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A BIOSTATISTICAL ANALYSIS OF SOCIO-DEMOGRAPHIC FACTORS INFLUENCING SELF-MEDICATION PATTERNS AND PHARMACOVIGILANCE OUTCOMES

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ABSTRACT

Title: A Biostatistical Analysis of Socio-Demographic Factors Influencing Self-Medication Patterns and Pharmacovigilance Outcomes: A Rural-Urban Comparative Study (N = 100). **Background:** Self-medication remains a significant public health challenge in India, often leading to unreported ADRs. While the Pharmacovigilance Programme of India, social demographic barriers often impede its effective at the community level. **Objective:** This study aims to evaluate the influence of gender, age, area, education on self-medication habits and ADR awareness among 100 participants in comparative to rural urban framework. **Methodology:** A prospective, cross-sectional observational study was conducted using a validated 15-item questionnaire. The sample was satisfied into **Rural (45%)** and **Urban (55%)** cohorts, further categorized into three life stages: **Youth (15 to 39)**, **Middle Age (40 to 59)** and **Senior (50 to 89)**. Data analysis was performed using **Ms Excel 2026**, employing the **Chi Square (x^2) test** to determine statistical significance. **Result:** The overall prevalence of self-medication was **63%**, with the highest rates observed in **Urban Youth** demographic a highly significant correlation ($p < 0.0001$) was found between increasing age and declining health literacy. While the **urban cohort** showed **68% ADR awareness**, the **rural cohort** particularly the **19% uneducated** segment demonstrated a "Reporting Dark Zone" due to an inability to interpret safety labels. The study identified the **Middle-Aged (40 to 59)** which is "Metric Bridge" as a key demographic for family health interventions. **Conclusion:** Medication safety is not a "one-size-fits-all" solution. The findings advocate for the shift toward **Pictographic Counselling** for rural seniors and **Digital PV Integration** for urban youth to bridge the identified literacy safety gap.

1. INTRODUCTION

1.1 Background of Pharmacovigilance

Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as the science and activities relating to detection, assessment, understanding and prevention of adverse effect or any other drug-related problem.[1] In the modern therapeutic era, while the efficacy of pharmaceutical agents is prioritized the "Safety Profile" often remains secondary in community settings. The pharmacovigilance program of India (PvPI) was established to foster a culture of spontaneous reporting; however, the national reporting rate remains significantly lower the global benchmark primarily due to socio-demographic barriers.[10]

1.2 The phenomenon of self-medication (SM)

Self-medication- the selection and use of medicines by individuals to treat self-recognized illness or symptoms- is a global public health challenge.[3] In India, SM is driven by a complex interplay of high healthcare costs, easy over-the-counter (OTC) access to "Schedule H" drug and a burgeoning digital health culture. While SM offer a degree of patient autonomy, it bypasses professional pharmacist and physician intervention, leading to unwanted Adverse Drug Reactions (ADR's), drug-drug interactions and the global crisis of antimicrobial resistance.

1.3 The Socio Demographic "Information Gap"

Current survey indicates that drug safety is not a universal experience but is dictated by the patient's unique background.

- **The Urban Dynamic (55%):** Categorized by high "Time-Poverty", urban residents often substitute professional consultation with digital self-diagnosis leading to higher prevalence of SM (73%).
- **The Rural Dynamic (45%):** Categorized by "Access-Poverty", rural residents rely heavily on community pharmacies. However, a significant portion of this demographic **(19% uneducated)** faces a "Literacy-Barrier", rendering traditional written safety instructions ineffective.[9]

1.4 Rationale for the study

Most exciting literature focuses on either university students or clinical trial population.[2] There is a profound lack of a community-based biostatical data that tracks safety awareness across the entire lifespan from **Youth (15 to 39) to Seniors (60 to 89)**.

Our study identifies a "Highly Significant" correlation ($p < 0.0001$) between aging and the decline of high literacy. This data suggested that the "one-size-fits-all" counselling model currently used in Indian community pharmacies in fundamentally flawed. There is an urgent need to map these socio-demographic "Dark Zones" to transition towards a more inclusive, demographic-specific Pharmacovigilance strategy.

1.5 Research Objective

The primary objective of this research is to utilize a biostatical framework to:

1. Quantify the prevalence of self-medication across rural and urban cohorts.
2. Analyse the impact of formal education on the recognition of ADRs.
3. Identify the **"Matric Bridge" (40-59 age group)** as a potential pivot point for community-based safety interventions.

