International Journal for Research in Biology and Pharmacy

GREEN PUBLICATION

ISSN (Online): 2208-2093
Volume 10 Issue 03 September 2024
Available on-line at: https://ijrbp.com/index.php/bp/issue/view/559

DOI:*https://doi.org/10.69980/bp.v10i3.2494* *Received: 16-Jun-2024 Accepted: 20-Aug-2024*

PHARMACOVIGILANCE PROFILING OF DRUG SIDE EFFECTS, THERAPEUTIC CLASSES, AND MEDICAL CONDITIONS

Dr. Marie Lindquist[1], Dr. Mira Harrison-Woolrych[2], Dr. Saad Shakir[3], Dr. Fatheya Al Awadi[4]

[1] Uppsala Monitoring Centre, Uppsala, Sweden
[2] New Zealand Pharmacovigilance Centre, University of Otago, Dunedin, New Zealand
[3] Drug Safety Research Unit, Southampton, United Kingdom
[4] Dubai Hospital, Dubai Health Authority, Dubai, United Arab Emirates

Corresponding Author
Email: marie.lindquist@who-umc.org

Abstract
Pharmacovigilance profiling is important for understanding how drug safety information is distributed across medicines, therapeutic classes, and medical conditions. This study aimed to profile drug side effects, therapeutic classes, prescription status, pregnancy category, controlled-substance classification, and patient-reported rating patterns using a secondary drug-information dataset. A retrospective data-based design was adopted. The study included 2,931 drug records covering 2,912 unique drug names and 47 medical conditions. Data were analyzed using frequency distribution, percentage analysis, cross-tabulation, and summary statistics. The highest representation was observed for pain, colds and flu, acne, and hypertension. Prescription-only medicines formed the largest category, accounting for 68.17% of records. Pregnancy category C was the most frequent classification, while most medicines were non-controlled substances. Therapeutic class analysis showed major representation of upper respiratory combinations, topical acne agents, topical steroids, antihistamines, nonsteroidal anti-inflammatory drugs, laxatives, opioid analgesics, CNS stimulants, insulin, antiviral combinations, and antirheumatics. Side-effect information was most frequently associated with dermatological, allergic, respiratory, neurological, and gastrointestinal categories. Rating and review activity was highest for acne, anxiety, weight loss, diabetes type 2, ADHD, depression, bipolar disorder, pain, insomnia, and hypertension. The findings indicate that secondary drug-information records can support pharmacovigilance-oriented profiling of safety information, therapeutic classes, and medical-condition patterns, although results should be interpreted as information patterns rather than confirmed adverse-event incidence.

Keywords: *Pharmacovigilance; drug side effects; therapeutic classes; medical conditions; drug safety; patient-reported ratings*

Introduction

Pharmacovigilance is a basic aspect of pharmacy and healthcare practice that provides insights into the detection, evaluation, interpretation, and prevention of any adverse drug reactions. Given that pharmacology touches upon different areas of treatment, the management and interpretation of drug safety data have become very important. Open pharmacovigilance sources have enabled this process through improving the availability of drug safety information for study and interpretation (Fouretier et al., 2016). In this regard, secondary databases on drug information could be used to systematically profile drugs, their adverse effects, therapeutic categories, and diseases when primary patient-level data is not available.

Adverse events associated with the use of drugs play an important role in pharmacovigilance studies. The benefits of mapping associations between drugs that cause adverse events were successfully established using a structured database like SIDER for drug-safety assessments and biomedicine interpretations (Kuhn et al., 2016). Nevertheless, the sources of adverse-event information do not necessarily have to be restricted only to official regulatory databases. There are also other sources of drug-related safety information such as patients, users of health care services, and health information websites. Patient reports have proved to be able to supplement the pharmacovigilance system with valuable information (Inácio et al., 2017). On the other hand, patient reports depend on certain criteria such as awareness, motivation, severity, confidence, and convenience (Al Dweik et al., 2017).

Communication on adverse events can affect how the patients perceive such adverse events. Information given through patient information leaflets, drug information sources, and publicly available pharmaceutical sources could play a role in influencing how people understand risk, tolerate therapy, and experience any problems (Webster et al., 2017). In the past few years, digital and patient-driven data have been identified as alternative sources in the field of pharmacovigilance. For example, social media use and patient reporting of their experiences have been analyzed for the identification of adverse drug reactions, with some comparison being made between the information given and the actual safety information (Arnoux-Guenegou et al., 2019). Adverse event databases that consider drugs as well as the combination of drugs will provide a comprehensive understanding of drug safety profiles in certain cases (Poleksic & Xie, 2019).

The occurrence of adverse drug reactions remains relevant in different healthcare environments, including ambulatory care, because it affects patient well-being, leads to changes in therapy, consultation needs, and unnecessary costs for health care (Khalil & Huang, 2020). Drug safety is also influenced by the level of patient literacy and knowledge, and individuals who possess more information about drugs and the potential hazards associated with them might be capable of recognizing and reporting adverse reactions (See et al., 2020). Another issue that adds to the complexity of drug safety is drug-drug interactions that increase the likelihood of adverse events and require continuous surveillance in regular pharmacotherapy (Jiang et al., 2022). Special consideration should also be given to vulnerable groups that include older people, who face additional risks associated with age-related changes in physiology, multimorbidity, and polypharmacy (Gray et al., 2023).

Current pharmacovigilance studies continue to emphasize the need for pattern analysis and evaluation of the impact of adverse drug reactions, their clinical severity, demographic variations, and the safety trend associated with drugs (Zhai et al., 2025). In spite of the growing number of literature in this field, there still exist opportunities to carry out more studies on how drug side effects data are distributed with respect to drug classes and diseases. This will help in understanding the distribution of safety information on the drugs as well as enable pharmacy-oriented analysis.

