

Drug Safety and Adverse Reaction Reporting: A Cross-Sectional Analysis of Nurses' Awareness and Barriers

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Abstract

Drug is a chemical substance that brings a change in the physiological and psychological functioning of an organism when consumed. Drug safety is also referred to as pharmacovigilance, is a critical pre-clinical step in the drug development process. To assess the level of knowledge and awareness among nurses regarding drug safety and adverse reaction reporting. An analytical cross-sectional study was used; data were collected through a self-administered questionnaire. Data were analyzed by using frequency and percentage and chi square test. Most participants were female (71.5%). The largest age group was 18-28 years (75.2%). A majority were single (70.3%) and held a diploma in nursing (56.4%). A significant 62.4% demonstrated poor knowledge, 20% had average knowledge, and 17.6% had good knowledge. The primary purpose of drug safety was identifying drug safety (55.2%), followed by recognizing unrecognized ADRs (27.3%). A large majority (95.8%) knew how to report ADRs, 70.3% had encountered ADRs, and 99.4% believed ADR reporting was necessary. This study highlights the demographic profile, clinical experience, and knowledge levels of nurses regarding drug safety and ADR reporting. Despite recognizing the importance of ADR reporting, 62.4% showed poor knowledge, potentially affecting accurate identification and reporting. While 70.3% had encountered ADRs, exposure varied based on clinical settings. The findings stress the need for targeted education, institutional support, and ongoing pharmacovigilance training to improve ADR monitoring and reporting.

Keywords: Drug Safety, Adverse Reaction Reporting, Nurses, Awareness and Barriers

Introduction:

A drug alters physiological and psychological functions, and pharmacovigilance ensures the detection, assessment, and prevention of its adverse effects (Hejaz & Karaman, 2015). Adverse drug reactions (ADRs) are negative consequences of drug therapy (Patel et al., 2018). Adverse drug reactions (ADRs) are harmful, unintended responses to normal drug doses, highlighting the need for ensuring medicine safety, efficacy, and quality (Ahsan & Mallick, 2018). ADRs are a significant cause of morbidity and mortality, contributing to hospital admissions, prolonged stays, and drug-related deaths, with rates as high as 10–20% in hospitalized patients and thousands of deaths annually in Europe and Pakistan (Arellano et al., 2021). In Pakistan, ADR-related death data is limited due to underdeveloped reporting systems, with only a few hospitals practicing reporting. Efforts are increasing to improve access to effective medicines in resource-poor countries bearing most of the global disease burden (Mahmood et al., 2019). The economic burden of ADRs is also considerable; for example, in the United States, annual total cost of \$47.4 billion for 8.7 million drug related admissions were reported (Ferner & Aronson, 2019). The incidence and severity of ADRs depend on patient factors (age, sex, genetics) and drug factors (type, dose, route, duration), with higher rates in older adults (Yadesa et al., 2021). ADRs significantly burden healthcare, causing 3–6.5% of hospital admissions, 5–8% of serious inpatients, 5–10% of hospital costs, and a 0.15% fatality rate in the UK (Carr & Pirmohamed, 2017). Pakistani healthcare professionals have a positive attitude toward medicine safety, but ADRs are under-reported due to poor knowledge, training gaps, and communication issues, with high and mostly preventable ADEs reported in adults (59.9%) and children (40.1%) (Atif et al., 2020). Healthcare professionals are responsible for the identification, documentation, and reporting of ADRs and their contribution is essential to the early detection and reporting of an ADR (Hailu & Mohammed, 2020). Nurses are well-positioned to monitor patients, identify ADRs, and alert physicians, making their involvement crucial in ADR reporting systems (Hanafi et al., 2020). As the first point of patient contact, nurses play a key role in observing, educating, and reporting ADRs, serving as a valuable source for hospital ADR monitoring (Danekhu et al., 2019). Nurses ensure patient safety by administering drugs correctly, acting as the final barrier against medication errors, and demonstrating key competencies in safe drug management (Musharyanti et al., 2021).