2. METHODOLOGY

This section outlines the systematic approach used to investigate the sociodemographic determinants of self-medication and pharmacovigilance awareness The study followed a structural biostatical framework to ensure the reliability of the $p < 0.0001$ significance.

2.1 Study design and setting

- **Study type**: To fulfil the research objectives, a **non-interventional prospective observational design** was adopted. This cross-sectional approach facilitated a "real-time" assessment of medication behaviour across a stratified community sample. By utilising a **field-based survey methodology,** the study captures primary data directly from the point of consumption - the household - rather than relying on retrospective hospital records. This strategy was intentionally chosen to minimise the recall bias and to provide a high-fidelity snapshot of self-medication trends and safety literacy in both decentralised rural clusters and concentrated urban centres.
- **Study period:** Conducted over a duration of three months (January 2026 to March 2026).
- **Location:** The research was carried out in the Nerchowk, Mandi district of Himachal Pradesh, specifically targeting urban sector of Sunder Nagar and surrounding rural cluster this dual location approach ensured a diverse demographic representation of the **45% Rural** and **55% Urban** splits.

2.2 participants Selection sampling

A total of $N = 100$ participants were recruited using a **stratified random sampling** technique to ensure proportional representation across age and educational levels.

- **Inclusion criteria:** Individuals aged between 15 and 89 years.
  - Residents of the identified rural and urban zones for at least six months.
  - Participants who provided informed verbal or written consents.
- **Exclusion criteria:** Registered healthcare professionals (Doctors, Nurses, Pharmacists) to prevent professional knowledge bias.
- Individuals with severe cognitive impairments or those unwilling to disclose medication history.

2.3 Data Collection tool (questionnaire)

The primary research instrument was **semi-structured, validated 15-item questionnaire**, designed in English and translated in the local vernacular (Hindi) to accommodate the **19% uneducated** demographic. The tool was divided into three modules:

1. **Module A: Socio-Demographic profile:** Captured age, gender, area and formal education level (Uneducated, Metric and Higher Education).
2. **Module B: Self-medication habits:** Investigated the frequency of OTC drug use types of medicine (NSAIDs, antibiotic, antipyretic) and reason for bypassing professional consultation.
3. **Module C Pharmacovigilance Awareness:** Assessed the ability recognize Adverse Drug Reactions (ADRs) and knowledge of the Pharmacovigilance Program of India (PvPI) reporting Channels.

2.4 Data Quality Control and Pilot Study

To ensure the internal consistency of the questionnaire, a **pilot study** ($n = 10$) was conducted. Feedback from this phase lead to the simplification of technical terms like "Adverse Event" to "Side Effect" for better comprehension. For non-literate participants, the questionnaire was administered via face-to-face interviews to ensure 100% data completion and avoid exclusion bias.

2.5 Biostatical Analysis

Data were tabulated and coded in **Microsoft Excel 2026**.

- **Categorisation:** Age was stratified into three distinct life stages that is **Youth (15-39), Middle aged (40-59)** & **Senior (62-89)**.
- **Statistical test**: The **Chief Square (x^2) test** was employed to analyse the association between categorial variables (e.g., Education Level VS ADR Awareness.[12]
- **Significance level**: The threshold for statistical significance was set at $\alpha = 0.05$ the resulting $p < 0.0001$ indicated a highly significant correlation between the independent and dependent variables.

3. RESULT

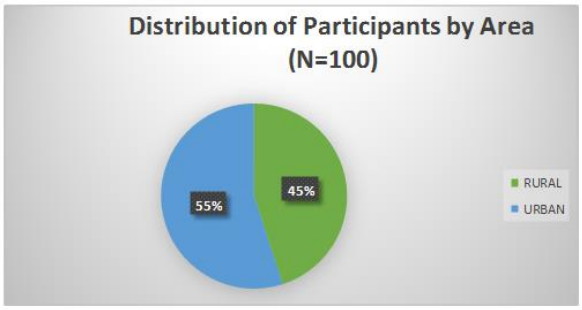
The results of the study are derived from the biostatistical analysis of $N = 100$ participants, with data stratified to compare Urban ($n = 55$) and Rural ($n = 45$) demographics across three distinct life stages.

