



Assessment of Contemporary Understanding and Anticipations Concerning Information about Negative Effects in Medication Labeling - A Cross-Sectional Study from the Viewpoint of Parents with Pediatric Patients

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Abstract:

In order to promote the safe and effective utilization of medications, it is essential for patients to have access to reliable and accurate information. This crucial role is often fulfilled by package inserts (PIs), which provide comprehensive information about marketed drugs. However, a lack of understanding of PIs among caregivers can have negative implications for pediatric treatment. To assess how well patients comprehend the adverse reactions outlined in drug labels and their preferences for receiving information about these reactions from healthcare providers, a web-based cross-sectional study was carried out in Lahore over a two-month period (from January 2021 to February 2021). The study adhered to established guidelines and employed a survey questionnaire, which was distributed through social media platforms. Among the 792 parents of pediatric patients who completed the survey accurately, approximately half of them reported heightened concerns when it came to drugs with a greater number of listed side effects. Notably, a majority of respondents expressed a keen interest in receiving education about drug side effects. A significant portion of participants indicated a preference for receiving a brief overview of potential side effects initially, with more detailed information being provided upon specific inquiries. The outcomes of this study strongly emphasize the urgent need to enhance patient awareness and understanding of PIs. Insights gained from understanding the public's knowledge-related factors regarding medication usage can be extremely valuable for healthcare practitioners and policymakers. This information can guide the development of targeted educational interventions aimed at enabling the public to use medications optimally while minimizing the occurrence of adverse drug effects. The survey, which utilized a questionnaire shared via social media, garnered positive responses from the general public. The study coordinators extend their heartfelt gratitude to the participants for their invaluable support.

Key Words: Drug, Adverse Reactions, Questionnaire, Public opinion



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Introduction:

Package inserts (PI) are printed pamphlets that come with marketed pharmaceutical goods and include information that has been authorized by regulatory bodies. It is the most important overview of all the research that was done while creating the product and the data that was produced in the process. A current, accurate PI that has been properly authorized by regulatory bodies in each region is a crucial source that gives the doctor a solid foundation for properly prescribing and dispensing the drug for safe and effective usage. The US FDA states that the PI must have three crucial elements: a summary of the main scientific knowledge required for safe and effective usage; be informative, accurate, and not inaccurate or misleading; and be updated whenever significant new information becomes available. These precise and trustworthy details enable patients to utilize their drugs in a safe and efficient manner (Grime et al., 2007; Jain et al., 2018). Additionally, due to workloads, healthcare practitioners frequently present patients with insufficient information. Health practitioners' insufficient communication and pharmacological understanding may also have a role (Deepak et al., 2018). The frequency and types of information that doctors and pharmacists provide on drug items also widely vary (Jacob, 2018). As a result, one of the sources that patients utilize to learn more about their medicine is written information about medicinal products, such as the PIs. PIs are pamphlets that are included in the packaging of both over-the-counter and prescription medications to offer detailed information regarding their administration, indication, safety measures to take when using them, dosage, possible adverse effects, and contraindications. According to regulatory requirements, the PIs are also known as patient package inserts or prescription drug labels. It is a crucial source of drug information for both patients and healthcare professionals, particularly in underdeveloped nations where access to up-to-date medical knowledge is constrained. Medication nonadherence may be facilitated by inadequate patient education, which may have a detrimental impact on the course of therapy. PIs increase patient

comprehension and satisfaction, which promotes therapy adherence (Bapat et al., 2017). One of the components that must be included in the labeling process is information on adverse reactions. How specifically the adverse responses should be listed on a medication insert is not clearly regulated internationally (Watson et al., 2009; Ishiguro et al., 2017). When a doctor tells a patient about potential side effects of a medication, the patient may get concerned and stop taking the medication, which might have an impact on therapy. The potential side effects of a medicine may not be disclosed to a patient by a doctor. When a patient obtains a prescription from the pharmacy and reads the label on his own, if he discovers that any of the possible bad responses are intolerable, he may return to the pharmacy and request a refund, which might result in a disagreement with the hospital. The goal of this study is to find out how well individuals comprehend what adverse responses on medicine labels actually mean. This will make it clearer what they already know and what they need to know about adverse medication responses in drug labelling.