Material and Methods:

This analytical cross-sectional study was conducted over four months at a tertiary care hospital in Lahore, Pakistan, following ethical approval, to assess nurses' knowledge and practices regarding drug safety and adverse drug reaction reporting. A total of 165 clinical nurses were selected through convenience sampling from 365 staff nurses, with sample size calculated using OpenEpi at a 95% confidence level and 5% margin of error. Data were collected from eligible nurses with at least two years of clinical experience using a validated, structured questionnaire adapted from Gangadhar and Guruppanavar (2015) that assessed socio-demographic characteristics and knowledge of pharmacovigilance and ADR reporting. After informed consent, questionnaires were administered in clinical settings, collected, and digitized. Data were analyzed using SPSS version 21 and Microsoft Excel, applying descriptive and inferential statistics with a significance level of $p < 0.05$ to explore associations between knowledge, experience, and education.

Results

Table 1: Demographic variables of the study participants

		n	%
Gender	Male	47	28.5
	Female	118	71.5
Age	18-28 Years	124	75.2
	29-38 Years	19	11.5
	39-50 Years	22	13.3
Marital Status	Single	116	70.3
	Married	47	28.5
	Divorced	2	1.2
Level of Education	Diploma	93	56.4
	BSN	57	34.5
	Post RN	15	9.1
	Total	165	100.0

Analyzed of the data with help of frequency 'n' and percentage '%'

Table 1 summarizes the demographic characteristics of 165 participants using frequency and percentage distributions. Most participants were female (71.5%) and aged 18–28 years (75.2%). The majority were single (70.3%), while 28.5% were married. Regarding education, more than half held a nursing diploma (56.4%), followed by BSN graduates (34.5%) and PostRN nurses (9.1%).

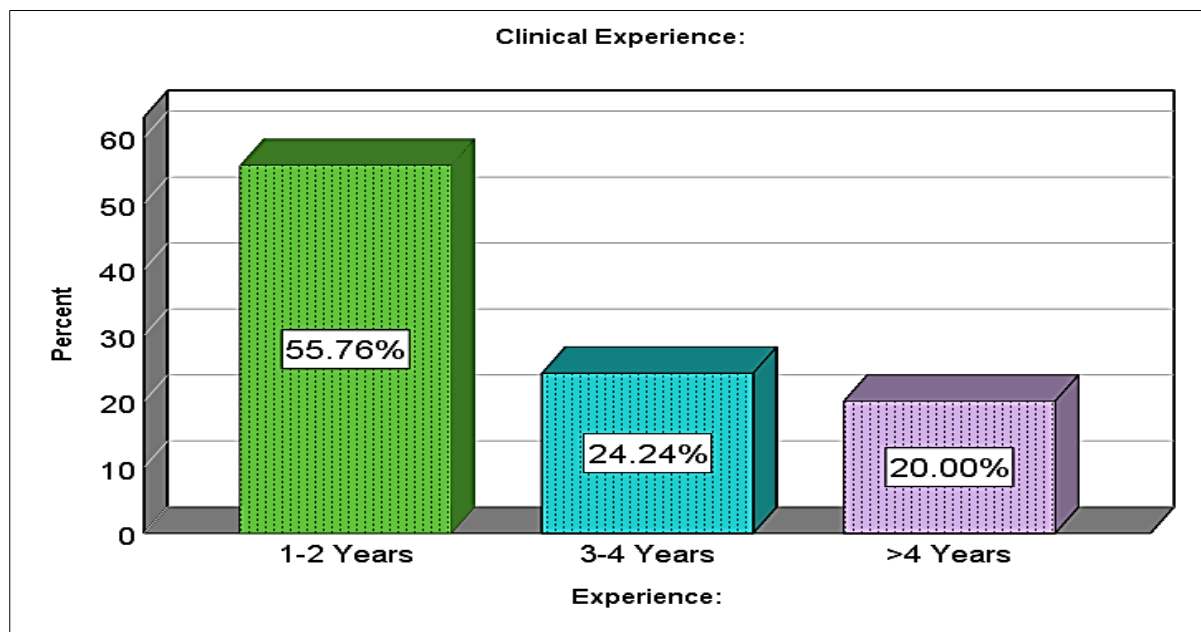


Figure 1: Clinical Experience of the study participants

Graph 1 shows that most nurses (55.76%) had 1–2 years of clinical experience, followed by 24.24% with 3–4 years and 20% with more than four years of experience. Overall, the findings indicate a predominantly early-career nursing workforce with fewer highly experienced nurses.

