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A Comparative Analysis of Pharmacovigilance Practices in Urban and Rural Healthcare Settings

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ABSTRACT
The problem of ADR is worldwide. Higher rates of morbidity and mortality could result from ADRs. Adverse drug reactions lead to unnecessary financial costs. As treatments become increasingly complex, robust pharmacovigilance systems are needed to guarantee the safe use of pharmaceuticals in all healthcare settings. In India, 1% ADR is reported. Globally, it is an average of 5-10%, which is much higher than India. The ineffective ADR monitoring system, insufficient pharmacovigilance, and ADR knowledge, attitudes and behaviours are mostly to blame for this. Pharmacovigilance, which monitors and assesses adverse drug reactions (ADRs), is crucial to guaranteeing the safety and efficacy of pharmaceuticals to examine healthcare workers' pharmacovigilance knowledge, attitudes, and behaviours in both rural and urban healthcare institutions.In terms of variations in reporting methods, infrastructure, the active involvement of healthcare professionals, and awareness levels, this study examines the pharmacovigilance procedures in urban and rural healthcare settings. Data was collected by structured questionnaires, interviews, and a review of the pharmacovigilance records of a select group of urban and rural health care settings. According to the results, pharmacovigilance systems in cities tend to be more technologically sophisticated and well-organized, with more experienced staff members and greater reporting rates of adverse drug reactions.Conversely, rural regions may face limited resources, inadequate training, and a lack of awareness among patients and healthcare professionals. The study highlights the necessity of focused interventions, such as better education, awareness campaigns, and infrastructure support, to improve rural pharmacovigilance procedures. This gap needs to be filled to increase patient safety and deliver equitable healthcare outcomes across different geographic regions.

Keywords: Morbidity, Mortality, Pharmacovigilance, Adverse Drug Reactions (ADRs)

I. INTRODUCTION

Pharmacovigilance (PV) is all about the science and activities that help us recognize, assess, understand, and prevent side effects or other issues related to drugs [1]. It plays a crucial role in ensuring that medications remain safe and effective throughout their life cycle by keeping an eye on adverse drug reactions (ADRs) in real-world settings. The World Health Organization (WHO) highlights the significance of PV as a vital part of public health and patient safety [1]. In fact, estimates suggest that ADRs account for about 36% of hospitalizations in many countries and are a leading cause of serious fatalities. They also impose significant financial strains due to extended hospital stays and extra treatments [2]. Despite on-going efforts, a big challenge remains: underreporting. For instance, it's estimated that India contributes only around 3% to the global ADR database, with less than 1% of ADR cases being reported internationally in Germany [3]. Common reasons for this underreporting include a lack of awareness about PV among health professionals and their families, limited training, inadequate infrastructure, and the belief that ADR reporting isn't a priority [4, 5, 6].Urban centres typically boast tertiary hospitals, specialized staff, and more consistent medical training, while rural regions often depend on primary health centres or district hospitals that have fewer specialists and limited access to PV resources. These disparities suggest that knowledge, attitudes, and practices (KAP) regarding PV and ADR reporting may vary between urban and rural health workers. However, only a handful of studies have directly compared PV practices in these different settings in India [6,7]. Understanding these differences is crucial for

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designing targeted interventions that can improve PV.

II. PROJECT OBJECTIVE/GOAL

- Assess and compare baseline knowledge of PV concepts (definitions, goals, reporting procedures) among urban vs. rural healthcare professionals.
- Measure and contrast toward ADR reporting (sense of obligation, confidence, support for PV integration) in both settings.
- Characterize ADR-reporting behaviours: frequency of encountering ADRs, actual reporting patterns, and familiarity with reporting processes.
- Identify and compare key barriers and facilitators to ADR reporting in urban and rural contexts.
- Evaluate sources and sufficiency of PV training and updates across settings.
- Gather actionable suggestions from participants for enhancing PV systems locally.
- Inform context-specific recommendations to improve ADR reporting and patient safety equitably.