Methods:

Study design, settings and study subjects:

A prospective web-based cross-sectional study was conducted using a survey questionnaire to obtain responses from general public regarding expectations and awareness of information regarding adverse reactions in drug labelling. The questionnaire was shared via social media among adults over 18 years for the period of 2 months in Lahore region, Pakistan. Individuals were excluded for the following reasons: not willing to participate in the survey, inability to speak or understand urdu, and having never been dispensed medication from pharmacies. The sample size was calculated using online sample size calculator. Among 800 samples, only 792 had the complete information which was taken for analysis. The STROBE guidelines for reporting cross-sectional studies were followed, and a checklist has been provided as supplementary file.

Procedure:

The data was collected using self-administered questionnaire. The questionnaire included five parts: demographic data, attitudes, awareness, knowledge

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of adverse reactions, and participant demand for adverse reaction information. The developed draft survey instrument has been distributed to ten randomly selected faculty members to assess the readability and content validity before pretesting among randomly selected participants for clarity, relevancy, and acceptability. The comprehensive and well-organized questionnaire was distributed to the study population.

Statistical Analysis:

The questionnaire was checked for completeness and accuracy, and the data was cleaned, coded, and entered into SPSS. Descriptive analysis was used to represent the socio-demographic data. Continuous variables were described as mean and standard deviation, while categorical variables were reported as frequencies and percentages. Independent associations between patient characteristics and regular intake of medications were assessed using Chi-squared or Fisher's exact tests. Binary logistic regression analysis was used to identify the key factors associated with regular intake of medications. Binary logistic regression analysis, controlling for gender, age, nationality, area of residence and marital status. If participants missed any of the questions in the questionnaire, the questionnaire was considered invalid.

Results:

Characteristics of the study sample

Out of 800 surveys data received from public, a total of 792 questionnaires were complete and included for analysis. The complete details of the participant demographics can be found in Table I. Participants' opinion on the incidence of ADR. Among the participants, 36% of them opines to consult the medical staff during any incidence of ADR and around 7% says that they will reduce the dosage of the drug by themselves in case of any ADR. About 31% of the samples say that they continue to take according to doctor's advice on any incidence of ADR. PI according to preferred language which shows that majority (84%) of the participants preferred to read the PI in Urdu. Among the participants, 90% said that they read the PI regularly whereas around 80% said that they experienced fear of taking medication after reading the PI. About 90% of them store the PI as a source of drug information. Participants' awareness of ADR and

PI. About 55% of the participants have the awareness to stop taking medicine immediately and consult medical professional when there is any ADR. Regarding the information on geriatric use and pediatric use in PI, 78% said that there was no such information and 63% said that the natural herbal products are safe and has no side effects. Regarding the additional information regarding side-effect-related information of drugs, 28.2% says that they get it from pharmacists and 25.4% from the physician. Need for explanation of ADR to special groups such as geriatric, pediatric and pregnant mothers etc. and information need about common and severe ADR is significantly associated with literacy level. The need for explanation about each possible ADR including rare ones was not associated with level of literacy. The participants attitude of ADR information in which the majority of the participants were having unfavorable attitude towards the ADR information as well as unsure about the same. Out of 792 participants, 350 had the attitude that the traditional medicines do not cause any side effects and 618 were unsure about that the over-the-counter medications do not cause any side effects. About 50% of the participants do not inform their doctors about their consumption of traditional medicines.

Discussion:

Information on medications should be provided by doctors and pharmacists to patients. However, it has also been noted in few reports that pharmacists and doctors' counseling practices during the dispensing of medications are subpar. Consequently, the requirement for high-quality medicine PIs is essential and the real knowledge on the medications available on the market comes from PIs. It has been established that patient compliance and satisfaction are influenced by the quality and quantity of information provided in the PIs. Patients who read the patient information sheets are more likely to adhere to the doctor's directions and are less likely to have major medication side effects. About 50% of the participants in this study thought that the more side effects mentioned on a medicine, the more dangerous it was. Perhaps this is because, they do not understand the definition of adverse drug reactions properly. In this survey, around 60% of the public believed that herbal medications were risk-