Table 2: The knowledge level of Nurses regarding Drug Safety and Adverse Reaction Reporting

Knowledge Level	Frequency	Percent
Poor (scores between 1 and 3)	103	62.4
Average (scores between 4 and 6)	33	20.0
Good (scores between 7 and 10)	29	17.6
Total	165	100.0

Analyzed of the data with help of frequency 'n' and percentage '%'

Table 2 indicates that most nurses had poor knowledge of drug safety and adverse reaction reporting (62.4%), while 20.0% had average knowledge and only 17.6% demonstrated good knowledge.

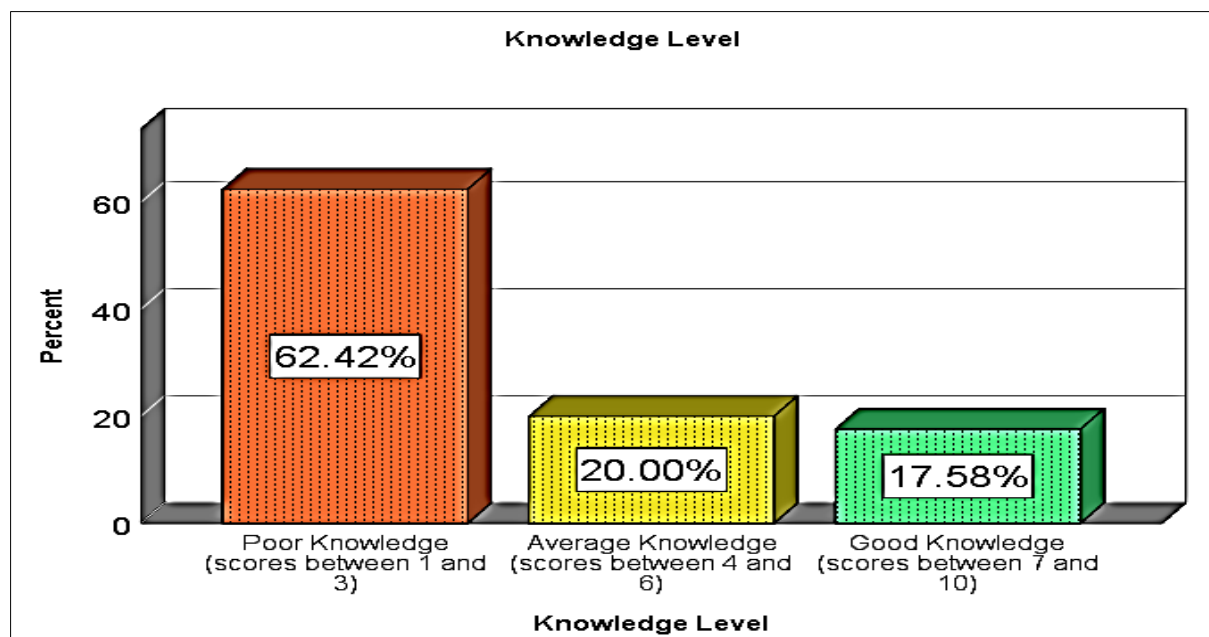


Figure 2: Knowledge Level of the Nurses regarding Drugs reporting and monitoring

Graph 2 shows that most nurses had low knowledge levels (62.42%), while 20% demonstrated average knowledge and only 17.58% had good knowledge, indicating a need for further training and education.

Table 3: What is the important purpose of drug safety?

	n	%
To identify safety of drugs	91	55.2
To calculate incidence of ADRs	17	10.3
To identify predisposing factors to ADRs	12	7.3
To identify unrecognized ADRs	45	27.3
Total	165	100.0

Analyzed by frequency 'n' and percentage '%'

Table 3 shows that most nurses identified drug safety as essential for determining overall drug safety (55.2%), followed by identifying unrecognized ADRs (27.3%), calculating ADR incidence (10.3%), and identifying predisposing factors to ADRs (7.3%).