This research aims to identify characteristics of drug side-effect information, therapeutic classes, and medical conditions using a secondary data set on drugs. The goals include analyzing the distribution of drugs by medical condition, investigating the characteristics of therapeutic classes, examining whether drugs are prescribed, categorized as pregnancy category drugs, and/or controlled substances, grouping side-effect information into categories, and investigating rating and review characteristics for major medical conditions.

Methodology

Study Design

Retrospective profiling in pharmacovigilance involving the use of a public secondary dataset was adopted in this study. The purpose of this study was to look at adverse effect information of drugs, their therapeutic classes, diseases, prescription status, pregnancy classification, controlled substance class, and patient rating pattern. Considering that the study involved the use of a dataset, no data collection or intervention was conducted.

Data Source

A secondary dataset has been utilized in this research (Goswami, 2025). It is made up of structured variables regarding drug names, diseases, adverse effects, drug generic names, drug categories, trade names, prescription status, drug pregnancy categories, controlled status, alcohol data, other drugs associated with them, disease descriptions, rating, review counts, and drug information links. The database consists of 2,931 drug instances in 17 variables that are sufficient in evaluating patterns of drug-side effect relationship, therapeutic class distribution, and medical conditions.

Data Preparation

Analysis was done on the data set concerning the validity of the information, redundancy, missing information, and consistency in recording variables. Records with accurate drug names and the diseases that the drugs cure were considered during analysis. Missing information was checked individually for each variable, and records were omitted only when

they had inadequate data for the particular analysis. For example, records with missing ratings were excluded only from ratings-related summary results and not from others such as disease categories, drug classes, prescriptions, and adverse reactions.

The therapeutic class variable included numerous instances that belonged to more than one class. These were broken down into specific class names to allow for better analysis of each class. The side-effect variable consisted of narratives and not adverse event codes; hence, side effects were categorized into general clinical categories, which include dermatologic, allergic, respiratory, neurologic, gastrointestinal, cardiovascular, hematologic, renal/urinary, psychiatric, hepatic, and reproductive side effects.

Data Analysis

The analysis was conducted for drug profiling based on medical condition, treatment class, prescription class, pregnancy class, controlled substance class, and related side effect information, ratings, and review count. The categorical variables were characterized by frequency and percentage, whereas the numerical variables were presented using central tendency and dispersion measures such as mean, median, minimum, maximum, and total counts where applicable.

Cross-tabulation was used to compare the chosen variables, focusing especially on the variable prescription in connection with the variables of pregnancy class and controlled-substance class. Condition-wise analysis was conducted to find out medical conditions having higher number of drugs and a greater number of reviews conducted for them. The side effects were considered to be patterns of information regarding drugs and not adverse events due to lack of clinical outcome data.

Statistical Approach

The analysis of the data used the descriptive statistics approach. The categories were analyzed through frequencies and percentages while means were calculated from the ratings and reviews. Chi-square analysis was performed to determine the association between categorical variables such as prescription drug, pregnancy category, and drug under control status. Comparison of the rating pattern by medical conditions was done via nonparametric tests considering that the distribution of the rating is not equal. Statistical significance is set at $p < 0.05$.

Results

Descriptive Statistics

The database consists of 2,931 medication entries, encompassing 2,912 unique medication names and 47 unique medical conditions. The following characteristics were considered for analysis: medical condition, therapeutic category, prescription medication, pregnancy risk, controlled substance, side effects, rating, and number of reviews. Among the medical conditions, the highest proportion was recorded in the category called “Pain,” with 264 entries (9.01%), followed by “Colds & Flu” (245 entries; 8.36%), “Acne” (238 entries; 8.12%), and “Hypertension” (177 entries; 6.04%). Other categories that contributed significantly to the data set include osteoarthritis, hay fever, eczema, AIDS/HIV, type 2 diabetes mellitus, and psoriasis. This indicates that the database includes a wide variety of medications used for different purposes, including pain treatment, respiratory infections, dermatological issues, heart conditions, infectious diseases, hormonal disorders, and inflammation.

Table 1. Distribution of drugs across major medical conditions

Medical condition	Number of records	Percentage
Pain	264	9.01%
Colds & Flu	245	8.36%
Acne	238	8.12%
Hypertension	177	6.04%
Osteoarthritis	129	4.40%
Hayfever	124	4.23%
Eczema	122	4.16%
AIDS/HIV	109	3.72%
Diabetes Type 2	104	3.55%
Psoriasis	93	3.17%

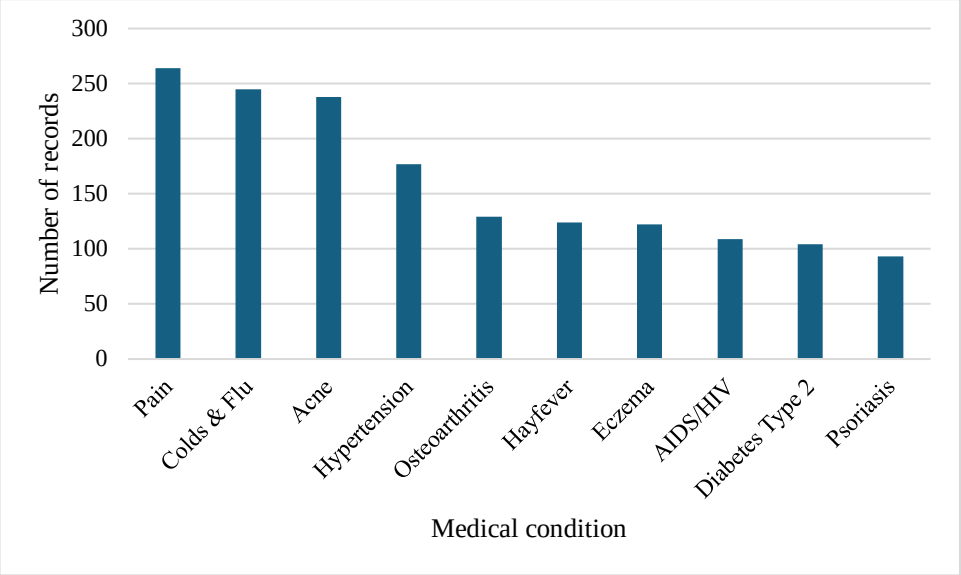

Figure 1. Distribution of drugs across major medical conditions

The trend illustrated in Table 1 and Figure 1 shows that no particular state was dominant in this research. This is because drugs have been distributed among various clinically relevant disease states.