free and had no adverse consequences. In past, a survey of citizens revealed that 61.4 percent of respondents believed that natural herbal products were safe since they were created using natural components. The majority of respondents in Lebanon had the mistaken impression that herbal remedies were completely safe for the general public and that they had to be in order for them to be sold. Similar understandings of the safety of herbal medicine have been found in studies conducted in China and other nations. More patients expect their doctors to provide more explanations of any potential side effects from prescription medications. This may be a result of the widespread perception that complete disclosure of information about adverse reactions will enable patients to make better treatment decisions. In a survey of the Omani population, 56.1% of respondents wanted to know about all potential negative side effects, while in a survey of respondents in Kansas, USA, 76.2% wanted to know about all potential negative side effects. However, 48.89% of the respondents to this poll said that they wanted to know about any potential negative effects. Currently, the package leaflet serves more as a legal document than as a tool for informing patients. In this case, medical practitioners believe there is a causal link between taking the medicine and experiencing the adverse effects indicated on the package leaflet. The fact that pharmaceutical corporations include adverse effects in the package leaflet whenever there is even the remotest chance of a causal relationship is therefore not unexpected. It is therefore unlikely that they will adequately advise patients about the possibility of side effects from medication administration. Then comes informed decision-making (Mühlbauer et al., 2015). Doctors are unlikely to spend a lot of time outlining all potential ADRs to patients. Patients are fully aware of this fact. Furthermore, patients with higher education levels need risk information more (58%) than patients with lower education levels do (35 %). This might be because people with less education think that doctors should decide what information has to be delivered and what advice is acceptable for different groups of people. About 90% of the general public represented in this survey stated that they are aware of ADR, and about 25% reported having had an ADR in the previous year. As

a result, it was a sample that had used medicines extensively. Our findings indicate that the general public has little understanding of the side effects of medications. The pharmacist, the doctor, information on packaging insert, and the internet were the four most favored sources of information on drug safety, in that order. This study has a few drawbacks. The study's subjects were all from the Lahore region, thus it was unclear whether the findings could be applied to other parts of Pakistan. Second, despite the clinical research's very modest sample size, it did cover individuals from a range of ages, educational backgrounds, and jobs. Additionally, the fact that almost half of the participants were receiving drug treatment may have made them more motivated to gather as much information as possible, which might have influenced the data's findings. The patient categories that are linked to lower levels of awareness regarding adverse effects should be defined in future study using bigger and more representative samples. Lastly, further research is required to determine whether knowledgeable patients are more likely to prevent interactions, manage expected side effects better, and identify and take action on potential harmful, idiosyncratic, or immunological responses sooner.

Conclusion:

The populations included in this study had lower levels of awareness regarding adverse effects. PIs have a significant impact on patient compliance, which in turn affects the efficacy of therapeutic usage. Patients must be encouraged to read PIs to be more informed about drug adverse reactions, and thereby prevents any untoward effects. Our study has important implications for healthcare workers. First, these results suggest providing adequate knowledge to general public to effectively use medications. Indeed, these result highlight, the importance of healthcare workers needs in providing required drug knowledge to their patients. Moreover, this result can help drug policy makers and health department in developing need based educational programs to promote safe use of drugs.

References:

1. Al Qarni, H., Alrahbini, T., AlQarni, A. M., & Alqarni, A. (2020). Community pharmacist



- counselling practices in the Bisha health directorate, Pakistan -simulated patient visits. *BMC health services research*, 20(1), 745.
2. Alhazmi, M., Bajuayfir, A., Cheema, E., Elrggal, M., & Ali, M. (2021). Evaluation of Current Community Pharmacist Practice in Pakistan-A Cross-Sectional Study from Pharmacists' Perspective (Part II). *Pharmacy (Basel, Switzerland)*, 10(2), 38.
 3. Alhomoud F. K. (2020). Act like a warrior to defeat medication counselling barriers: A cross sectional study. *Saudi pharmaceutical journal : SPJ : the official publication of the Saudi Pharmaceutical Society*, 28(9), 1084–1092.
 4. Alsayari, A., Almghaslah, D., Khaled, A., Annadurai, S., Alkhairy, M. A., Alqahtani, H. A., Alsayed, B. A., AlLahorei, R. M., & Assiri, A. M. (2018). Community Pharmacists' Knowledge, Attitudes, and Practice of Herbal Medicines in Lahore Region, Kingdom of Pakistan. *Evidence-based complementary and alternative medicine : eCAM*, 2018, 1568139.
 5. Awad, A., & Al-Shaye, D. (2014). Public awareness, patterns of use and attitudes toward natural health products in Kuwait: a cross-sectional survey. *BMC complementary and alternative medicine*, 14, 105.
 6. Bapat, S. S., Patel, H. K., & Sansgiry, S. S. (2017). Role of Information Anxiety and Information Load on Processing of Prescription Drug Information Leaflets. *Pharmacy (Basel, Switzerland)*, 5(4), 57.
 7. Clerehan, R., Hirsh, D., & Buchbinder, R. (2009). Medication information leaflets for patients: the further validation of an analytic linguistic framework. *Communication & medicine*, 6(2), 117–127.
 8. Deepak, K, Gaur, A (2018) Scope of improvement of patient information leaflets in randomly selected therapeutic classes of drugs. *International Journal of Pharma Sciences and Research*, 9: 46–50.
 9. El Khoury, G., Ramadan, W., & Zeeni, N. (2016). Herbal Products and Dietary Supplements: A Cross-Sectional Survey of Use, Attitudes, and Knowledge Among the Lebanese Population. *Journal of community health*, 41(3), 566–573.
 10. European Commission. Council Directive 92/27/EEC on the labelling of medicinal products for human use and on package leaflets limits (No. L113 of 31 March 1992). https://www.legislation.gov.uk/eudr/1992/27/pdfs/eudr_1992027_adopted_en.pdf. Accessed 29 Apr 2020.
 11. Evaluation of medication package inserts in Pakistan. *Drug, healthcare and patient safety*, 4, 33–38.
 12. Grime, J., Blenkinsopp, A., Raynor, D. K., Pollock, K., & Knapp, P. (2007). The role and value of written information for patients about individual medicines: a systematic review. *Health expectations: an international journal of public participation in health care and health policy*, 10(3), 286–298.
 13. Herber, O. R., Gies, V., Schwappach, D., Thürmann, P., & Wilm, S. (2014). Patient information leaflets: informing or frightening? A focus group study exploring patients' emotional reactions and subsequent behavior towards package leaflets of commonly prescribed medications in family practices. *BMC family practice*, 15, 163.
 14. Herber, O. R., Gies, V., Schwappach, D., Thürmann, P., & Wilm, S. (2014). Patient information leaflets: informing or frightening? A focus group study exploring patients' emotional reactions and subsequent behavior towards package leaflets of commonly prescribed medications in family practices. *BMC family practice*, 15, 163.
 15. Ishiguro, C., Misu, T., Iwasa, E., & Izawa, T. (2017). Analysis of safety-related regulatory actions by Japan's pharmaceutical regulatory agency. *Pharmacoepidemiology and drug safety*, 26(11), 1314–1320.
 16. Jacob N. T. (2018). Drug promotion practices: A review. *British journal of clinical pharmacology*, 84(8), 1659–1667.
 17. Jain, A., Jindal, A., Bansal, N., & Arora, H. (2018). Comparison of drug information in package inserts with standard medical textbook of pharmacology. *International Journal of Basic & Clinical Pharmacology*, 7(5), 1002–1005.