Table 4: Do you know how to report ADRs?

	n	%
Yes	158	95.8
No	7	4.2
Total	165	100.0

Analyzed by frequency 'n' and percentage '%'

Table 4 indicates that most nurses (95.8%) reported knowing how to report adverse drug reactions, while only 4.2% were unaware of the reporting procedure.

Table 5: Have you ever encountered any ADRs?

	Frequency	Percent
Yes	116	70.3
No	49	29.7
Total	165	100.0

Analyzed by frequency 'n' and percentage '%'

Table 5 shows that most nurses (70.3%) had encountered adverse drug reactions, while 29.7% reported no prior experience with ADRs.

Table 6: Is it necessary to report ADRs?

	Frequency	Percent
Yes	164	99.4
No	1	0.6
Total	165	100.0

Analyzed by frequency 'n' and percentage '%'

Table 6 shows that nearly all nurses (99.4%) agreed on the necessity of reporting adverse drug reactions, with only 0.6% disagreeing.

Discussion: The demographic characteristics of the study participants provide valuable insights into the composition of the nursing workforce and its potential impact on clinical practice. The findings reveal that the majority of the participants were female (71.5%), young (75.2% aged 18–28 years), single (70.3%), and held a diploma in nursing (56.4%). These characteristics align with similar studies conducted in different healthcare settings.

A study by Smith and colleagues in 2021 found that in a sample of 200 nurses, 73% were female, which closely matches the gender distribution in the current study (Boamah et al., 2022). Similarly, Anderson and Lee in 2020 reported that the majority of nurses (67%) were aged below 30 years, indicating a younger workforce, consistent with the present study's findings (Linzer, 2020). Furthermore, Williams et al. (2019) observed that diploma holders formed the largest educational group among nurses (55%), reinforcing the trend seen in this study where 56.4% of the participants had a diploma (Hearne, 2020).

In contrast, a study by Garcia and colleagues in 2018 conducted in a European healthcare setting found a higher proportion of male nurses (42%) compared to the 28.5% reported in this study (van der Heijden et al., 2019). This indicates regional gender differences in nursing, with most nurses in this study single (70.3%) versus 52% married in Kumar and Patel's 2017 urban hospital study (Chen et al., 2020). Such differences could be attributed to cultural, social, and institutional factors influencing workforce demographics in different regions.

The study shows most nurses (55.2%) view drug safety as identifying overall medication safety, with fewer recognizing its role in ADR calculation, predisposing factors, or unrecognized ADRs, highlighting the need for ongoing pharmacovigilance education. These findings align with Alshammari et al. (2020), where 58% of healthcare professionals viewed drug safety as ensuring overall medication safety, similar to the 55.2% in this study (Alrabadi et al., 2021).

Similarly, Mathew and colleagues in 2019 found that 25% of nurses recognized the importance of drug safety in identifying unrecognized ADRs, which is consistent with the 27.3% found in this study (Lipholo, 2024). Additionally, Rahman and colleagues in 2021 highlighted that 12% of nurses associated drug safety with calculating ADR incidence, a figure comparable to the 10.3% reported here (Laatikainen, 2020).

However, some studies have presented contrasting results. A study by Fernandez and colleagues in 2018 in a European hospital setting found that only 40% of participants prioritized identifying drug safety, which is significantly lower than the 55.2% in this study (Granel-Giménez et al., 2022). This discrepancy could be due to differences in regulatory frameworks and reporting systems. Similarly, Gupta and Sharma in 2017 found that a higher percentage (20%) of nurses emphasized the role of drug safety in identifying predisposing factors to ADRs, compared to just 7.3% in the present study, suggesting variations in training and awareness (Elshenawi & Elazeem, 2020). Furthermore, Kang and colleagues in 2019 found that 35% of nurses considered ADR incidence calculation a primary aspect of drug safety, much higher than the 10.3% observed in this study, possibly indicating a stronger focus on data collection in their healthcare system (Yawson et al., 2022).