Prescription Status, Pregnancy Category, and Controlled-Substance Profile

The prescription only medicine category was the largest with 1,998 entries (68.17%). Combination prescription and over-the-counter medicines had 604 entries (20.61%), and over-the-counter medicines had 328 entries (11.19%). This shows that the largest number of drugs analyzed requires professional monitoring from a physician. The most common pregnancy category was C with 1,382 entries (47.15%). The pregnancy category B had 509 entries (17.37%), and the pregnancy category N had 436 entries (14.88%). The pregnancy category D had 228 entries (7.78%), and the pregnancy category X had 129 entries (4.40%). These categories are significant in interpreting pharmacovigilance because they show different degrees of caution when using drugs during pregnancy. Totally, there were 2,688 instances (91.71%) falling under non-controlled drugs category. Among the different schedules, the Schedule 2 had 101 instances (3.45%), Schedule 3 had 26 instances (0.89%), Schedule 4 had 71 cases (2.42%), and Schedule 5 had 20 cases (0.68%).

Table 2. Prescription, pregnancy, and controlled-substance classification

Classification variable	Category	Number of records	Percentage
Prescription status	Prescription only	1,998	68.17%
Prescription status	Rx/OTC	604	20.61%
Prescription status	OTC	328	11.19%
Pregnancy category	A	18	0.61%
Pregnancy category	B	509	17.37%
Pregnancy category	C	1,382	47.15%
Pregnancy category	D	228	7.78%
Pregnancy category	X	129	4.40%
Pregnancy category	N	436	14.88%
Controlled-substance category	Non-controlled	2,688	91.71%
Controlled-substance category	Schedule 2	101	3.45%
Controlled-substance category	Schedule 3	26	0.89%
Controlled-substance category	Schedule 4	71	2.42%
Controlled-substance category	Schedule 5	20	0.68%

