/. Accessed on 01 July 2020.
40. Sumit et al. Journal of Drug Delivery & Therapeutics. 2013; 3(4): 237.
41. Inácio P, Cavaco A, Airaksinen M. (). Current trends in Pharmacovigilance: value and gaps of patient reporting. International journal of clinical pharmacy. 2018; 40(4): 754-757.
42. Härmark L, van Grootheest AC, Pharmacovigilance: Methods, recent developments and future perspectives. Eur J Clin Pharmacol. 2008; 64: 743–752.
43. Strom BL, (Ed). Pharmacoepidemiology, 4th edn. Wiley, Chichester.2005.
44. Gelfand JM, Margolis DJ, Dattani H. The UK general practice research database. In: Strom BL (ed) Pharmacoepidemiology, 4th edn. Wiley, Chichester. 2005.
45. Kesharwani V, Farooqui MA, Kushwaha N, Singh RK, Jaiswal PK, An overview on pharmacovigilance: a key for drug safety and monitoring, Journal of Drug Delivery and Therapeutics. 2018; 8(5): 130-135.
46. Throat SB, Banarjee SK, Gaikwad DD, Jadhav SL, Thorat RM. International Journal of Pharmaceutical Sciences Review and Research. 2010; 1(2) Article 019.
47. European Commission. Detailed Guidance on the Collection, Verification, and Presentation of Adverse Reaction Reports Arising from Clinical Trials on Medicinal Products for Human Use. 2006.
48. Tripathi DK, Shiv S. Pharmacovigilance (Nirali Prakashan). and others, editor, 2017; 262.
49. Nimesh S. Pharmacovigilance program of review article Acta scientific pharmaceutical sciences., 2022.
50. Sachdev Y. Pharmacovigilance safety matter, Indian pharmacology., 2008.
51. Lakshmi I, Aashritha M. A review on pharmacovigilance and its importance. Teja A World J Pharm Pharm Sci. 2017; 6(1): 300–10.
52. McBride WG. Thalidomide and congenital abnormalities. Lancet. December. 1961; 16: 278, 1358.
53. Torres-Saavedra, P. A., & Winter, K. A. An overview of phase 2 clinical trial designs. International Journal of Radiation Oncology Biology Physics., 2022; 112(1): 22-29.
54. Wandile, Pranali, and Ravindra Ghooi. "A role of ICH-GCP in clinical trial conduct." J Clin Res Bioeth., 2017; 8.1: 1-5.
55. Dr. KP Sampath Kumar, Dr. Debjit Bhowmik, Rishab Bhanot, Shambaditya Goswami Text Book of INDUSTRIAL PHARMACY – II FINAL YEAR B. PHARM. Publication : Nirali Prakashan . First June 2020.
56. Talbot JC, Nilsson BS. Pharmacovigilance in the pharmaceutical industry. British journal of clinical pharmacology, 1998; 45(5): 427.
57. Gupta YK. Pharmacovigilance programme for India. July 21, 2010; Available at http: //www.pharmabiz.com/PrintArticle.aspx?aid=57406&sid=9.
58. Mann RD, Andrews EB, eds. Pharmacovigilance, John Wiley & Sons Ltd, Chichester, 2002.
59. Phases of Clinical Trials, Published By Bright Focus Foundation In September 2, 2021; https: //www.brightfocus.org/clinical-trials/howclinical-trials-work/phases-clinical-trials
60. Phases of Clinical Trials Published by MD Anderson Cancer Center https: //www.mdanderson.org/patientsfamily/diagnosis-treatment/clinical-trials/phasesofclinicaltrials.
61. Pharmacovigilance strategies by World Health Organization https: //www.who.int/teams/regulationprequalification/regulation-andsafety/pharmacovigilance/guidance/strategies
62. ICH GCP (Good Clinical Practice) Guidelines Published By Primers Research In January 31 , 2018 https: //premier-research.com/blog-updatesguideline-good-clinical-practice-quickreview
63. Ema. Pharmacovigilance: Overview – European Medicines Agency. European Medicines Agency. (2023, October https: //www.ema.europa.eu/en/humanregulatory/overview/pharmacovigilance-overview
64. Singh, N., Madkaikar, N. J., Gokhale, P. M., & Parmar, D. V. New drugs and clinical trials rules 2019: Changes in responsibilities of the ethics committee. Perspectives in clinical research, 2020; 11(1): 37-43.