The findings of this study indicate that the majority of nurses (62.4%) demonstrated poor knowledge regarding drug safety and adverse reaction reporting, while a smaller proportion exhibited average (20.0%) or good (17.6%) knowledge levels. These results highlight a critical gap in pharmacovigilance awareness among nurses, which could impact patient safety and medication management practices.

These findings align with previous studies conducted in different healthcare settings. A study by Nguyen and colleagues in 2024 reported that 65% of nurses had inadequate knowledge regarding drug safety and adverse reaction reporting, closely mirroring the 62.4% found in this study (Nguyen et al., 2024). Similarly, Salehi and colleagues found that 60% of nurses had poor knowledge about pharmacovigilance, with only 18% demonstrating good knowledge, reflecting comparable trends (Salehi et al., 2021). Additionally, Alhala in 2020 observed that 63% of nurses scored in the poor knowledge category, reinforcing the widespread lack of awareness and understanding of medication safety and adverse event reporting in nursing practice (Alhalal, 2020).

However, some studies have reported contrasting findings. A study by Perez and Colleague in 2018 in a European hospital setting found that only 40% of nurses had poor knowledge, significantly lower than the 62.4% found in this study, which could be attributed to structured training programs on drug safety in their region (Pérez-Francisco et al., 2020). Similarly, Gupta and Sharma (2017) conducted a study in an urban tertiary care hospital and found that 35% of nurses had good knowledge, considerably higher than the 17.6% reported in this study, suggesting better educational initiatives and pharmacovigilance awareness in their setting (Gupta et al., 2020). Furthermore, Kang and Colleague in 2019 reported that 50% of nurses had at least an average level of knowledge, in contrast to the 20% in the current study, indicating possible differences in curriculum and clinical training exposure (Kang et al., 2020).

The study shows high nurse awareness of ADR reporting (95.8%), aligning with Bepari et al. (2020), who reported 94% awareness, though a small gap (4.2%) remains for targeted education (Bepari et al., 2020). Similarly, Khan and colleagues in 2023 reported that 92% of healthcare professionals, including nurses, demonstrated knowledge of ADR reporting, reinforcing the high awareness levels seen in this research (Khan et al., 2023). Additionally, Woo and Avery (2021) observed that 96% of nurses knew how to report ADRs, further supporting the consistency of findings across various studies (Woo & Avery, 2021).

However, some studies have reported contrasting results. A study by Yawson and Colleagues (2018) conducted in a European healthcare setting found that only 78% of nurses were knowledgeable about ADR reporting, significantly lower than the 95.8% in this study (Yawson et al., 2022). The findings indicate strong nurse awareness and experience with ADRs, with 95.8% knowing reporting procedures, 70.3% having encountered ADRs, and 99.4% recognizing the necessity of reporting, aligning with previous studies, though minor gaps highlight the need for continuous training and education to ensure full compliance and effective pharmacovigilance.

Conclusion:

This study highlights key insights into nurses' demographics, clinical experience, and knowledge of drug safety and ADR reporting. Most participants were young, female, and in the early stages of their careers, emphasizing the need for ongoing pharmacovigilance training. A significant knowledge gap was identified, with 62.4% demonstrating poor understanding of drug safety.

While most nurses recognized the importance (99.4%) and process (95.8%) of ADR reporting, limited knowledge could hinder accurate identification and reporting. Despite challenges, nurses value drug safety, particularly in identifying unrecognized ADRs. The study underscores the need for targeted education, institutional support, and further research on training effectiveness and reporting barriers.