III. MATERIALS & METHODS

3.1 Study Design and Setting

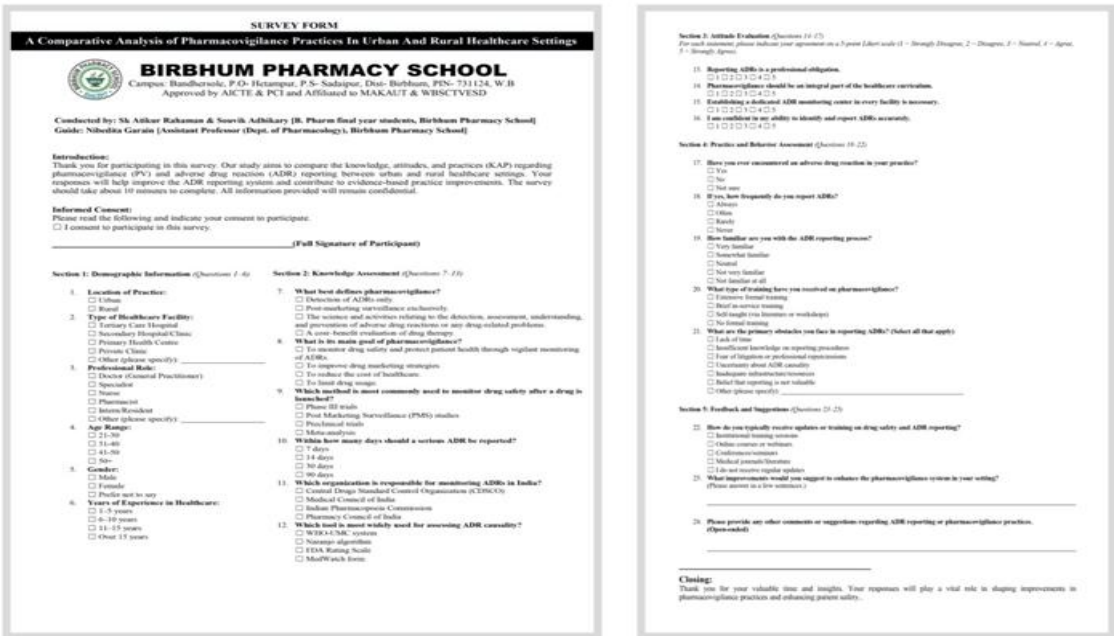
A cross-sectional field survey was conducted in West Bengal, India, targeting healthcare professionals in one urban area (City A) and one rural area (District B). Data collection took place over April 2025 to May 2025, entirely offline via in-person visits.

3.2 Participants and Sampling

Forty healthcare professionals (n = 40) participated: 18 from urban facilities and 22 from rural facilities. Convenience sampling was used: investigators visited tertiary, secondary, and primary health centres, private clinics, and community health centres to invite doctors (general practitioners and specialists), nurses, pharmacists, and interns/residents involved in patient care or medication management. Participation was voluntary, and informed consent was obtained.

3.3 Survey Instrument

A structured questionnaire (Survey Form) with five sections was employed.



SURVEY FORM

A Comparative Analysis of Pharmacovigilance Practices In Urban And Rural Healthcare Settings

BIRBHUM PHARMACY SCHOOL

Campus: Bandhersole, P.O- Hetampur, P.S- Sadaipur, Dist- Birbhum, PIN- 731124, W.B
Approved by AICTE & PCI and Affiliated to MAKAUT & WBSCTVESD

Figure 1: Survey Form

3.4 Ethics

Ethical approval was obtained from the institutional review board of Birbhum Pharmacy School. Participants provided written informed consent. Responses were collected anonymously; no personal identifiers were recorded.

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3.5 Data Collection

Investigators conducted face-to-face visits to each facility, explained the study purpose, obtained consent, and handed paper survey forms. Participants completed forms on the spot (approximately 10 minutes). Completed forms (n=40) were securely stored and later entered into an Excel file matching the survey template.