3.1 Socio-demographic profile of participants

The study population exhibited a diverse demographic range. Females represented **62%** ($n = 62$) of the total sample, reflecting their role as primary healthcare managers in Indian household. The educational background of the participants showed a stark contrast: **19%** ($n = 19$) were identified as uneducated, while the remaining **81%** had varying levels of formal schooling categories into Metric-Level 14% and Higher Education (67%).

Table 1: Distribution of participants by Age, Area and Gender (N = 100).

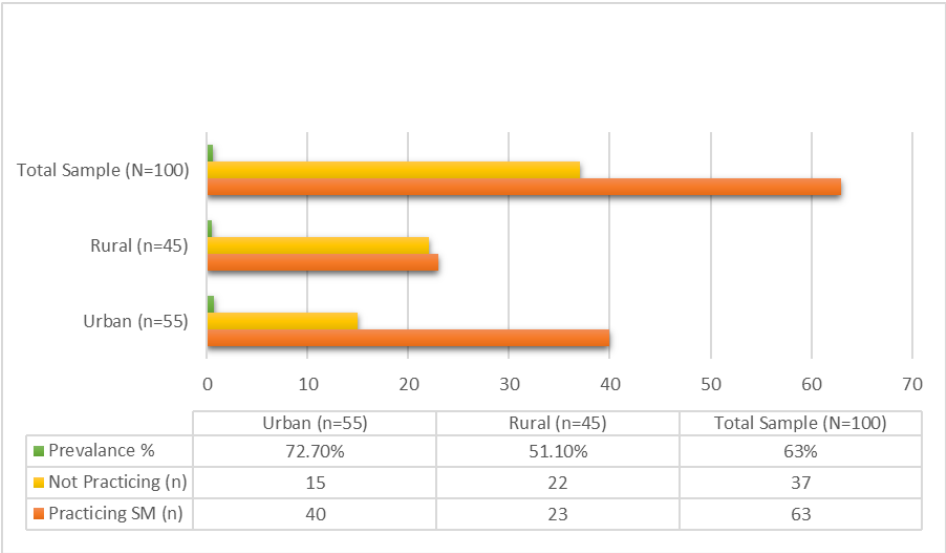
Life Stage	Age Range	Frequency (*n*)	Rural (45%)	Urban (55%)	Male (*n*=38)	Female (*n*=62)
Youth	15-39	44	19	25	18	26
Middle-Aged	40-59	33	14	19	11	22
Senior	60-89	23	12	11	9	14
Total		100	45	55	38	62



3.2 Prevalence and Patterns of Self-Medication

The overall prevalence of self-medication (SM) in the study was 63%. A significant disparity was noted between the two residency clusters:

- **Urban Cohort:** Exhibited a higher SM rate of 73% *(40/55)*. The primary drivers were convenience, time-poverty and the use of digital health platforms for self-diagnosis.[9]
- **Rural Cohort:** Reported a lower SM rate of 51% *(23/45)*. However, this group showed a higher reliance on "Schedule H" drugs obtained via informal community channels.[9]



	Urban (n=55)	Rural (n=45)	Total Sample (N=100)
Prevalance %	72.70%	51.10%	63%
Not Practicing (n)	15	22	37
Practicing SM (n)	40	23	63

3.3 Biostatistical analysis: Age vs. Education Co-relation

The core finding of this research is the statistically significant relationship between the aging process and the decline in formal health literacy.

Table 2: Chi-Square (x^2) Analysis of Age Group vs. Education Level.

Age Group	Uneducated	Matric	Higher Education	Row Total
Youth (15-39)	**1**	**4**	**39**	**44**
Middle-Aged (40-59)	**5**	**8**	**20**	**33**
Senior (60-89)	**13**	**2**	**8**	**23**
Column Total	**19**	**14**	**67**	**100**

