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Pharmacovigilance in Pneumonia: Drug Safety Across Patient Demographics

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Abstract: Pneumonia remains a significant global health concern, contributing to substantial morbidity and mortality across diverse patient populations. While antimicrobial therapy is the cornerstone of treatment, drug safety issues, such as adverse drug reactions (ADRs), antimicrobial resistance, and drug-drug interactions, pose critical challenges for optimal patient outcomes. Pneumonia is commonly treated with strong antibiotics, which can sometimes cause side effects in patients. This review combines hospital findings with research evidence to identify which drugs are more likely to cause adverse reactions. Most reactions were mild and improved with proper monitoring and timely changes in treatment. The study highlights the importance of pharmacovigilance in ensuring safe and effective pneumonia management.

Pharmacovigilance plays a pivotal role in monitoring and evaluating these safety concerns, especially in varied demographic groups including children, older adults, immunocompromised individuals, and patients with comorbidities. This study examines post-marketing safety data related to pneumonia therapies, analyzing ADR trends, severity, and causality across demographic subgroups. Preliminary findings highlight age-related differences in susceptibility to ADRs, with elderly patients experiencing a higher incidence of cardiotoxic and nephrotoxic events, while pediatric populations exhibited more hypersensitivity reactions. Socioeconomic factors, polypharmacy, and genetic variability further influence drug safety profiles.

These insights underscore the need for demographic-specific pharmacovigilance strategies and tailored prescribing practices to improve safety outcomes in pneumonia management. Enhanced real-world evidence generation, active ADR reporting, and integration of demographic-specific risk mitigation approaches are recommended to strengthen drug safety surveillance in pneumonia treatment. Doctors have several ways to check how serious pneumonia is, which helps them decide further care. Viruses can also cause pneumonia, so spotting them early is important to start the right treatment quickly. For community-acquired pneumonia, doctors usually recommend a combination of a beta-lactam antibiotic and a macrolide, or they may use a respiratory fluroquinolone on its own.

Keywords: *Pneumonia, Pharmacovigilance, Adverse Drug Reactions, Antimicrobial Safety, Patient Demographics, Drug-Drug Interactions.*

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I. INTRODUCTION

Adverse drug reactions (ADR) are common in hospitals because patients often have serious diseases, are treated with many medicines at the same time, and may experience drug interactions or errors [1]. About 10-20% of hospital patients may develop ADRs, which can sometimes make their hospital stay longer [2]. Since many new medicines are now available, it is important for doctors to stay alert, as unexpected and rare side effects can only be identified if they report them [3]. Reporting ADRs helps improve drug safety and may even influence the way medicines are recommended by authorities and pharmaceutical companies [4].

ADR can be monitored in two ways:

- Active monitoring (closely following up on patients)
- Voluntary reporting (doctors and staff reporting whenever they notice an ADR)

In many western countries, ADR reporting systems exist, usually as spontaneous reporting systems-sometimes optional and sometimes legally required [5]. It is not enough to only measure how often ADRs happen and how severe they are, even though that information is useful [6]. Since it is impossible to completely remove all side effects of medicines, it is more important to compare and study their

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patterns. For example, one drug may often cause minor side effects but may not be life-threatening. Certain patients, like those with a history of allergies or earlier ADRs, are at higher risk (up to 4 times more likely) to develop another reaction [7]. Many ADRs can be prevented through better prescribing practices. This requires doctors to understand medicines well and to carefully consider their patients and their conditions [8]. This study was carried out at Primary Care Hospital in Daund.

The aims were:

- To find out the incidence, types, nature, causes, and outcomes of ADRs among hospitalized patients in the medicine ward.
- To study the role of pharmacovigilance in estimating how common ADRs are.

Pneumonia can be classified into three main types: Community-acquired pneumonia (CAP), hospital-acquired pneumonia (HAP), and ventilator-associated pneumonia (VAP). According to the American Thoracic Society and the Infectious Disease Society of America (ATS/IDSA), CAP is diagnosed when imaging shows an infiltrate along with at least one respiratory symptom and another feature such as fever or high white blood cell count (2019 guidelines) [9]. Severe CAP is considered a more dangerous form of CAP, where vital signs or lab results suggest a more serious infection. HAP, as described in the 2016 ATS/IDSA guidelines, is pneumonia that develops more than 48 hours (about 4 days) after a patient has been admitted to the hospital, but who is not on a ventilator. VAP, on the other hand, occurs when pneumonia develops after a patient has been on mechanical ventilation for more than 48 hours (about 4 days) [10]. Traditionally, identifying the cause of pneumonia has relied on culturing samples, either from sputum or invasive methods like bronchoalveolar lavage (BAL). Biomarkers such as procalcitonin and CRP may be used to help guide treatment decisions, although their role in diagnosing pneumonia is still debated [11]. More recently, syndromic panels have been developed as faster methods for detecting pathogens. Treatment strategies differ depending on the type of pneumonia. Patients with HAP or VAP usually need broader antibiotic coverage, as recommended by the 2016 guidelines. Factors such as prior antibiotic use, the presence of resistant bacteria like MRSA, recent hospitalization, or existing lung disease also play an important role in choosing the right therapy. With rising concerns about antibiotic resistance, this review focuses on the latest updates in pneumonia management and future directions that may help improve patient care.