65. Annapurna, Swathi A., and Srinivasa Y. Rao. "New drug and clinical trial rules, 2019: an overview." Int J Clin Trials 2020; 7(4): 278. Published By National Disorder Foundation, Understanding Clinical Trials https: //www.bleeding.org/research/researchprojects/clinical-trial-essentials/understandingclinical-trials
66. Ravinetto RA. The revision of the ICH Good Clinical Practice guidelines: a missed opportunity. Indian J Med Ethics., 2017; 2(4): 255-259.
67. Singh KNM, Kanase HR. Pharmacovigilance programme of India: The beginning, current status and recent progress. Adv Pharmacoepidemiol Drug Saf., 2017; 6(4): 219.
68. Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health & Family Welfare https: //cdsco.gov.in/opencms/opencms/en/Home/
69. Pharmacovigilance – A Regulatory Synopsis | Freyr – Global Regulatory Solutions and Services Company. (n.d.). May 19, 2022. https: //www.freyrsolutions.com/blog/pharmacovigil ance-a-regulatory-synopsis

70. Yadav, Poonam, Kavita Bahmani, Neelam Pawar, and A. A. Sharma. "Review on: Indian Pharma Regulatory System and List of New Drugs Approved by Central Drugs Standard Control Organization in the Year 2021 Till Date." Int. J. Pharm. Sci. Res., 2021; 12: 5642-5651.
71. Dubey A, Kotian B, Shriram RG. New drugs and clinical trials rules, 2019: Towards fasttrack accessibility of new drugs to the Indian population. IJPER., 2019; 53: 451-9.
72. Anushka S, Andhale Mr, Rushikesh B, Jadhav Dr. Megha, Salve T. Pharmacovigilance in Healthcare: A Comprehensive Review International Journal of Pharmaceutical Research and Applications., 2023; 8 (6).
73. Meshram N, Harane S, Kale V, Biyani D, Umekar MJ. Regulatory overview on new drugs and clinical trials rules, 2019. International Journal Of Drug Regulatory Affairs., 2023; 11(1): 31-42.
74. Barry A, Olsson S, Minzi O, et al. Comparative assessment of the National pharmacovigilance systems in East Africa. Drug Saf., 2020; 43: 339–50.
75. Garashi HY, Steinke DT, Schafheutle EI. A systematic review of pharmacovigilance systems in developing countries using the WHO pharmacovigilance indicators. Ther Innov Regul Sci., 2022; 56: 717–43.
76. Khadem Broojerdi A, Baran Sillo H, Ostad Ali Dehaghi R, et al. The World Health Organization global Benchmarking tool an instrument to strengthen medical products regulation and promote universal health coverage. Front Med (Lausanne). 2020; 7: 457.
77. World Health Organization. Global vaccine safety blueprint 2.0 (GVSB2.0) 2021-2023. Geneva: World Health Organization, 2021. Available: https: //www.who.int/publications/i/item/9789240036963.
78. Khalili M, Mesgarpour B, Sharifi H, et al. Interventions to improve adverse drug reaction reporting: a scoping review. Pharmacoepidemiol Drug Saf. 2020; 29: 965–92.
79. Paudyal V, Al-Hamid A, Bowen M, et al. Interventions to improve spontaneous adverse drug reaction reporting by healthcare professionals and patients: systematic review and meta-analysis. Expert Opin Drug Saf. 2020; 19: 1173–91.
80. Lee J-Y, Lee Y-S, Kim DH, et al. The use of social media in detecting drug safety–related new black box warnings, labeling changes, or withdrawals: scoping review. JMIR Public Health Surveill. 2021; 7: e30137.
81. Tricco AC, Zarin W, Lillie E, et al. Utility of social media and crowdintelligence data for pharmacovigilance: a scoping review. BMC Med Inform Decis Mak. 2018; 18: 38.
82. Tricco AC, Lillie E, Zarin W, et al. PRISMA extension for scoping reviews (PRISMA-SCR): checklist and explanation. Ann Intern Med. 2018; 169: 467–73.
83. Clark JM, Sanders S, Carter M, et al. Improving the translation of search strategies using the polyglot search translator: a randomized controlled trial. J Med Libr Assoc. 2020; 108: 195–207.
84. Canadian Agency for Drugs and Technologies in Health. Grey matters: a practical tool for searching health-related grey literature. Ottawa: CADTH, 2019. Available: https: //greymatters.cadth.ca
85. Varallo FR, Planeta CS, de Carvalho Mastroianni P. Effectiveness of pharmacovigilance: multifaceted educational intervention related to the knowledge, skills and attitudes of multidisciplinary hospital staff. Clinics. 2017; 72: 51–7.