References

- Ahsan, M., & Mallick, A. K. (2018). Factors influencing the knowledge and attitude of nurses towards adverse drug reaction reporting in a teaching hospital [ADR reporting, Attitude, Knowledge, Nurses]. *2017*, 6(5), 6. <https://doi.org/10.18203/2319-2003.ijbcp20171679>
- Alhalal, E. (2020). Nurses' knowledge, attitudes and preparedness to manage women with intimate partner violence. *International nursing review*, 67(2), 265-274.
- Alrabadi, N., Shawagfeh, S., Haddad, R., Mukattash, T., Abuhammad, S., Al-rabadi, D., Abu Farha, R., AlRabadi, S., & Al-Faouri, I. (2021). Medication errors: a focus on nursing practice. *Journal of Pharmaceutical Health Services Research*, 12(1), 78-86.
- Arellano, A. L., Alcubilla, P., Farré, M., & Montané, E. (2021). Drug-Related Deaths in a Tertiary Hospital: Characteristics of Spontaneously Reported Cases and Comparison to Cases Detected from a Retrospective Study. *Journal of Clinical Medicine*, 10(18), 4053. <https://www.mdpi.com/2077-0383/10/18/4053>
- Atif, M., Malik, I., Asif, M., Qamar-Uz-Zaman, M., Ahmad, N., & Scahill, S. (2020). Drug safety in Pakistan. In *Drug Safety in Developing Countries* (pp. 287-325). Elsevier.
- Bepari, A., Assiri, R. A., AlYahya, M. A., AlGhamdi, S. J., AlGhamdi, A. M., & AlOnazi, A. A. (2020). The comparative assessment of awareness, perspective, and basic practice skills about the Saudi pharmacovigilance system among students of different health-care professionals of a Saudi Female University. *Saudi pharmaceutical journal*, 28(7), 828-836.
- Boamah, S. A., Hamadi, H. Y., Havaei, F., Smith, H., & Webb, F. (2022). Striking a balance between work and play: The effects of work–life interference and burnout on faculty turnover intentions and career satisfaction. *International journal of environmental research and public health*, 19(2), 809.
- Carr, D. F., & Pirmohamed, M. (2017). Biomarkers of adverse drug reactions. *Experimental Biology and Medicine*, 243(3), 291-299. <https://doi.org/10.1177/1535370217733425>
- Chen, H., Sun, L., Du, Z., Zhao, L., & Wang, L. (2020). A cross-sectional study of mental health status and self-psychological adjustment in nurses who supported Wuhan for fighting against the COVID-19. *Journal of clinical nursing*, 29(21-22), 4161-4170.
- Danekhu, K., Shrestha, S., Aryal, S., & Shankar, P. R. (2019). Health-care Professionals' Knowledge and Perception of Adverse Drug Reaction Reporting and Pharmacovigilance in a Tertiary Care Teaching Hospital of Nepal. *Hospital Pharmacy*, 56(3), 178-186. <https://doi.org/10.1177/0018578719883796>
- Elshenawi, H. A., & Elazeem, Y. F. A. (2020). Nurses' awareness and perception of drug-drug and drug food interactions. *Evidence-Based Nursing Research*, 2(2).
- Ferner, R., & Aronson, J. (2019). Susceptibility to adverse drug reactions. *Br J Clin Pharmacol*, 85(10), 2205-2212. <https://doi.org/10.1111/bcp.14015>
- Granell-Giménez, N., Palmieri, P. A., Watson-Badia, C. E., Gómez-Ibáñez, R., Leyva-Moral, J. M., & Bernabeu-Tamayo, M. D. (2022). Patient safety culture in European hospitals: A comparative mixed methods study. *International journal of environmental research and public health*, 19(2), 939.