3.6 Data Entry and Cleaning

Data from all 40 forms were entered into a single-sheet Excel workbook with columns corresponding to each question. Categorical responses were coded uniformly (e.g., "Urban"/"Rural"; Likert scores 1–5 as numeric). For multi-select obstacles, separate binary columns (Yes/No) were used. Blank cells indicated non-response. The dataset was saved as CSV for analysis.

3.7 Statistical Analysis

Data were analysed using Python (pandas, matplotlib). Descriptive statistics included counts and percentages for categorical variables, and means ± standard deviation (SD) for Likert-scale attitude items. Knowledge questions were summarized as percentage correct overall. Attitude scores for each statement were averaged by location group. Overall attitude score per respondent was the sum of the four Likert items (range 4–20). Comparisons between urban and rural groups were done descriptively (percentages and mean differences); formal statistical tests (e.g., chi-square, t-tests) could be applied but given sample size (n=40) and convenience sampling, emphasis is on descriptive patterns. Tables summarized key findings. Open-ended feedback was reviewed qualitatively to identify common themes.

IV. RESULTS

4.1 Respondent Demographics

Characteristic	Urban (n = 18)	Rural (n = 22)	Total (n = 40)
1. Location of Practice			
Urban	18	—	18 (45.0%)
Rural	—	22	22 (55.0%)
2. Type of Healthcare Facility			
Secondary Hospital/Clinic	11	3	14 (35.0%)
Primary Health Centre	0	10	10 (25.0%)
Private Clinic	3	3	6 (15.0%)
Tertiary Care Hospital	0	5	5 (12.5%)
Other (Non Govt. Hospital)	2	1	3 (7.5%)
Other (BPHC)	1	0	1 (2.5%)
Other (Apollo Retail)	1	0	1 (2.5%)
3. Professional Role			
Doctor	3	4	7 (17.5%)
Nurse	7	10	17 (42.5%)
Pharmacist	4	7	11 (27.5%)
Intern/Resident	2	0	2 (5.0%)
Other	3	0	3 (7.5%)
4. Age Range			
21–30	13	14	27 (67.5%)
31–40	5	8	13 (32.5%)
5. Gender			
Male	7	11	18 (45.0%)
Female	11	11	22 (55.0%)
6. Years of Experience			
1–5 years	12	13	25 (62.5%)
6–10 years	5	8	13 (32.5%)
11–15 years	1	1	2 (5.0%)

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Table 1: Respondent Demographics Report

4.2 Knowledge Assessment

Question	Urban n (%)	Rural n (%)	Total n (%)
7. Definition of pharmacovigilance	12 (66.7%)	16 (72.7%)	28 (70.0%)
8. Main goal of pharmacovigilance	15 (83.3%)	18 (81.8%)	33 (82.5%)
9. Method to monitor drug safety post-launch	11 (61.1%)	13 (59.1%)	24 (60.0%)
10. Timeline for serious ADR reporting	10 (55.6%)	12 (54.5%)	22 (55.0%)
11. Organization responsible for ADR monitoring in India	14 (77.8%)	16 (72.7%)	30 (75.0%)
12. Tool for assessing ADR causality	5 (27.8%)	5 (22.7%)	10 (25.0%)

Table 2:Knowledge Assessment Report

Observations:

- Strong grasp of PV purpose:>80% in both groups identified the main goal of pharmacovigilance correctly.
- Definition awareness: ~70% knew PV's formal definition, leaving ~30% unclear.
- Process knowledge gap: Only 60% recognized post-marketing surveillance as the primary ADR-monitoring method.
- Timeline confusion: Just 55% knew the 14-day serious ADR reporting window.
- Regulatory gap: 25% of professionals could not name the national ADR-monitoring authority.
- Causality tool deficit: Only 1 in 4 knew the standard causality assessment tool, highlighting a key training need.