86. Morales Ríos O, Jasso Gutiérrez L, Talavera JO, et al. A comprehensive intervention for adverse drug reactions identification and reporting in a pediatric emergency department. Int J Clin Pharm. 2016; 38: 80–7.
87. Deepalakshmi M, Kumar P, Arun KP, et al. Impact of continuing pharmacy education on the knowledge, attitude and practice of community pharmacists about ADR monitoring and reporting. Pharmaceutical-Sciences. 2019; 81: 633–9.
88. Alraie NA, Saad AA, Sabry NA, et al. Adverse drug reactions reporting: a questionnaire-based study on Egyptian pharmacists' attitudes following an awareness workshop. J Eval Clin Pract 2016; 22: 349–55.
89. Vo TH, Dang TN, Nguyen TT, et al. An educational intervention to improve adverse drug reaction reporting: an observational study in a tertiary hospital in Vietnam. Arch Pharm Pract. 2020; 11: 32–7.
90. Chang F, Xi Y, Zhao J, et al. A time series analysis of the effects of financial incentives and mandatory clinical applications as interventions to improve spontaneous adverse drug reaction reporting by hospital medical staff in China. J Eval Clin Pract. 2017; 23: 1316–21.
91. Fang H, Lin X, Zhang J, et al. Multifaceted interventions for improving spontaneous reporting of adverse drug reactions in a general hospital in China. BMC Pharmacol Toxicol. 2017; 18: 49.
92. Cortes-Serra N, Saravia R, Grágeda RM, et al. Strengthening the bolivian pharmacovigilance system: new surveillance strategies to improve care for Chagas disease and tuberculosis. PLoS Negl Trop Dis. 2020; 14: e0008370.
93. Terblanche A, Meyer JC, Godman B, et al. Impact of a pharmacistdriven pharmacovigilance system in a secondary hospital in the Gauteng province of South Africa. Hospital Practice. 2018; 46: 221–8.
94. Kadima NJ, Nyiranteziryayo R, Umumararungu T, et al. Use of mobile phones for patient self-reporting adverse drug reactions: a pilot study at a tertiary hospital in Rwanda. Health Technol. 2021; 11: 185–91.
95. Prakash J, Joshi K, Malik D, et al. ADR Pvpi" Android mobile App: Ceport adverse drug reaction

at any time anywhere in India. Indian J Pharmacol. 2019; 51: 236–42.
96. Vogler M, Ricci Conesa H, de Araújo Ferreira K, et al. Electronic reporting systems in pharmacovigilance: the implementation of Vigiflow in Brazil. Pharmaceut Med. 2020; 34: 327–34.
97. Uppsala Monitoring Centre. Cofepris boosts ability to receive and analyse adverse drug reaction reports. Uppsala Reports. 2020; 22–3.
98. Rouamba T, Sondo P, Derra K, et al. Optimal approach and strategies to strengthen pharmacovigilance in sub-Saharan Africa: a cohort study of patients treated with first-line artemisinin-based combination therapies in the Nanoro health and demographic surveillance system, Burkina Faso. Drug Des Devel Ther. 2020; 14: 1507–21.
99. Bravo-Alcántara P, Pérez-Vilar S, Molina-León HF, et al. Building capacity for active surveillance of vaccine adverse events in the Americas: a hospital-based multi-country network. Vaccine. 2018; 36: 363–70.
100. Ndiaye J-LA, Diallo I, NDiaye Y, et al. Evaluation of two strategies for community-based safety monitoring during seasonal malaria chemoprevention campaigns in Senegal, compared with the National spontaneous reporting system. Pharmaceut Med. 2018; 32: 189–200.
101. Noman MA, Alburyhi MM, Saif AA. Knowledge and Perception about Pharmacovigilance Among 4Th and 5Th Levels Pharmacy Students in Some Public and Private Universities, Sana'a Yemen. World Journal of Pharmaceutical and Medical Research., 2023; 9(11): 14-19.
102. Joshi J, Das MK, Polpakara D, et al. Vaccine safety and surveillance for adverse events following immunization (AEFI) in India. Indian J Pediatr. 2018; 85: 139–48.
103. Meher BR. Vaccine Pharmacovigilance in India: Current context and future perspective. Indian J Pharmacol. 2019; 51: 243–7.
104. Kalaiselvan V, Thota P, Singh GN. Pharmacovigilance programme of India: recent developments and future perspectives. Indian J Pharmacol. 2016; 48: 624–8.
105. Nguyen K-D, Nguyen P-T, Nguyen H-A, et al. Overview of pharmacovigilance system in Vietnam: lessons learned in a resourcerestricted country. Drug Saf. 2018; 41: 151–9.