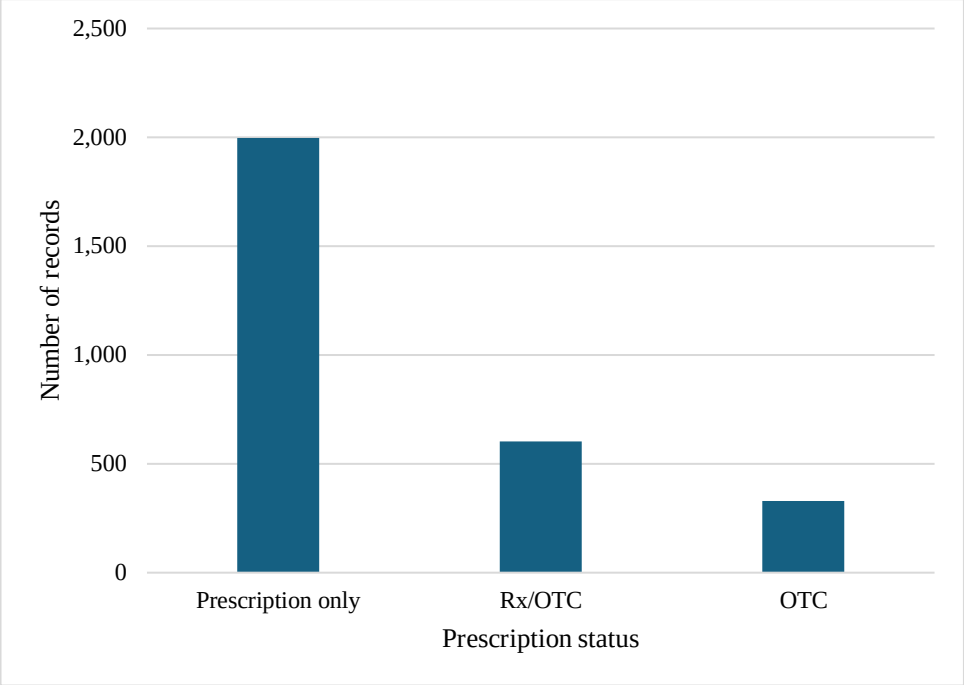

Figure 2(A). Prescription status

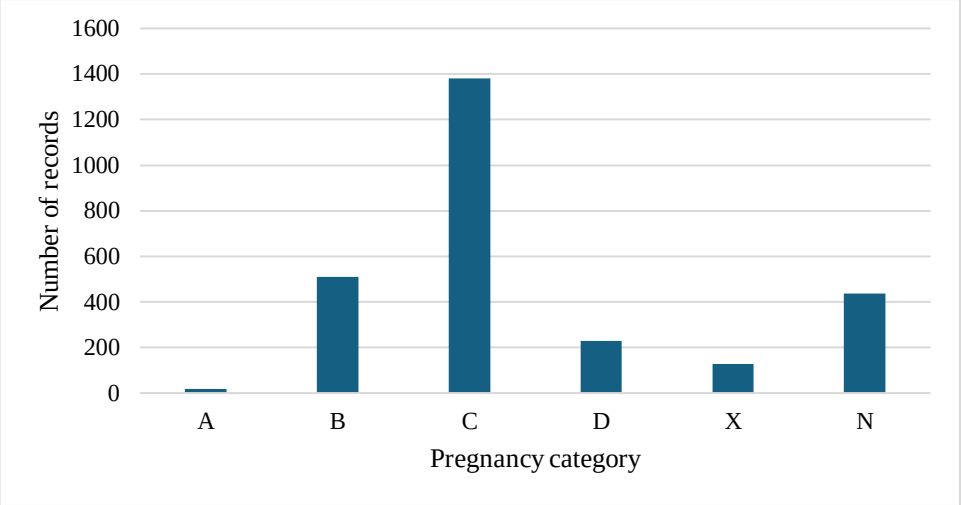

Figure 2(B). Pregnancy category

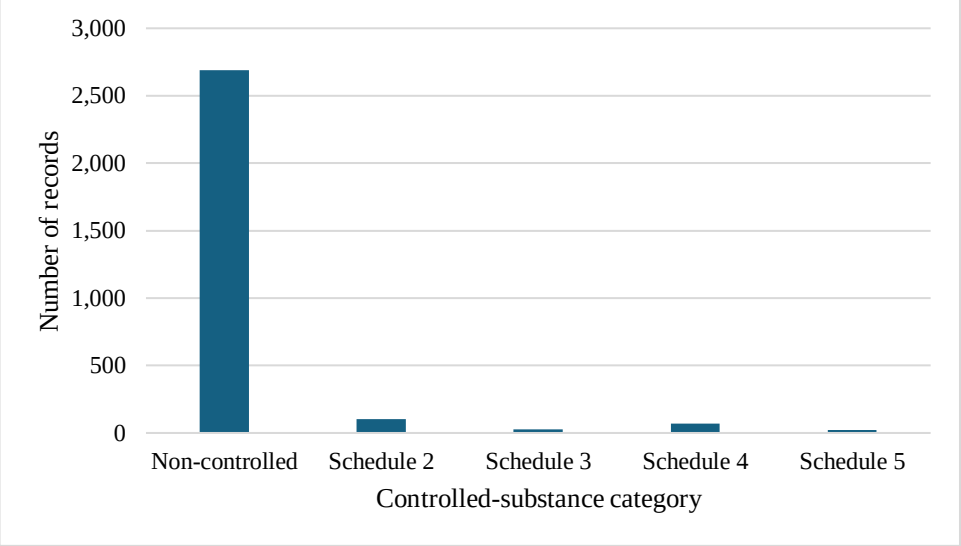

Figure 2(C). Controlled-substance classification

Figure 2. Distribution of regulatory and safety-related drug classifications: (A) prescription status, (B) pregnancy category, and (C) controlled-substance classification

According to Table 2 and Figure 2 below, there appears to be a high representation of prescription only drugs, pregnancy classification drugs, and also controlled substances classification. This proves that there was indeed pharmacovigilance focus on this study since these variables are clearly concerned with drug accessibility, safety, and regulation.

Therapeutic Class Distribution

The therapeutic class analysis revealed that the upper respiratory tract combination was the highest-ranking group with 245 entries. The following groups were acne topical preparations with 125 entries, corticosteroid topical preparations with 94 entries, antihistamines with 82 entries, and NSAIDs with 72 entries. Other frequently ranking classes included laxatives, anesthetic topicals, opioid analgesics, CNS stimulants, antiviral combinations, insulin, analgesic combinations, and antirheumatics.

Table 3. Major therapeutic drug classes

Therapeutic class	Frequency
Upper respiratory combinations	245
Topical acne agents	125
Topical steroids	94
Antihistamines	82
Nonsteroidal anti-inflammatory drugs	72
Laxatives	59
Miscellaneous topical agents	56
Topical rubefacient	56
Topical anesthetics	54
Opioids / narcotic analgesics	53
CNS stimulants	50
Antiviral combinations	50
Insulin	50
Analgesic combinations	49
Antirheumatics	44