18. Jain, A., Jindal, A., Bansal, N., & Arora, H. (2018). Comparison of drug information in package inserts with standard medical textbook of pharmacology. *International Journal of Basic & Clinical Pharmacology*, 7(5), 1002–1005.
19. Jose, J., Jimmy, B., Al-Mamari, M. N., Al-Hadrami, T. S., & Al-Zadjali, H. M. (2015). Knowledge, Beliefs and Behaviours Regarding the Adverse Effects of Medicines in an Omani Population: Cross-sectional survey. *Sultan Qaboos University medical journal*, 15(2), e250–e256.
20. Joseph, B. N., Asiegbu, U. O., Aya, B. M., Nyam, M. N., Umar, D. M., Jimam, N. S., & Dapar, M. L. P. (2017). Usability of Medicine Package Inserts for Chronic Diseases: A Survey of the Pharmaceutical Market in Jos, Nigeria. *Journal of Pharmaceutical Research International*, 17(4), 1-10
21. Joseph, B. N., Asiegbu, U. O., Aya, B. M., Nyam, M. N., Umar, D. M., Jimam, N. S., & Dapar, M. L. P. (2017). Usability of Medicine Package Inserts for Chronic Diseases: A Survey of the Pharmaceutical Market in Jos, Nigeria. *Journal of Pharmaceutical Research International*, 17(4), 1-10.
22. Lal, R., & Kremzner, M. (2007). Introduction to the new prescription drug labeling by the Food and Drug Administration. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, 64(23), 2488–2494.
23. Medicinal Products Act in the version published on 12 December 2005, §84. Available from: http://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p1702
24. Medicines and Healthcare Products Regulatory Agency, Committee on Safety of Medicines, Working Group on Patient Information: Always Read the Leaflet. Getting the best information with every medicine 2005. Available from: [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/391090/Always_Read_the_Leaflet___getting_the_](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/391090/Always_Read_the_Leaflet___getting_the_best_information_with_every_medicine.pdf)
25. Mühlbauer, V., & Mühlhauser, I. (2015). Understanding adverse drug reactions in package leaflets - an exploratory survey among health care professionals. *BMC health services research*, 15, 505.
26. Nair, K., Dolovich, L., Cassels, A., McCormack, J., Levine, M., Gray, J., Mann, K., & Burns, S. (2002). What patients want to know about their medications. Focus group study of patient and clinician perspectives. *Canadian family physician Medecin de famille canadien*, 48, 104–110.
27. Qatmosh, S. A., Koni, A. A., Qeenno, B. G., Arandy, D. A., Abu-Hashia, M. W., Al-Hroub, B. M., & Zyoud, S. H. (2017). Comparative analysis of package inserts of local and imported antihypertensive medications in Palestine. *BMC public health*, 17(1), 741.
28. Qatmosh, S. A., Koni, A. A., Qeenno, B. G., Arandy, D. A., Abu-Hashia, M. W., Al-Hroub, B. M., & Zyoud, S. H. (2017). Comparative analysis of package inserts of local and imported antihypertensive medications in Palestine. *BMC public health*, 17(1), 741.
29. Rasheed, M. K., Alqasoumi, A., Hasan, S. S., & Babar, Z. U. (2020). The community pharmacy practice change towards patient-centered care in Pakistan: a qualitative perspective. *Journal of pharmaceutical policy and practice*, 13, 59.
30. Samojlik, I., Mijatović, V., Gavarić, N., Krstin, S., & Božin, B. (2013). Consumers' attitude towards the use and safety of herbal medicines and herbal dietary supplements in Serbia. *International journal of clinical pharmacy*, 35(5), 835–840.
31. Shivkar, Y.M. (2009). Clinical information in drug package inserts in India. *Journal of postgraduate medicine*, 55(2), 104–107.
32. Trewin, V. F., & Veitch, G. B. (2003). Patient sources of drug information and attitudes to their provision: a corticosteroid model. *Pharmacy world & science: PWS*, 25(5), 191–196.



33. USFDA. Available from: [fda.gov/drugs/laws-acts-and-rules/prescription-drug-labelling-resources](https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labelling-resources). Last accessed on 2020 Nov 25.
34. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP.(2007). STROBE Initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies: BMJ. 335(7624):806-808.
35. Watson, K. T., & Barash, P. G. (2009). The new Food and Drug Administration drug package insert: implications for patient safety and clinical care. *Anesthesia and analgesia*, 108(1), 211–218.
36. Zarea Gavvani, V., Mirzadeh-Qasabeh, S., Hanaee, J., & Hamishehkar, H. (2018). Calculating reading ease score of patient package inserts in Iran. *Drug, healthcare and patient safety*, 10, 9–19.
37. Ziegler, D. K., Mosier, M. C., Buenaver, M., & Okuyemi, K. (2001). How much information about adverse effects of medication do patients want from physicians?. *Archives of internal medicine*, 161(5), 706–713.