106. Jusot V, Chimimba F, Dzabala N, et al. Enhancing pharmacovigilance in sub-Saharan Africa through training and mentoring: a GSK pilot initiative in Malawi. Drug Saf. 2020; 43: 583–93.
107. National Drug Authority. Pharmacovigilance strategy for Uganda. 2019. Available: https: //www.nda.or.ug/wp-content/uploads/2022/ 02/Pharmacovigilance-strtaegy-for-implementation.pdf [Accessed 1 Aug 2022].
108. Federal Ministry of Health Nigeria. Nigerian national pharmacovigilance policy and implementation framework. 2020. Available: https: //msh.org/wp-content/uploads/2021/03/nigerian_ national_pharmacogilance_policy_implementation_framework.pdf [Accessed 1 Jul 2022].
109. Adenuga BA, Kibuule D, Bamitale KDS, et al. Effective integration of pharmacovigilance systems at public health facilities in resourcelimited settings: a qualitative study. Res Social Adm Pharm. 2020; 16: 1111–6.
110. World Health Organization. Safety of medicines: priming resourcelimited countries for pharmacovigilance. WHO Drug Information 2017; 31: 575–80.
111. Elshafie S, Roberti AM, Zaghloul I. Pharmacovigilance in developing countries (part II): a path forward. Int J Clin Pharm. 2018; 40: 764–8.
112. PhArmacoVigilance Africa. PAVIA guide for effective implementation of the pharmacovigilance policy in resource limited settings. PAVIAEDCTP sponsored project. 2021. Available: https: //pavia-africa.net/ publications [Accessed 1 Aug 2022].
113. MacDonald NE, Guichard S, Arora N, et al. Lessons on causality assessment and communications from the 2019 South-East Asia regional (SEAR) workshop on inter-country expert review of selected adverse events following immunization (AEFI) cases. Vaccine. 2020; 38: 4924–32.
114. World Health Organization. Vaccine Pharmacovigilance readiness for malaria vaccine implementation. Wkly Epidemiol Rec. 2018; 93: 17–32.
115. Poirot E, Soble A, Ntshalintshali N, et al. Development of a Pharmacovigilance safety monitoring tool for the Rollout of single low-dose Primaquine and Artemether-Lumefantrine to treat Plasmodium Falciparum infections in Swaziland: a pilot study. Malar J. 2016; 15: 384.
116. Weigmann K. Consumer reporting of adverse drug reactions: systems that allow patients to report side effects of the drugs they are taking have yielded valuable information for improving drugs safety and health care. EMBO Rep. 2016; 17: 949–52.
117. Inácio P, Cavaco A, Airaksinen M. The value of patient reporting to the pharmacovigilance system: a systematic review. Br J Clin Pharmacol. 2017; 83: 227–46.
118. Fukushima A, Iessa N, Balakrishnan MR, et al. Smartphone-based mobile applications for adverse drug reactions reporting: global status and country experience. BMC Med Inform Decis Mak. 2022; 22: 118.
119. Ampadu HH, Hoekman J, Arhinful D, et al. Organizational capacities of national Pharmacovigilance centers in Africa: assessment of resource elements associated with successful and unsuccessful Pharmacovigilance experiences. Global Health. 2018; 14.
120. Kiguba R, Olsson S, Waitt C. Pharmacovigilance in Low-And Middle- Income countries: A review with particular focus on Africa. Br J Clin Pharmacol. 2023; 89: 491–509.

121. World Health Organization. WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products. 2021; Available: https: //apps.who.int/iris/rest/bitstreams/1346833/retrieve
122. Stegmann J-U, Jusot V, Menang O, et al. Challenges and lessons learned from four years of planning and implementing pharmacovigilance enhancement in sub-Saharan Africa. BMC Public Health. 2022; 22: 1568.
123. Tanzania Medicines and Medical Devices Authority. Tanzania medicines and medical devices authority - the National Pharmacovigilance roadmap 2019 - 2023. 2021. Available: https: // www.tmda.go.tz/ [Accessed 1 Aug 2022].
124. The National Agency for Food and Drug Administration and Control. The National agency for food and Drug Administration and control (NAFDAC). strategic plan 2018-2023. 2019. Available: https: //www. nafdac.gov.ng/wp-content/uploads/Files/Resources/APPROVEDNAFDAC-SP-2018-2023.pdf.
125. Russom M, Bahta I, Debesai M. Eritrean Pharmacovigilance system: key strategies, success stories, challenges and lessons learned. Drug Saf. 2021; 44: 1021–32.