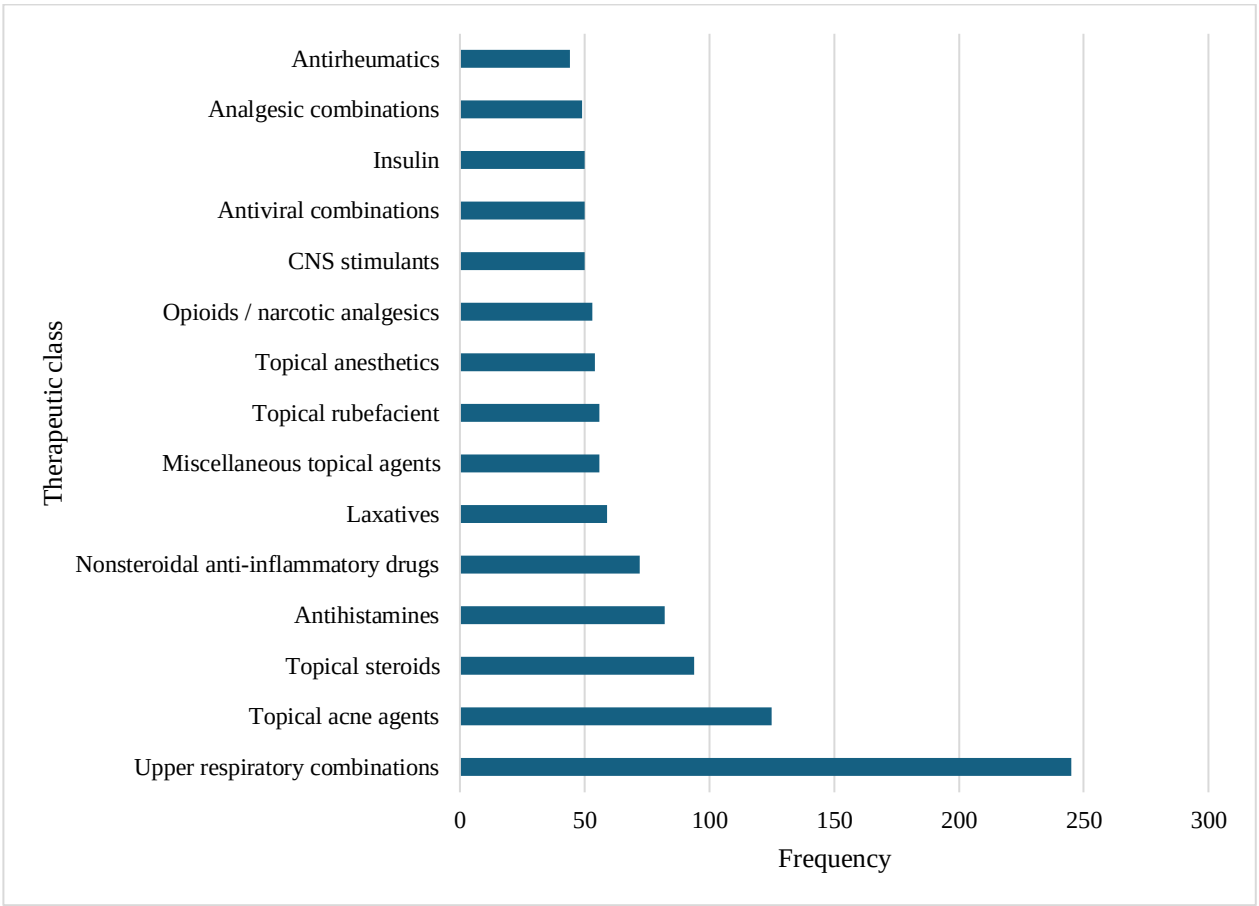

Figure 3. Frequency distribution of major therapeutic drug classes

Based on Table 3 and Figure 3, the major drug class categories included respiratory medications, skin drugs, painkillers, antihistamine drugs, diabetic medications, anti-viral combinations, and drugs related to the central nervous system. This reflects the objectives of the research paper which seeks to categorize therapeutic classes based on side effects and medical condition information.

Side-Effect Information Patterns

The side effects were classified under general clinical categories since side effect information was made up of narrative drug information. Skin-related words were most common with an occurrence rate of 2,767 (94.40%). Allergy- or hypersensitivity-related terms came second with an occurrence rate of 2,718 (92.73%). The occurrence rate of words that related to the respiratory system was 2,668 (91.03%). Neurological words and words associated with the gastrointestinal system were also common; 2,282 incidences (77.86%) and 2,274 incidences (77.58%).

Table 4. Major side-effect information categories

Side-effect category	Records mentioning category	Percentage
Dermatological-related terms	2,767	94.40%
Allergic / hypersensitivity-related terms	2,718	92.73%
Respiratory-related terms	2,668	91.03%
Neurological-related terms	2,282	77.86%
Gastrointestinal-related terms	2,274	77.58%
Cardiovascular-related terms	1,716	58.55%
Hematological-related terms	1,482	50.56%
Renal / urinary-related terms	1,107	37.77%
Psychiatric-related terms	1,077	36.75%
Hepatic-related terms	744	25.38%
Pregnancy / reproductive-related terms	341	11.63%