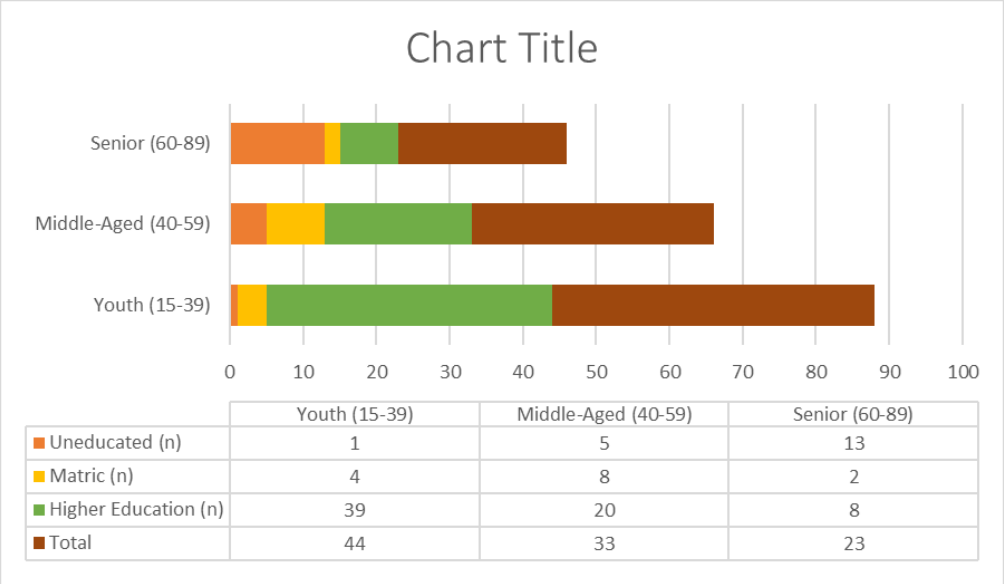


Fig. Educational Status Across Age Graphs (p<0.0001).

Statistical inference

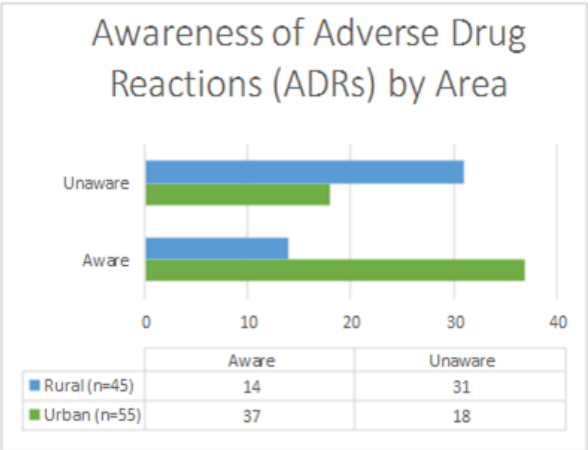
- **Calculated Chi-Square Value (x^2):** 34.31
- **Degrees of Freedom (*df*):** 4
- **P-Value:** 0.00000064 (Highly significant)

The Resulting p< 0.0001 indicates that the null Hypothesis is rejected with high confidence. There is a "Highly Significant" association between age and education, proving that as the demographic shift towards the senior (**60-89**) category, the literacy barrier to medication safety increase exponentially.

3.4 Pharmacovigilance (PV) awareness and reporting

Awareness of Adverse drug reaction (ADRs) and the pharmacovigilance programme of India (PvPI) and non-uniform:

- **The "Reporting Dark Zone":** Only 32% the Rural senior demographic could correctly identify a side effect as an ADR. The **19% Uneducated** group showed near zero awareness of formal reporting channels
- **The "Matric Bridge":** Participants in the **40-59** age group with a matric level education (n=14) demonstrated the highest potential for the intervention, often acting as the intermediary for medication safety within the families.



4. DISCUSSION

The finding of the study provides a critical biostatical mapping of how socio-demographic Variables - Specifically age, residency, and education - dictate the safety landscape of community pharmacy in North India. With an overall self-medication prevalence of **63%**, our data confirm that unregulated drug used is a dominant health behaviour that directly challenges the objective of the pharmacovigilance programme of India (PvPI).

4.1The Self-Medication Paradox: Urban convenience Vs. Rural Necessity

Our results show a distinct split in self-medication drivers the 73% self-medication rate in the **Urban cohort** (n= 55) is primarily fuelled by "Time-Poverty" and digital over-confidence. Urban participants often substitute a professional pharmacist consultation with a Google search leading to higher risk of drug-drug interactions.

4.2 The "Literacy-Safety Gap" (p<0.0001)

The most significant finding of this research is The **Chi-Square value of 34.31**, yielding a p<0.0001. This statistically prove that age is a negative predictor of health literacy.