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Table I: Socio-Demographic Characteristics of the study Participants

Socio-Demographic Characteristics	No. (n = 792)	%
Gender		
Male	506	58.7
Female	386	41.3
Age		
Median age	39	5.6
Nationality		
Saudi	658	95.1
Non-Saudi	34	4.9
Education		
Below secondary	37	5.3
Secondary	167	24.1
Professional Qualification	84	12.1
Bachelors	259	37.4
Masters/PhD	145	21.0
Area of residence		
Urban	456	65.9
Rural	236	34.1
Occupation		
Student	109	15.8
Non- Health Care	284	41.0
Health Care	89	12.9
Own Business	194	28.0
Others	16	2.3
Marital status		



Single	213	30.8
Married	467	67.5
Divorced/widowed	12	1.7
Average monthly family income		
5000 to 10000 PKR	112	16.2
10000 to 20000 PKR	246	35.5
More than 20000 PKR	334	48.3
Comorbidities		
Hypertension	68	9.8
Hyperlipidemia	162	23.4
Diabetes mellitus	94	13.6
Any chronic illnesses	64	9.2
No chronic illness	304	43.9

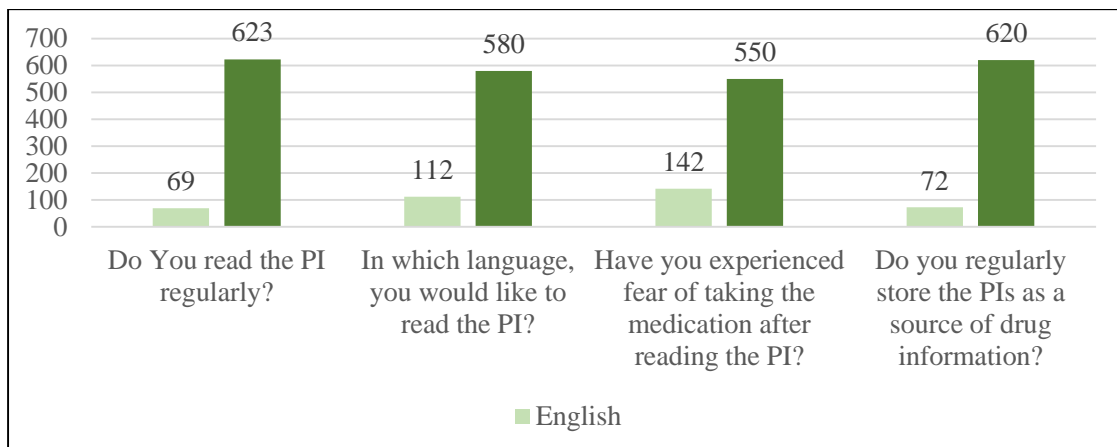


Figure II: Readership of the Technical Package Insert (PI) according to preferred language