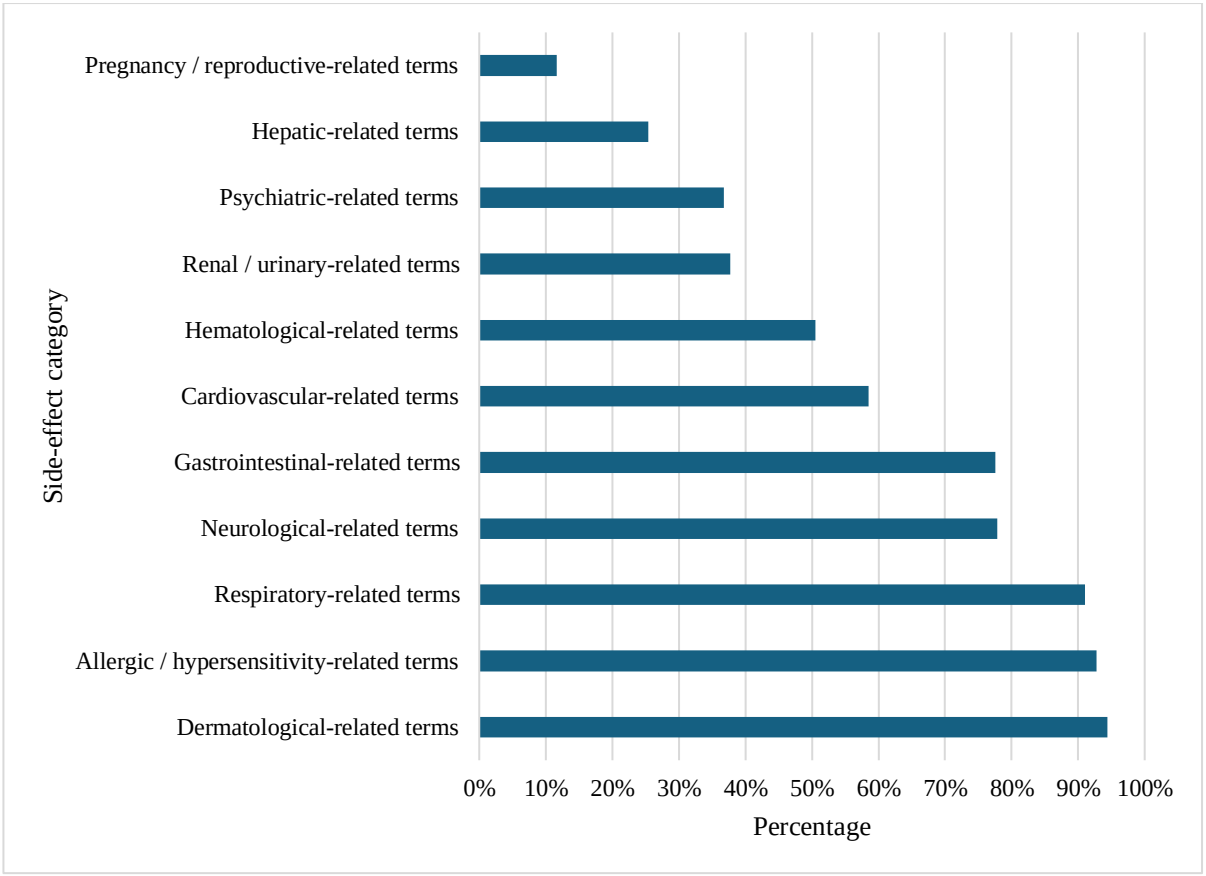

Figure 4. Distribution of side-effect information categories

The side effects' profile shown in Table 4 and Figure 4 demonstrates a strong presence of data about dermatological, allergic, respiratory, neurological, and gastrointestinal conditions. The obtained results coincide with the key safety concerns usually covered in pharmaceutical files. As the side effect item includes free-form text, the findings represent side effect data patterns and not adverse event frequency.

Rating and Review Patterns

There were 1,586 records that had rating and review information. The average rating of the records was 6.81, while the median rating was 7.00, implying a fairly positive trend for the rated records. There was great variability in the number of reviews, with an average of 75.06 reviews, a median of 12 reviews, and a maximum of 2,934 reviews for a single drug record. The most reviews were associated with Acne, having a total of 11,863 reviews, with a mean rating of 7.57. The second most reviewed condition was Anxiety, with 11,516 reviews, with a mean rating of 7.80, followed by Weight Loss, having 11,188 reviews with an average rating of 7.57. Other conditions with high review activity included diabetes type 2, ADHD, depression, bipolar disorder, pain, insomnia, and hypertension.

Table 5. Medical conditions with highest rating and review activity

Medical condition	Rated records	Mean rating	Total reviews
Acne	120	7.57	11,863
Anxiety	44	7.80	11,516
Weight Loss	18	7.57	11,188
Diabetes Type 2	86	5.73	8,001
ADHD	53	7.06	7,665
Depression	47	7.19	7,509
Bipolar Disorder	44	6.68	7,478
Pain	99	7.11	6,533
Insomnia	51	6.73	5,696
Hypertension	126	5.98	4,360

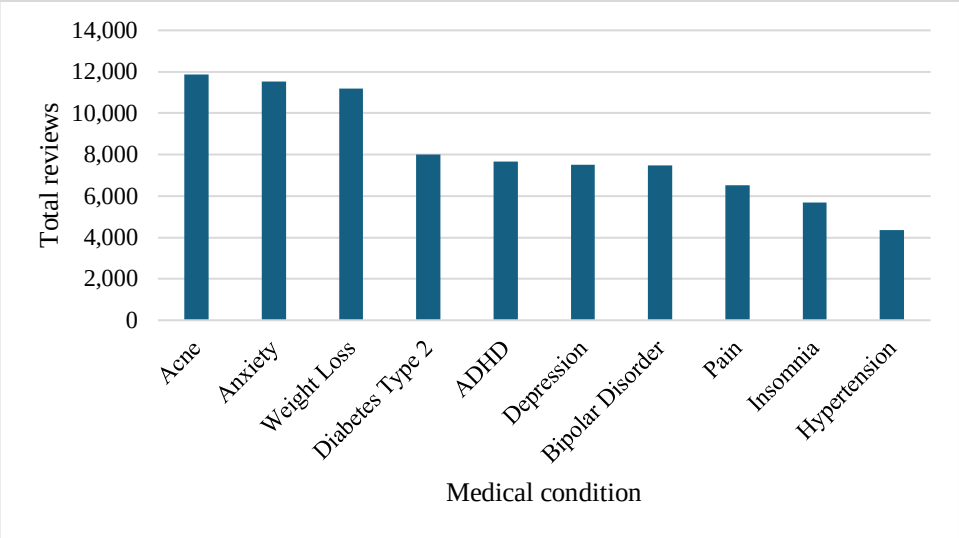

Figure 5. Total review volume across major medical conditions

It is evident from the pattern shown in Table 5 & Figure 5 that the patient reported activities revolve around a few medical conditions only. These medical conditions are acne, anxiety, weight loss, type 2 diabetes, attention deficit hyperactivity disorder (ADHD), depression, bipolar disorder, pain, insomnia, and high blood pressure (hypertension). These rating and reviews need to be taken as an indicator of patients' experience only.

Association Between Regulatory and Safety-Related Variables

The use of cross tabulation was done in order to determine the relationship between the selected regulatory and safety variables. The variable prescription status showed a significant association with the variable pregnancy category (χ^2 = 938.24, $p < 0.001$; Cramer's V = 0.327), which means there is a moderate association. It also showed a significant association with the variable controlled substance category (χ^2 = 468.03, $p < 0.001$; Cramer's V = 0.231), meaning there is a weak-to-moderate association. In addition, rating distribution differed significantly across medical conditions, with H = 189.45 and $p < 0.001$.

Table 6. Association between selected study variables

Variable comparison	Test used	Test value	p-value	Interpretation
Prescription status vs pregnancy category	Chi-square test	χ^2 = 938.24	<0.001	Significant moderate association
Prescription status vs controlled-substance category	Chi-square test	χ^2 = 468.03	<0.001	Significant weak-to-moderate association

Rating distribution across medical conditions	Kruskal-Wallis test	H = 189.45	<0.001	Ratings differed significantly by condition

From the data provided in Table 6, there is evidence of significant correlations between the chosen regulatory, safety, and condition variables. The correlation between prescription status and pregnancy category implies that there may be unequal representation of pregnancy categories among the prescription and non-prescription statuses. Similarly, the correlation between prescription status and controlled substance implies that there will be differences in regulatory control between different medicine categories as expected. There is considerable disparity in the ratings for different medical conditions.