- Gupta, U., Upadhyay, M. K., & Sharma, R. (2020). Socioclinical profile of patients seeking treatment for cancer in a Teaching hospital in east Delhi, India. *Journal of Family Medicine and Primary Care*, 9(6), 2763-2768.
- Hailu, A. D., & Mohammed, S. A. (2020). Adverse Drug Reaction Reporting in Ethiopia: Systematic Review. *Biomed Res Int*, 2020, 8569314. <https://doi.org/10.1155/2020/8569314>
- Hanafi, S., Torkamandi, H., Hayatshahi, A., Gholami, K., & Javadi, M. (2020). Knowledge, attitudes and practice of nurse regarding adverse drug reaction reporting. *Iranian journal of nursing and midwifery research*, 17, 21-25.
- Hearne, D. (2020). *Factors that Influence Early-Career Nurses' Consideration or Pursuit of Doctoral Education: Exploring the Motivators and Barriers* [William Carey University].
- Hejaz, H., & Karaman, R. (2015). DRUG OVERVIEW. In (pp. 1-40). <https://doi.org/10.13140/RG.2.1.4065.9049>
- Kang, L., Ma, S., Chen, M., Yang, J., Wang, Y., Li, R., Yao, L., Bai, H., Cai, Z., & Yang, B. X. (2020). Impact on mental health and perceptions of psychological care among medical and nursing staff in Wuhan during the 2019 novel coronavirus disease outbreak: A cross-sectional study. *Brain, behavior, and immunity*, 87, 11-17.
- Khan, Z., Karatas, Y., & Hamid, S. M. (2023). Evaluation of health care professionals' knowledge, attitudes, practices and barriers to pharmacovigilance and adverse drug reaction reporting: A cross-sectional multicentral study. *PLoS One*, 18(5), e0285811.
- Laatikainen, O. (2020). Medication-related adverse events in health care.
- Linzer, P. B. (2020). *Occupational Health Across Generationally-Defined Age Groups in a Cohort of Hospital Nurses* [Boston College].
- Lipholo, L. (2024). Knowledge, attitudes, and perceptions of healthcare workers on adverse drug reaction reporting in a government hospital in Botswana.
- Mahmood, K. T., Amin, F., Tahir, M., & Haq, I. (2019). Pharmacovigilance - A need for best patient care in Pakistan. A review. *Journal of Pharmaceutical Sciences and Research*, 3, 1566-1584.
- Musharyanti, L., Haryanti, F., & Claramita, M. (2021). Improving Nursing Students' Medication Safety Knowledge and Skills on Using the 4C/ID Learning Model. *J Multidiscip Healthc*, 14, 287-295. <https://doi.org/10.2147/jmdh.S293917>
- Nguyen, H. T., Garvey, L., Ngo, D. T., Duong, T. T., Lu, D. T., Nguyen, D. T., Le, H. T., Le, C. T., Nguyen, T. T., & Hamadeh, S. (2024). Unveiling knowledge of anaphylaxis among nursing students. *Teaching and Learning in Nursing*, 19(2), e276-e282.
- Patel, P. B., Patel, T. K., Anturlikar, S., Khatun, S., Bhabhor, P., & Saurabh, M. K. (2018). Adverse drug reactions reporting by undergraduate medical students in a tertiary care teaching hospital of India: Content and quality analysis in comparison to physician reporting. *Perspect Clin Res*, 8(3), 137-144. <https://doi.org/10.4103/2229-3485.210453>
- Pérez-Francisco, D. H., Duarte-Clíments, G., del Rosario-Melián, J. M., Gómez-Salgado, J., Romero-Martín, M., & Sánchez-Gómez, M. B. (2020). Influence of workload on primary care nurses' health and burnout, patients' safety, and quality of care: Integrative review. *Healthcare*,
- Salehi, T., Seyedfatemi, N., Mirzaee, M. S., Maleki, M., & Mardani, A. (2021). Nurses' knowledge, attitudes, and practice in relation to pharmacovigilance and adverse drug reaction reporting: a systematic review. *BioMed research international*, 2021(1), 6630404.

- van der Heijden, B., Estry-Béhar, M., & Heerkens, H. (2019). Prevalence of, and risk factors for, physical disability among nurses in Europe.
- Woo, M. W. J., & Avery, M. J. (2021). Nurses' experiences in voluntary error reporting: an integrative literature review. *International Journal of Nursing Sciences*, 8(4), 453-469.
- Yadesa, T. M., Kitutu, F. E., Tamukong, R., & Alele, P. E. (2021). Prevalence, Incidence, and Characteristics of Adverse Drug Reactions Among Older Adults Hospitalized at Mbarara Regional Referral Hospital, Uganda: A Prospective Cohort Study. *Clin Interv Aging*, 16, 1705-1721. <https://doi.org/10.2147/cia.S332251>
- Yawson, A. A., Abekah-Nkrumah, G., Okai, G. A., & Ofori, C. G. (2022). Awareness, knowledge, and attitude toward adverse drug reaction (ADR) reporting among healthcare professionals in Ghana. *Therapeutic Advances in Drug Safety*, 13, 20420986221116468.