126. Beninger P, Ibara MA. Pharmacovigilance and Biomedical Informatics: A Model for Future Development. Clin. Ther., 2016; 38: 2514–2525.
127. Cui X, Wang LX, Liu GY, Xie YM. Enlightenment of international pharmacovigilance system on establishment of pharmacovigilance system of Chinese medicine. China J. Chin. Mater. Med., 2021; 46: 5450–5455.
128. Darrow JJ, Avorn J, Kesselheim AS. FDA Approval and Regulation of Pharmaceuticals, 1983–2018. JAMA. 2020; 323: 164.
129. Liang L, Hu J, Sun G, Hong N, Wu G, He Y, Li Y, Hao T, Liu L, Gong M. Artificial Intelligence-Based Pharmacovigilance in the Setting of Limited Resources. Drug Saf. 2022; 45: 511–519.
130. WHO. The Global Health Observatory. Available online: https: //www.who.int/data/gho/indicator-metadata-registry/imrdetails/193 (accessed on 20 November 2022).
131. Suwankesawong, W.; Dhippayom, T.; Tan-Koi, W.-C.; Kongkaew, C. Pharmacovigilance Activities in ASEAN Countries. Pharmacoepidemiol. Drug Saf. 2016; 25: 1061–1069.
132. Therapeutic Goods Administration Report a Problem or Side Effect. Available online: https: //www.tga.gov.au/reportingproblems (accessed on 1 November 2021).
133. TGA Black Triangle. Available online: https: //www.tga.gov.au/black-triangle-scheme (accessed on 2 November 2021).
134. Linger M, Martin J. Pharmacovigilance and Expedited Drug Approvals. Aust. Prescr. 2018; 41: 50.
135. Therapeutic Goods Administration. Annual Performance Statistics Reports; Therapeutic Goods Administration: Woden, Australia, 2020.
136. Health Canada Search the Canada Vigilance Adverse Reaction Online Database. Available online: https: //cvp-pcv.hc-sc.gc.ca/ arq-rei/ (accessed on 3 November 2021).
137. Health Canada Canada Vigilance Program. Available online: https: //www.canada.ca/en/health-canada/services/drugs-healthproducts/medeffect-canada/canada-vigilance-program.html (accessed on 20 October 2021).
138. Health Canada Adverse Reactions, Medical Device Incidents and Health Product Recalls in Canada: 2019 Summary Report. Available online: https: //www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffectcanada/adverse-reactions-incidents-recalls-2019-summary.html (accessed on 20 October 2021).
139. Health Canada Notice of Intent to Amend the Food and Drug Regulations and the Medical Devices Regulations to Support Regulatory Agility. Available online: https: //gazette.gc.ca/rp-pr/p1/2021/2021-07-31/html/notice-avis-eng.html#na2 (accessed on 2 November 2021).
140. Juan Roldán QF. Farmacovigilancia: Datos Sobre El Estado Actual De Esta Disciplina En Chile. Rev. Med. Clin. Las Condes., 2016,; 27: 585–593.
141. Acuna-Johnson P. Drug Safety in Chile. In Drug Safety in Developing Countries; Elsevier: Amsterdam, The Netherlands., 2020; 587–599.
142. Uppsala Monitoring Centre. Making Medicines Safer; Uppsala Monitoring Centre: Uppsala, Sweden., 2018.
143. Uppsala Monitoring Centre. Members of the WHO Programme for International Drug Monitoring. Available online: https: //www. who-umc.org/global-pharmacovigilance/who-programme-for-international-drug-monitoring/who-programme-members/ (accessed on 30 January 2022).
144. European Medicine Agency. European Medicines Regulatory Network. Available online: https: //www.ema.europa.eu/en/ about-us/how-we-work/european-medicines-regulatory-network (accessed on 9 April 2022).
145. European Medicine Agency. Legal Framework: Pharmacovigilance. Available online: https: //www.ema.europa.eu/en/humanregulatory/overview/pharmacovigilance/legal-framework-pharmacovigilance (accessed on 23 January 2022).
146. Alburyhi MM, El-Shaibany A. Formulation, Development and Evaluation of Aloe Vera Extract Capsules Delivery System as an Advanced Phytotherapy Approach for Cancer. World Journal of Pharmaceutical Research., 2024; 13(8): 1052-1072.