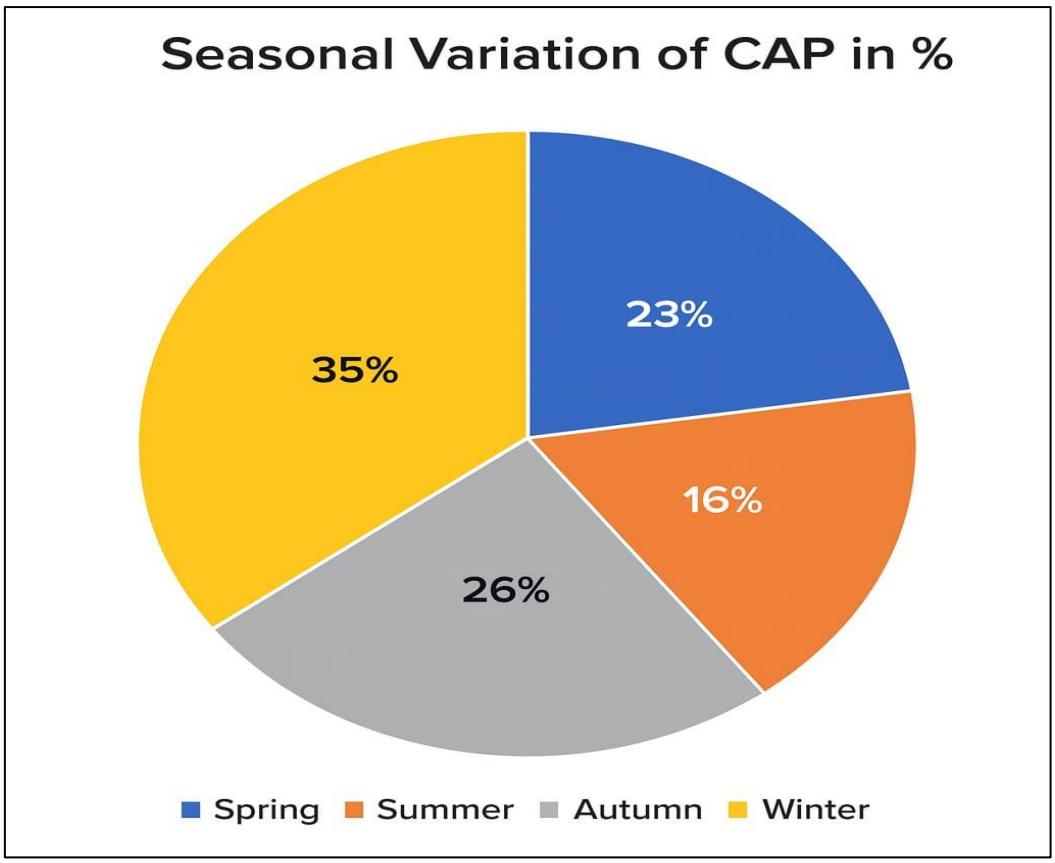

Fig 1: Distribution of Seasonal Variation of Cap in % [12]

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Table 1. Risk Factors and Infectious Causes in Community-Acquired Pneumonia

Risk Factor	Infectious
Agricultural animals	Coxiella burnetii (Q fever)
AIDS	Aspergillus and Cryptococcus species, Histoplasma capsulatum, Haemophilus influenzae, Nocardia species, nontuberculous mycobacteria, Pneumocystis jiroveci
Alcoholism (aspiration)	Anaerobic oral flora, Klebsiella pneumoniae, Mycobacterium tuberculosis, Streptococcus pneumoniae
Avian fecal matter	H. capsulatum
Chronic obstructive pulmonary disease	Chlamydophila pneumoniae, H. influenzae, Legionella species, Moraxella catarrhalis, Pseudomonas aeruginosa or other gram-negative rods, S. pneumoniae
HIV infection	H. influenzae, M. tuberculosis, S. pneumoniae
Hotel or cruise ship travel (recent)	Legionella species
Influenza	H. influenzae, influenza and other respiratory viruses, S. pneumoniae, Staphylococcus aureus (including MRSA)
Pulmonary abscess	Anaerobic oral flora, M. tuberculosis, nontuberculous mycobacteria, S. aureus (including MRSA)
Intravenous drug use	Anaerobes, M. tuberculosis, S aureus (including MRSA), S. pneumoniae
Travel (national/international)	Blastomyces dermatitidis, Coccidioides species, Hantavirus species Middle East respiratory syndrome, Avian influenza, inter alia