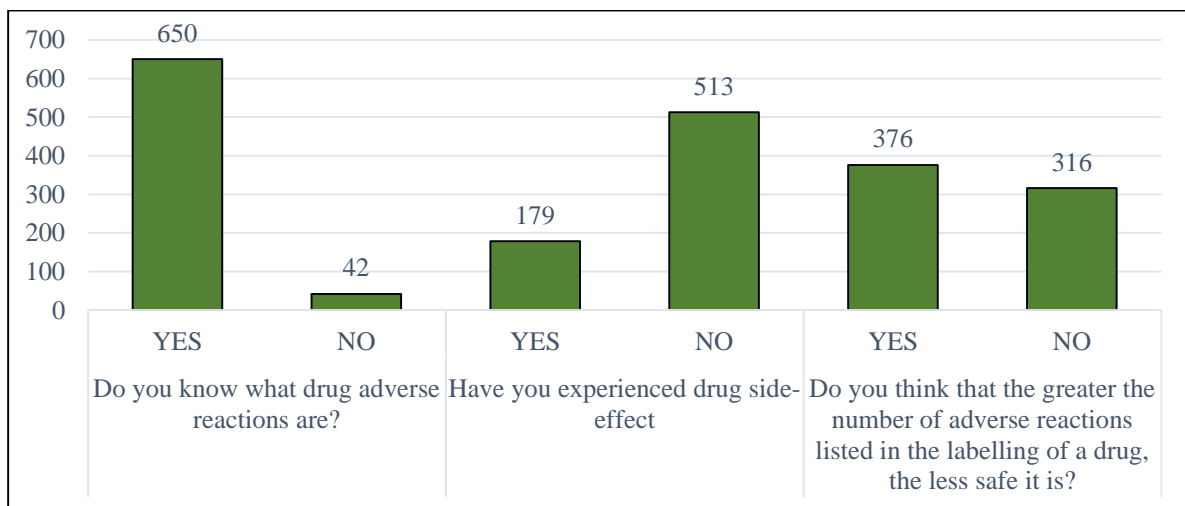


Figure III: Participants' awareness of Adverse Drug Reactions (ADR)

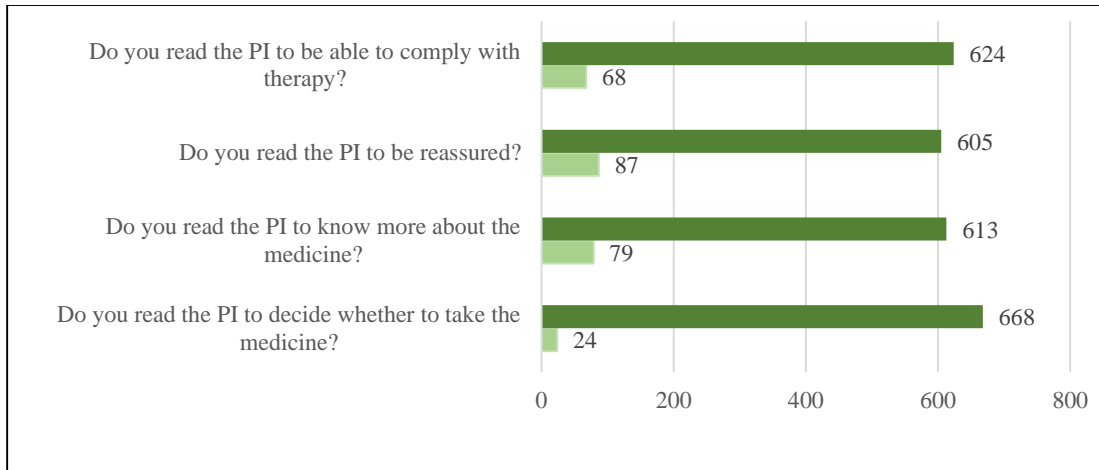


Figure : Motives for reading the Package Insert (PI)

Table : Participants' opinion on the incidence of Adverse Drug Reactions (ADR)

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Opinion	%
Continue to take according to doctor's advice	31
Reduce the dosage myself	6.9
Consult medical staff	35.6
Seek help from others/network	17.2
Do not use; seek safer alternatives	9.3

Table : Participants characteristics in relation to attitude on ADR information

Socio-Demographic Characteristics	n (n = 792)	Unfavourable Attitude	Favourable Attitude	p' Value	OR (95% CI)
Gender					
Female	41.3	24	17.6	0.809	NA
Age (Years)					
18 - 30	10.7	6.07	4.6	0.032	NA
31 - 45	37.8	21.2	16.6		
46 - 60	6.65	1.68	1.51		
Education					
Below secondary	5.35	3.03	2.3	0.05	0.9
Secondary	24.1	13.6	10.6		1.39 (0.71 - 2.0)
Professional Qualification	12.14	6.8	5.3		1.7 (1.3 - 2.9) ^b
Bachelors	37.43	20.9	16.5		3.1 (1.9 - 5.12) ^b
Masters/PhD	21	11.7	9.24		
Occupation					
Student	15.75	8.7	7.08	0.041	1
Non-Health care	12.9	7.23	5.6		1.6 (1.3 - 2.2) ^b



Health care	41.04	23.12	17.9		2.8 (1.6 - 4.4) ^b
Own business	20.03	15.8	12.3		0.9(1.3-2.9) ^b
Others	2.3	1.3	1.01		
Average Monthly Income (in PKR)					
5000 - 10000	16.18	9.1	7.08		1
10000 - 20000	35.6	19.9	15.6		0.96 (0.8 - 1.7)
More than 20000	48.27	27.03	21.2		0.4 (0.29 -0.8) ^b