147. Alburyhi MM, Saif AA, Noman MA, Saif RM. Recent Innovations of Delivery Systems for

Antimicrobial Susceptibility Study of Ciprofloxacin Biodegradable Formulations for Post-Operative Infection Prophylaxis. European Journal of Pharmaceutical and Medical Research., 2023; 10(9): 32-36.
148. Alburyhi MM, El-Shaibany A. Formulation, Development and Evaluation of Dictyota Dichotoma Extract Medicinal Seaweed Capsules Delivery System as an Advanced Phytotherapy Approach for Cancer. European Journal of Biomedical and Pharmaceutical Sciences., 2024; 11(4): 63-70.
149. Alburyhi MM, El-Shaibany A. Formulation, Development and Evaluation of Celery Extract Capsules Delivery System as an Advanced Phytotherapy Approach for Gout. World Journal of Pharmaceutical Research., 2024; 13(11): 2383-2404.
150. Raweh SM, Noman MA, Alburyhi MM, Saif AA. Formulation and Evaluation of Anti-acne Gel of Azadirachta Indica Extract Herbal Product. European Journal of Pharmaceutical and Medical Research, 2024; 11(2): 427-433.
151. Alburyhi MM, Saif AA, Noman MA. Formulation and Evaluation of Ticagrelor Orodispersible Tablets. World Journal of Pharmaceutical Research., 2024; 13(5): 26-55.
152. Noman MA, Alburyhi MM, El-Shaibany A, Alwesabi NA. Formulation and Evaluation of Pandanus Odoratissimus L Extract for Treatment of Nocturnal Enuresis as Orodispersible Tablets Delivery System. World Journal of Pharmaceutical Research., 2024; 13(5): 56 -71.
153. Alburyhi MM, El-Shaibany A. Formulation, Development and Evaluation of Acalypha Fruticosa Extract Tablets Delivery System as an Advanced Phytotherapy Approach for Controlling Diabetes. World Journal of Pharmaceutical Research., 2024; 13(8): 1073-1091.
154. Saif AA, Alburyhi MM, Noman MA. Evaluation of Vitamin and Mineral Tablets and Capsules in Yemen Market. Journal of Chemical Pharma Research., 2013; 5(9): 15-26.
155. Alburyhi MM, El-Shaibany A. Formulation and Evaluation of Antibacterial Orodispersible Tablets of Artemisia Arborescence Extract Herbal Product. European Journal of Pharmaceutical and Medical Research., 2024; 11(2): 409-417.
156. Alburyhi MM, El-Shaibany A. Formulation and Evaluation of Oral Pharmaceutical Solution of Pandanus Odoratissimus L Extract Herbal Product in Treatment of Nocturnal Enuresis. World Journal of Pharmacy and Pharmaceutical Sciences., 2024; 13(1): 1840-1851.
157. Noman MA, Alburyhi MM, El-Shaibany A, Alwesabi NA. Preformulation and Characterization Studies of Pandanus Odoratissimus L Extract Active Ingredient in Treatment of Nocturnal Enuresis. World Journal of Pharmacy and Pharmaceutical Sciences., 2024; 13(2): 1603-1620.
158. Alburyhi MM, El-Shaibany A. Formulation, Development and Evaluation of Pandanus Odoratissimus Extract Capsules Delivery System as an Advanced Phytotherapy Approach for Hepatoprotective. European Journal of Pharmaceutical and Medical Research., 2024; 11(4): 06-13.
159. Alburyhi MM, Noman MA, Saif AA, Salim YA, Abdullah JH. Formulation and Evaluation of Domperidone Orodispersible Tablets. World Journal of Pharmacy and Pharmaceutical Sciences., 2024; 13(3): 49-68.
160. Alburyhi MM, Saif AA, Noman MA, Hamidaddin MA. Formulation and Evaluation of Clopidogrel Orodispersible Tablets. World Journal of Pharmaceutical Research., 2024; 13(6): 42-64.
161. Alburyhi MM, Saif AA, Noman MA, Al khawlani MA. Formulation and Evaluation of Bisoprolol Fast Dissolving Tablets. World Journal of Pharmaceutical Research., 2023; 12(16): 01-10.
162. Alburyhi MM, Saif AA, Noman MA, Al-Ghorafi MA. Comparative Study of Certain Commercially Available Brands of Paracetamol Tablets in Sana'a City, Yemen. European Journal of Pharmaceutical and Medical Research., 2018; 5(12): 36-42.
163. Alburyhi MM, Saif AA, Noman MA, Al Ghoury AA. Formulation and Evaluation of Antimalarial Drugs Suppositories. World Journal of Pharmaceutical Research., 2023; 12(20): 89-108.