4.3 Attitude Evaluation

Statement	Urban Mean (SD)	Rural Mean (SD)	Total Mean (SD)
13. Reporting ADRs is a professional obligation	4.06 (1.30)	3.60 (0.70)	3.82 (1.20)
14. PV should be integral to healthcare curriculum	4.11 (1.32)	4.40 (0.75)	4.26 (1.06)
15. ADR centre in every facility is necessary	4.17 (1.04)	4.16 (1.12)	4.16 (1.07)
16. Confidence in identifying/reporting ADRs	3.94 (1.59)	3.90 (1.07)	3.92 (1.32)
Overall attitude score (sum Q13–16, max = 20)	16.28 (4.34)	16.06 (5.64)	16.16 (5.12)

Table 3: Attitude Evaluation Report

Observations:

- Positive attitudes overall; highest agreement on PV integration into curriculum.
- Confidence lower (mean ~3.7), indicating some uncertainty.
- Urban respondents slightly more positive/confident than rural.

4.4 Practice and Behaviours

Practice Question	Response	**Urbann** (%)	**Ruraln** (%)	**Totaln** (%)
17. Ever encountered an ADR?	Yes	9 (50.0%)	8 (36.4%)	17 (42.5%)
	No	8 (44.4%)	13 (59.1%)	21 (52.5%)
	Not sure	1 (5.6%)	1 (4.5%)	2 (5.0%)
18. Reporting frequency (of those who saw ADR)	Always	2 (22.2%)	1 (12.5%)	3 (17.6%)
	Often	4 (44.4%)	2 (25.0%)	6 (35.3%)
	Rarely	3 (33.3%)	4 (50.0%)	7 (41.2%)

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	Never	0 (0.0%)	1 (12.5%)	1 (5.9%)
19. Familiarity with ADR-reporting process	Very familiar	3 (16.7%)	3 (13.6%)	6 (15.0%)
	Somewhat familiar	5 (27.8%)	6 (27.3%)	11 (27.5%)
	Neutral	4 (22.2%)	15 (68.2%)	19 (47.5%)
	Not very familiar	4 (22.2%)	9 (40.9%)	13 (32.5%)
	Not familiar at all	2 (11.1%)	0 (0.0%)	2 (5.0%)
20. Type of PV training received	Extensive formal training	1 (5.6%)	2 (9.1%)	3 (7.5%)
	Brief in-service training	3 (16.7%)	5 (22.7%)	8 (20.0%)
	Self-taught (literature/workshops)	7 (38.9%)	9 (40.9%)	16 (40.0%)
	No formal training	7 (38.9%)	6 (27.3%)	13 (32.5%)
22. Source of updates/training on drug safety	Institutional training sessions	2 (11.1%)	3 (13.6%)	5 (12.5%)
	Online courses or webinars	2 (11.1%)	0 (0.0%)	2 (5.0%)
	Conferences/seminars	3 (16.7%)	3 (13.6%)	6 (15.0%)
	Medical journals/literature	2 (11.1%)	2 (9.1%)	4 (10.0%)
	I do not receive regular updates	9 (50.0%)	14 (63.6%)	23 (57.5%)

Table 4: Practice and Behaviours Report

Observations:

- ADR Exposure: Urban providers (50.0%) reported encountering ADRs more often than rural ones (36.4%), with 42.5% overall.
- Reporting Frequency: Among those who saw ADRs, urban staff tended to report "Always" or "Often" more (66.6%) than rural staff (37.5%), indicating higher reporting consistency in urban settings.
- Process Familiarity: Most respondents were "Somewhat familiar" or "Neutral" with ADR reporting (57.5% total), but urban participants had slightly greater confidence (44.5% combined "Very"/"Somewhat familiar") than rural (40.9%).
- Training Gaps: Self-taught methods dominated (40.0%), while formal training was limited (7.5% extensive, 20.0% brief), especially in rural areas.
- Information Sources: Over half (57.5%) received no regular updates; conferences and institutional sessions each reached only ~15%, highlighting the need for more consistent PV education.

4.5 Primary Obstacles

Note: n (%) is calculated relative to the number of respondents in that subgroup (Urban n=18, Rural n=22, Total n=40).Because participants could "select all that apply," the **sum of the counts across obstacles** will normally **exceed the subgroup total**.