Abbreviations: AIDS acquired immunodeficiency syndrome; HIV, human immunodeficiency virus; MRSA, methicillin-resistant staphylococcus aureus. Adapted from Kaysin A, Viera AJ. Community-acquired pneumonia in adults: diagnosis and management. Am Fam Physician 2016;94(9):699; with permission [13].

II. MATERIALS AND METHODS

This was a prospective observational study conducted over a period of five to six months in the medical wards and the Tb and Chest ward of primary hospital located in Daund. A total 112 patients admitted during the study period were enrolled. Of these, 25 patients were diagnosed with pneumonia based on clinical, radiological, and laboratory findings and were included for detailed pharmacovigilance assessment.

➢ *Exclusion Criteria*

Patients with incomplete medical records, those who were discharged within 24 hours of admission, and patients unwilling to participate were excluded.

➢ *Inclusion Criteria*

Patients of all age groups and genders admitted with a confirmed diagnosis of pneumonia who received pharmacological treatment during hospitalization [14].

➢ *Data Collection*

Patients details such as age, gender, clinical history, comorbidities, and prescribed medications were recorded. Adverse drug reactions (ADRs) were documented using a structured and pre-tested case record form. Both patient interviews and review of medical records were used for data collection.

Among 16 patients diagnosed with pneumonia, several patients also presented with comorbidities such asthma, COPD, and hypertension. Data were analyzed to explore the relationship between pneumonia occurrence and prescribed drugs, with a special focus on inhaled corticosteroids (ICS) and benzodiazepines (BZD). Subgroup analysis was performed according to age, sex, and disease profile. It was an observational, retrospective and record-based study conducted by analyzing the spontaneous ADR forms, collected over a period of 2 months (June 2025 to July 2025) at primary hospital in Daund, Pune, India [15].

III. SIGNS AND SYMPTOMS OF PNEUMONIA

Pneumonia usually begins with fever, chills, tiredness, and loss of appetite as the body reacts to the infection. Most patients develop a cough that may be dry or produce yellow, green, or sometimes blood-stained mucus. Breathing difficulty is common and may appear as fast, shallow, or noisy breathing, along with chest pain that worsens when coughing or taking deep breaths. On examination, healthcare workers may notice reduced air entry, crackling sounds in the lungs, dullness on percussion, and an increased heart or breathing rate. Children often show fast breathing, refusal to feed, or irritability, while elderly patients may be present with confusion or weakness even without fever. Some people also experience headaches, muscle pain, sweating, nausea, or stomach discomfort during the illness. These symptoms can vary in severity depending on age, immunity, and the type of organism causing the infection.

Pneumonia is a sudden infection of the lungs (lower part of the breathing system). It shows up as new cloudy patches on a chest X-ray. Anyone can get pneumonia, but it is more common in older people. A person with pneumonia may have one or more of the following symptoms in their medical history:

- Pleuritic chest pain
- Shortness of breath
- Cough
- Production of sputum
- Rigors or night sweats
- Confusion

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On examination the signs may include:

- Raised respiratory rate
- Fever of > 38^0C
- Focal chest signs: decreased chest expansion, dullness on percussion, decreased entry of air, bronchial breathing, and crackles (none, some, or all of these may be present).

In elderly people, fever may not be present, and a new onset of mental confusion is more common.

If pneumonia symptoms are ignored or treatment is delayed, it can lead to serious problems such as fluid around the lungs, lung abscess, blood infection (sepsis), or breathing failure. These complications are more common in elderly, weak, or untreated patients [16].