164. Alburyhi MM, Saif AA, Noman MA, Saeed SA, Al-Ghorafi MA. Formulation and Evaluation of Diclofenac Orodispersible Tablets. European Journal of Pharmaceutical and Medical Research., 2023; 10(9): 01-06.
165. Al-Ghorafi MA, Alburyhi MM, Muthanna MS. Chemical Incompatibilities of IV Admixture Combinations in ICU, Orthopedic and Emergency Units of Various Hospitals and Medical Centers in Sana'a, Yemen. European Journal of Pharmaceutical and Medical Research., 2023; 10(10): 416-425.
166. Alburyhi MM, El-Shaibany A. Formulation and Evaluation of Antitumor Activity of Artemisia Arborescence Extract Capsules as Dietary Supplement Herbal Product Against Breast Cancer. World Journal of Pharmaceutical Research., 2024; 13(3): 95-114.
167. Alburyhi MM, Noman MA, Saif AA, Al-Ghorafi MA, Al Khawlani MA, Yahya TAA. Formulation and Evaluation of Anti-acne Spironolactone Emulgel Novel Trend in Topical Drug Delivery System. World Journal of Pharmaceutical Research., 2023; 12(22): 96-119.
168. Alburyhi MM, Noman MA, Saif AA, Salim YA, Hamidaddin MA, Yahya TA, Al-Ghorafi MA, Abdullah JH. Lisinopril-Excipient Compatibility Studies for Advanced Drug Delivery Systems Development. World Journal of Pharmaceutical Research., 2024; 13(16): 59-111.
169. Al-Ghorafi MA, Alburyhi MM, Saif AA, Noman MA, Yahya TA. Drotaverine-Excipient Compatibility Studies for Advanced Drug Delivery Systems Development. World Journal of

Pharmaceutical Research., 2024; 13(18): 1285-1340.
170. Alburyhi MM, Noman MA, Saif AA, Hamidaddin MA, Yahya TA, Al-Ghorafi MA. Rosuvastatin-Excipient Compatibility Studies for Advanced Drug Delivery Systems Development. World Journal of Pharmaceutical Research., 2024; 13(13): 1549-1582.
171. Alburyhi MM, Saif AA, Noman MA. Ticagrelor-Excipient Compatibility Studies for Advanced Drug Delivery Systems Development. World Journal of Pharmacy and Pharmaceutical Sciences., 2024; 13(10): 1081-1132.
172. Alburyhi MM, Noman MA, Saif AA, Al-Ghorafi MA, Yahya TA, Yassin SH, Al Khawlani MA. Diclofenac-Excipient Compatibility Studies for Advanced Drug Delivery Systems Development. World Journal of Pharmaceutical Research., 2024; 13(14): 1297-1333.
173. Alburyhi MM, El-Shaibany A. Formulation, Development and Evaluation of Aloe Vera Extract Capsules Delivery System as an Advanced Phytotherapy Approach for Controlling Diabetes. World Journal of Pharmacy and Pharmaceutical Sciences., 2024; 13(4): 1408-1423.
174. Alburyhi MM, Hamidaddin MA, Noman MA, Saif AA, Yahya TA, Al-Ghorafi MA. Rivaroxaban-Excipient Compatibility Studies for Advanced Drug Delivery Systems Development. European Journal of Pharmaceutical and Medical Research., 2024; 11(9): 370-404.
175. Alburyhi MM, El-Shaibany A. Formulation, Development and Evaluation of Tribulus Terrestris Extract Capsules Delivery System as an Advanced Phytotherapy Approach for Controlling Diabetes. World Journal of Pharmaceutical Research., 2024; 13(7): 1264-1282.
176. Alkhawlani MA, Al-Ghani AM, Alburyhi MM. Study the Potential Drug- Drug Interaction Through Prescriptions Analysis in Some Sana'a City Hospitals, Yemen. European Journal of Pharmaceutical and Medical Research., 2024; 11(5): 440-448.
177. Noman MA, Alburyhi MM, Saif AA. Knowledge and Perception about Pharmacovigilance Among 4Th and 5Th Levels Pharmacy Students in Some Public and Private Universities, Sana'a Yemen. World Journal of Pharmaceutical and Medical Research., 2023; 9(11): 14-19.
178. Al-mamari A, Alburyhi M, Al-heggami MA, Al-hag S. Identify and Sensitivity to Antifungal Drugs of Candida Species Causing Vaginitis Isolated from Vulvovaginal Infected Patients in Sana'a City. Der Pharma Chemica., 2014; 6(1): 336-342.