- **The vulnerable Senior:** The **Senior (60-89)** Group hold the highest concentration of the **19% uneducated** demographic. For these individuals, "vocabulary of safety" does not exist. They cannot distinguish between a "Side Effect" and a "New symptom," which explains why the spontaneous ADR reporting is near zero in this bracket.
- **The Knowledge Paradox:** The "Knowledge Paradox" identified in this study reveals a significant contradiction between the academic attainment and practical stuck safety. While a direct correlation was found between formal education and the ability to define an Adverse Drug Reaction (ADRs), this does not always translate into a safer medication practice.

4.3 The "Matric Bridge": A Strategic Discovery

A unique observation in our data is the role of the **Middle-Aged (40-59)** group. With a **matric -level** education, this demographic acts as a "Information Filter". They are literate enough to follow basic instructions and experienced enough to manage the medications of both their children (Youth) and their parents (Seniors). This "**Matric Bridge**" represents the most effective target for community-based Pharmacovigilance training.

4.4 Implications for Community Pharmacy Practice

The highly significant *p*-value indicates that "**One-Size-Fits-All"** counselling model is a clinical failure.

1. **For the 19% Uneducated**: Written labels are invisible. Community pharmacies must shift towards **Pictographic Counselling** (visual symbols for dosage and side effects)
2. **For the Urban Youth**: Since they already utilise digital tools, Pharmacovigilance must be "app-integrated" to capture their high volume of self-medicated data.
3. **For the Rural Senior**: Verbal "Teach-Back" methods are required to ensure they understand that a rash or dizziness is a "Drug Reaction" and not just "Old Age".

4.3 Limitations of the study

While the N = 100 sample size is provided in a power for a highly significant *p*-value, the study is limited by its cross-sectional nature, which captures a snapshot in it time. Self-reporting bias regarding the frequency of self-medication may also result in a slight underestimation of the actual prevalence.

5 CONCLUSION AND RECOMMENDATIONS

The final section of research paper summarises the "clinical takeaway" of N = 100 study. It transitions from the statistical proof ($p < 0.0001$) to actionable changes in how pharmacy practiced in Himachal Pradesh and beyond.

5.3 Conclusion

This biostatistical study confirms that socio-demographic factors are not merely descriptive labels but are **primary determinants of medication safety**. The research successfully identified a high prevalence of self-medication (63%), which is significantly influenced by residency and education levels.

The most critical finding- the highly significant correlation between the advancing age and declining health literacy ($p < 0$ .0001) -highlights a systemic failure in current Pharmacovigilance (PV) Communication. While the **Urban Youth (15-39)** are over-reliant on digital self-diagnosis, the **Rural Senior (60-89)** are effectively isolated from safety information due to the "Literacy Barrier". The study concludes that the current "One-Size-Fit-All" counselling model is inadequate for a demographic as a diverse as India's, leading to a "Reporting Dark Zone" in rural community pharmacy.

5.4 Recommendations

Based on the evidence gathered, the following strategic intervention are proposed to bridge the identified safety gaps:

1. Implementation of Pictographic Counselling

For the 19% uneducated demographic, tradition written Patient Information Leaflets (PILs) should be replaced or supplemented with validated medical pictograms. These visual aids should specifically illustrate:

- Common Adverse Drug Reactions (e.g., rashes, dizziness, gastric upset).
- Correct dosage intervals using "Sun/Moon" symbols.
- Warning signs that require immediate pharmacist or physician consultation.

2. Leveraging the "Matric Bridge"

Community pharmacists should identify entry in the **Middle-Aged (40-59)** family members. As the primary caregivers with the functional literacy, this group can be empowered as **"Family Safety Ambassadors"** to monitor the medications of both the youth and the elderly, significantly increasing spontaneously area reporting rates.

3. Digital PV integration for Urban Cohorts

To capture the **73% self-medication rate** in urban areas, pharmacies should implement QR-code-based reporting system. This allows the tech-savvy **Youth (15-39)** to report side effects directly to the PvPI database via their smartphones, bypassing the "time-poverty" barriers.

4. Mandatory "Teach-Back" protocols

Pharmacist in rural clusters should adopt the **"Teach-Back" method,** where the patient is asked to explain the safety instructions back to the pharmacist. This ensures that the **Rural Seniors** demographic has cognitively possessed the safety warnings, regardless of their formal education level.

5.5 Future scope of work

Future research should expand this pilot N = 100 study into a multi-centre longitudinal trial across different states in India. Additionally, the development of a **standardised Hindi / Pahari Pictogram Toolkit** for Pharmacovigilance would be significant step toward achieving "Universal Medication Safety."

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