Discussion

This research provides a pharmacovigilance-based analysis of adverse drug effects, drug classes, and diseases. These drugs are widely spread among different clinical conditions; pain, colds/flu, acne, and hypertension appear to be the most prominent drug classes. This is significant as pharmacovigilance not only includes monitoring of adverse drug events but also requires knowledge of safety issues related to drug information in prevalent drug groups. Pharmacovigilance includes ongoing detection, evaluation, and communication of adverse drug information; however, in some cases, spontaneous reports may suffer from under-reporting, incompleteness, and poor quality (Desai, 2022). In light of these concerns, this research provides a unique contribution by classifying drug information across several drug groups.

The presence of prescription-only drugs means that the study primarily included those drugs which need professional supervision. This conclusion has great significance from a pharmacological point of view since prescription drugs involve complicated decision-making regarding dosage adjustment and other factors. Even though over-the-counter drugs were included in the study, their relatively lower percentage suggests that there was greater inclusion of medicines that usually need medical supervision. Another important observation made in the study was the connection between the prescription status and the pregnancy category of medicines, which shows that the categorization of medicines by access has some relation to safety concerns.

Category C drugs were the most common in the list, followed by category B and category N. While less frequent, the use of drugs classified as categories D and X reinforces the need for proper medication evaluation when dealing with pregnancies. The use of drugs during pregnancy and lactation involves balancing the benefits for the mother and the risks for the fetus/newborn, thus making reliable safety data necessary (Nooney et al., 2021). The distribution pattern does not necessarily correlate with clinical risk among pregnant individuals; instead, it shows that safety classification within the context of pregnancy is an important aspect of drug information evaluation.

The classification of drugs under controlled substances revealed that most drugs fell into the category of non-controlled substances, while there was an even distribution of drugs into schedules 2, 3, 4, and 5 respectively. Although they represent a minority group, their inclusion in the dataset is significant from a pharmacovigilance perspective, as they pose various threats such as abuse, dependency, withdrawal symptoms, sedation, and regulation challenges. The relationship between prescription and the classification of drugs as controlled substances further confirms this assertion.

The findings from the classification of therapeutics showed considerable use of upper respiratory combination products, topical acne medications, topical steroids, antihistamines, NSAIDs, laxatives, topical anesthetics, opioid painkillers, CNS stimulants, antiviral combinations, insulin, analgesic combinations, and antirheumatics. The findings indicate that the study has managed to address commonly used symptomatic medications and important therapeutic classifications. Adverse effects of medication form part of the burden of care, including drug-induced admissions into hospitals; therefore, profiling therapeutic classes helps identify areas that require safety improvement (Haerdtlein et al., 2023).

There was a large presence of terminology regarding dermatological, allergic or hypersensitivity reactions, respiratory problems, neurological events, and gastrointestinal issues. This trend is consistent with information available from public sources about drugs, as skin reactions, allergic reactions, dyspnea, dizziness, headache, nausea, vomiting, and gastrointestinal complaints are often highlighted in those cases. However, this trend cannot be understood as reflecting adverse-event occurrence rates, as the side effect variable involved narrative information instead of coded information about actual adverse events experienced by patients. Adverse effects can differ depending on the source used, which may include social media, regulatory reports, databases, or systematic reviews (Golder et al., 2020). Therefore, the findings are best interpreted as side-effect information patterns rather than direct adverse-event frequency.

The results of the analysis of ratings and reviews have added the patient experience element to the pharmacovigilance assessment. There were high levels of reviewing seen in relation to such health problems as acne, anxiety, weight loss, type 2 diabetes, ADHD, depression, bipolar disorder, pain, insomnia, and hypertension. This finding suggests that patients' involvement is usually seen in conditions where there are factors of the experience of treatment, its tolerance, prolonged use, and effectiveness. Patient-generated online data can also serve as a complementary tool for pharmacovigilance because it can reflect experiences that are not accounted for in formal reports (Sarker et al., 2015). However, ratings and reviews should not be treated as clinical evidence of efficacy or safety.

Since there is a great difference in ratings among the various types of diseases, it means that the experiences of the patients vary according to the type of treatment being offered. The kind of treatment that requires long-term treatment or treatment whose outcome depends on lifestyle choices can lead to ratings different from those associated with acute illnesses. Crowd-generated intelligence and health-related information from social media platforms can be helpful for pharmacovigilance activities, but it will depend on how they are filtered and interpreted (Tricco et al., 2018). Therefore,

the rating and review patterns should be interpreted as supplementary indicators of patient engagement and perceived treatment experience.

The implications of this study lie in the fact that pharmacovigilance profiling can combine side-effect information, therapeutic classification, disease pattern, regulatory information, pregnancy category, controlled-substance information, and patient experiences. Such findings are best understood as being reflective of drug safety information patterns and not actual clinical outcomes. Future research would be valuable in associating public drug safety profiles with post-marketing safety information. This is important given that post-approval efforts continue to play an integral role in providing drug safety information especially regarding pregnancy and breastfeeding (Fernandes et al., 2025).