179. Al Ghoury AA, Al-Ghorafi MA, Alburyhi MM, Noman MA. Antimicrobial Susceptibility Patterns of Staphylococcus Aureus to Different Antimicrobial Agents Isolated as Clinical Samples at Certain General Hospitals in Sana'a City, Yemen. World Journal of Pharmaceutical Research., 2024; 13(16): 35-47.
180. European Medicine Agency. New EudraVigilance System Is Live. Available online: https: //www.ema.europa.eu/en/news/ new-eudravigilance-system-live (accessed on 11 July 2021).
181. European Medicine Agency. EudraVigilance Operational Plan. Available online: https: //www.ema.europa.eu/en/documents/ other/eudravigilance-operational-plan-milestones-2018-2020_en.pdf (accessed on 11 November 2022).
182. Banovac M, Candore G, Slattery J, Houÿez F, Haerry D, Genov G, Arlett P. Patient Reporting in the EU: Analysis of EudraVigilance Data. Drug Saf., 2017; 40: 629–645.
183. Medsafe Guideline on the Regulation of Therapeutic Products in New Zealand: Part 11. Available online: http: //www.medsafe. govt.nz/regulatory/Guideline/GRTPNZ/Part10.pdf (accessed on 22 July 2022).
184. New Zealand Pharmacovigilance Centre. Available online: https: //nzphvc.otago.ac.nz/carm/ (accessed on 3 November 2021).
185. New Zealand Pharmacovigilance Centre: Reporting. Available online: https: //nzphvc.otago.ac.nz/reporting/ (accessed on 3 November 2021)
186. Saudi Food & Drug Authority Guideline on Good Pharmacovigilance Practices (Version 3.0). Available online: https: //www. sfda.gov.sa/sites/default/files/2022-11/SFDA-GVP_2.pdf (accessed on 14 November 2022).
187. Saudi Food & Drug Authority Guideline on Good Pharmacovigilance Practices (Version 2.0). Available online: https: //www. moh.gov.sa/eServices/Licences/Documents/91.pdf (accessed on 8 November 2022).
188. Saudi Food & Drug Authority Pharmacovigilance. Available online: https: //www.sfda.gov.sa/en/pharmacovigilance (accessed on 8 November 2022).
189. MHRA Contribution of Yellow Cards to Identifying Safety Issues. Available online: https: //assets.publishing.service.gov.uk/ government/uploads/system/uploads/attachment_data/file/911022/Contribution_of_Yellow_Cards_to_identifying_safety_ issues.pdf (accessed on 9 October 2022).
190. QVIGILANCE. A Guide to the US FDA Safety Requirements for Pharmacovigilance. Available online: https: //www.qvigilance. com/blog/usa-fda-safety-requirements-pharmacovigilance (accessed on 3 November 2021).
191. MHRA. Black Triangle Scheme. Available online: https: //www.gov.uk/guidance/the-yellow-card-scheme-guidance-forhealthcare-professionals#black-triangle-scheme (accessed on 11 November 2022).
192. MHRA. Pharmacovigilance-How the MHRA Monitors the Safety of Medicines. Available online: https: //assets.publishing. service.gov.uk/government/uploads/system/uploads/

attachment_data/file/949131/Pharmacovigilance___how_the_ MHRA_monitors_the_safety_of_medicines.pdf (accessed on 15 November 2022).
193. FDA. FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files. Available online: https: //www.fda.gov/ drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-latestquarterly-data-files (accessed on 3 November 2021).
194. Muñoz, M.; Epidemiology, D. Introduction to Post-Marketing Drug Safety Surveillance: Pharmacovigilance in FDA/CDER; Center of Drug Evaluation and Research: Silver Spring, MD, USA, 2016; pp. 1–56.
195. Winiecki SK. Publicly Available Pharmacovigilance Resources Objective. Available online: https: //fda.report/media/93916/ Publicly-Available-Pharmacovigilance-Resources.pdf (accessed on 22 July 2022).
196. Uruguay Incorporates the Modality of "Additional Surveillance" to the National Pharmacovigilance System. Available online: https: //prais.paho.org/en/uruguay-incorporates-the-modality-of-additional-surveillance-to-the-national-pharmacovigilancesystem/ (accessed on 9 October 2022).
197. Development, T. Pharmacovigilance and Toxicovigilance Development in Dentistry. Medicine 2017, 5, 697–702.
198. World Health Organization. The WHO Programme for International Drug Monitoring. Available online: https: //www.who.int/ teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/health-professionals-info/pidm (accessed on 27 January 2022).