Obstacle	**Urbann** (%)	**Ruraln** (%)	**Totaln** (%)
Lack of time	2 (11.1%)	8 (36.4%)	10 (25.0%)
Insufficient knowledge on reporting procedures	6 (33.3%)	5 (22.7%)	11 (27.5%)
Fear of litigation/professional repercussions	1 (5.6%)	1 (4.5%)	2 (5.0%)
Uncertainty about ADR causality	5 (27.8%)	2 (9.1%)	7 (17.5%)
Inadequate infrastructure/resources	3 (16.7%)	10 (45.5%)	13 (32.5%)
Belief that reporting is not valuable	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	0 (0.0%)	0 (0.0%)	0 (0.0%)

Table 5: Primary Obstacles Report

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Observations:

- Time vs. Infrastructure: Rural respondents (36.4%) more frequently cited "Lack of time" compared to urban (11.1%), while urban respondents (27.8%) reported "Uncertainty about ADR causality" more than rural (9.1%).
- Knowledge Gaps: "Insufficient knowledge on reporting procedures" was the second-highest obstacle for both groups, but slightly more urban (33.3%) than rural (22.7%).
- Infrastructure Disparity: "Inadequate infrastructure/resources" was a major barrier in rural settings (45.5%) versus urban (16.7%), underscoring the need to bolster rural PV infrastructure.

4.6 Open-Ended Feedback

Common themes in suggestions:

- More frequent and accessible PV training workshops, especially in rural areas.
- Simplified ADR reporting forms and processes (e.g., mobile app usage, helpline reminders).
- Integration of PV modules into undergraduate/continuing education.
- Administrative support: designating PV focal persons in each facility.
- Improved communication channels between rural facilities and central ADR Monitoring Centres.

V. DISCUSSION

The comparative analysis revealed that, although a majority of participants correctly understood the basic definition and goals of pharmacovigilance, significant procedural knowledge gaps persisted: only 55% knew the correct timeline for reporting serious ADRs and just 25% identified the appropriate causality tool (Naranjo algorithm). Attitudes toward ADR reporting were uniformly positive—most agreed it was a professional obligation and favoured integrating PV into curricula—but confidence in one's own reporting ability was moderate (mean ≈3.7/5), indicating uncertainty about applying theoretical knowledge in practice. Practice patterns mirrored these gaps: fewer than half of respondents had encountered an ADR, and among those, just over half reported "always" or "often," suggesting both under-recognition and under-reporting in routine care. Primary barriers differed by setting: rural professionals cited time constraints and infrastructural shortfalls more frequently, while urban staff more often noted procedural knowledge deficits and causality uncertainty; legal fears and belief in reporting's low value were negligible obstacles in either group. These findings imply that multifaceted interventions are essential—targeted training (workshops, e-learning), streamlined reporting mechanisms (mobile apps, simplified forms), and strengthened infrastructure (rural help lines, PV focal persons)—to translate positive attitudes into consistent reporting behaviours. Monitoring reporting rates and providing feedback, coupled with professional recognition for active reporters, will further reinforce PV engagement. Tailoring content depth (basic reporting steps for rural, advanced signal detection for urban) will optimize resource use and strengthen India's pharmacovigilance system overall.

VI. CONCLUSION

This study reveals that while healthcare professionals in both urban and rural settings value pharmacovigilance and recognize ADR reporting as a professional obligation, substantive gaps in procedural knowledge, confidence, and actual reporting practices persist. Knowledge of reporting timelines and causality tools was limited in both groups, and only a minority had received formal training. Rural practitioners faced additional barriers related to infrastructure and time constraints, whereas urban practitioners more often cited knowledge deficits. Most respondents received no regular updates on PV. These findings underscore an urgent need for tailored interventions: comprehensive PV training programs, streamlined reporting processes, and strengthened infrastructure and support mechanisms—especially in rural areas. By addressing setting-specific barriers and leveraging positive attitudes, policymakers and institutions can enhance ADR reporting rates, thereby improving early detection of drug safety signals and safeguarding patient health across both urban and rural India.

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