Conclusion

In this study, a profile of drug adverse events, therapeutic classes, and diseases is created based on secondary drug information data. The findings show good coverage in 47 different types of diseases, with pain, colds/flu, acne, and hypertension as the most prevalent types. The largest share belongs to prescription medicines, implying that the majority of the medicines under review need proper oversight and safety control. Regarding pregnancy category, the most prevalent one was category C, while non-controlled status dominated among all other types. Analysis of therapeutic class shows significant representation of upper respiratory combination drugs, topical acne medication, topical steroids, antihistamines, NSAIDs, laxatives, opioids, CNS stimulants, insulin, antiviral combination drugs, and antirheumatics. In relation to side-effect profiling, a strong presence was found for words referring to skin, allergy, breathing, nervous system, and digestion. This finding suggested that safety concerns for these specific areas are commonly featured in drug information databases. Review of ratings and reviews showed that patient engagement was found in only a few disease areas, namely, acne, anxiety, weight loss, type 2 diabetes, ADHD, depression, bipolar disorders, pain, insomnia, and high blood pressure. In addition, correlations were established between prescription use and pregnancy category, prescription use and drug control status, and ratings and disease. Such findings demonstrate that pharmacovigilance profile is a helpful tool when it comes to obtaining insights into the safety of the drugs, drug distribution within the range of therapeutic areas and patient experience. Nonetheless, it is necessary to view the findings as representations of patterns in the data on drugs but not actual clinical events. In general, one can claim that the paper highlights the importance of secondary drug information for conducting pharmaceutical studies.

References

1. Al Dweik, R., Stacey, D., Kohen, D., & Yaya, S. (2017). Factors affecting patient reporting of adverse drug reactions: a systematic review. *British journal of clinical pharmacology*, *83*(4), 875-883.
2. Arnoux-Guenegou, A., Girardeau, Y., Chen, X., Deldossi, M., Aboukhamis, R., Faviez, C., ... & Katsahian, S. (2019). The adverse drug reactions from patient reports in social media project: Protocol for an evaluation against a gold standard. *JMIR research protocols*, *8*(5), e11448.
3. Desai, M. (2022). Pharmacovigilance and spontaneous adverse drug reaction reporting: Challenges and opportunities. *Perspectives in Clinical Research*, *13*(4), 177-179.
4. Fernandes, M. F. S., Alexe, A., Apara, O., Force, L., Taeter, C., Weber, M., ... & Würtele, J. M. (2025). Post-approval activities providing data on the safety of medication use during pregnancy and lactation—a transcelerate perspective. *Therapeutic Innovation & Regulatory Science*, *59*(3), 527-541.
5. Fouretier, A., Malriq, A., & Bertram, D. (2016). Open access pharmacovigilance databases: analysis of 11 databases. *Pharmaceutical medicine*, *30*(4), 221-231.
6. Golder, S., Smith, K., O'Connor, K., Gross, R., Hennessy, S., & Gonzalez-Hernandez, G. (2020). A comparative view of reported adverse effects of statins in social media, regulatory data, drug information databases and systematic reviews. *Drug safety*, *44*(2), 167.
7. Goswami, I. (2025). *Drugs, side effects, and medical conditions* [Data set]. Kaggle. https://www.kaggle.com/datasets/ishiigoswami/drugs-side-effects-and-medical-conditions
8. Gray, S. L., Perera, S., Soverns, T., & Hanlon, J. T. (2023). Systematic review and meta-analysis of interventions to reduce adverse drug reactions in older adults: an update. *Drugs & aging*, *40*(11), 965.
9. Haerdtlein, A., Debold, E., Rottenkolber, M., Boehmer, A. M., Pudritz, Y. M., Shahid, F., ... & Dreischulte, T. (2023). Which adverse events and which drugs are implicated in drug-related hospital admissions? A systematic review and meta-analysis. *Journal of Clinical Medicine*, *12*(4), 1320.
10. Inácio, P., Cavaco, A., & Airaksinen, M. (2017). The value of patient reporting to the pharmacovigilance system: a systematic review. *British journal of clinical pharmacology*, *83*(2), 227-246.
11. Jiang, H., Lin, Y., Ren, W., Fang, Z., Liu, Y., Tan, X., ... & Zhang, N. (2022). Adverse drug reactions and correlations with drug–drug interactions: A retrospective study of reports from 2011 to 2020. *Frontiers in pharmacology*, *13*, 923939.
12. Khalil, H., & Huang, C. (2020). Adverse drug reactions in primary care: a scoping review. *BMC health services research*, *20*(1), 5.
13. Kuhn, M., Letunic, I., Jensen, L. J., & Bork, P. (2016). The SIDER database of drugs and side effects. *Nucleic acids research*, *44*(D1), D1075-D1079.
14. Nooney, J., Thor, S., de Vries, C., Clements, J., Sahin, L., Hua, W., ... & Kweder, S. (2021). Assuring access to safe medicines in pregnancy and breastfeeding. *Clinical Pharmacology & Therapeutics*, *110*(4), 941-945.

15. Poleksic, A., & Xie, L. (2019). Database of adverse events associated with drugs and drug combinations. *Scientific reports*, *9*(1), 20025.
16. Sarker, A., Ginn, R., Nikfarjam, A., O'Connor, K., Smith, K., Jayaraman, S., ... & Gonzalez, G. (2015). Utilizing social media data for pharmacovigilance: a review. *Journal of biomedical informatics*, *54*, 202-212.
17. See, M., Butcher, B. E., & Banh, A. (2020). Patient literacy and awareness of medicine safety. *International Journal of Pharmacy Practice*, *28*(6), 552-560.
18. Tricco, A. C., Zarin, W., Lillie, E., Jeblee, S., Warren, R., Khan, P. A., ... & Straus, S. E. (2018). Utility of social media and crowd-intelligence data for pharmacovigilance: a scoping review. *BMC medical informatics and decision making*, *18*(1), 38.
19. Webster, R. K., Weinman, J., & Rubin, G. J. (2017). How does the side-effect information in patient information leaflets influence peoples' side-effect expectations? A cross-sectional national survey of 18-to 65-year-olds in England. *Health Expectations*, *20*(6), 1411-1420.
20. Zhai, J., Yan, H., Zhang, J., Yan, H., Ma, J., & Zhang, S. (2025). A comprehensive analysis of adverse drug reactions in 2020–2023: case studies. *Frontiers in Pharmacology*, *16*, 1628347.