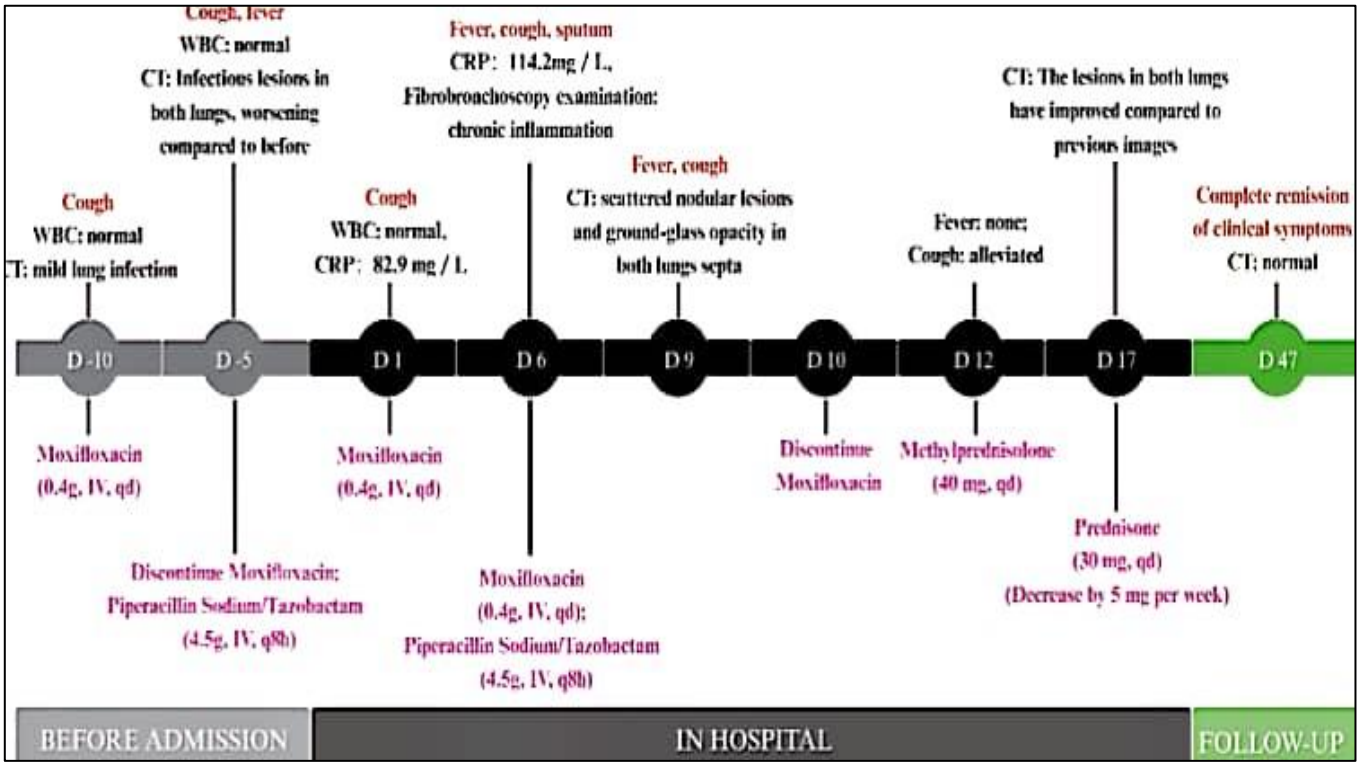

Fig 2: Flow Chart of Patient Diagnosis and Treatment [17]

Table 2 Drug Utilization of Antibiotics Among Pneumonia Cases (Elderly Patients)

Antibiotic Name	Dose Previously Used (mg/kg/day)	Recommended Geriatric Dose (mg/kg/day)	Dosage Form	Route of Administration	Dosing Frequency
Amikacin	25–30	7.5–15 (adjust as per kidney function)	Injection	Intravenous	Once or twice daily
Gentamicin	5–7	3–5 (based on renal clearance)	Injection	Intravenous	Once daily
Ceftriaxone	40–50	25–50	Injection	Intravenous	Once or twice daily
Azithromycin	20	10	Tablet / Capsule	Oral	Once daily
Meropenem	45	20–40 (as per renal function)	Injection	Intravenous	Twice or thrice daily
Doxycycline	8–12	2–4	Tablet / Capsule / Liquid	Oral or Intravenous	Once or twice daily
Linezolid	15–20	10–15	Injection / Tablet	Intravenous or Oral	Twice daily
Vancomycin	60	15–20 (based on serum levels)	Injection	Intravenous	Once or twice daily
Piperacillin–Tazobactam	270–375	200–300	Injection	Intravenous	Twice or thrice daily
Metronidazole	15	7.5–10	Injection / Tablet	Intravenous or Oral	Twice daily

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Upon observation of Table No. 2, except for azithromycin (Oral), all antibiotics were administered via IV route. In this study, the dosing schedule for amikacin and ceftriaxone showed patient-to-patient variation. Antibiotics doses were mostly with recommended level [18].

Table 3. Drug Utilization of Antibiotics Among Under-5 Pneumonia Cases

Name of Antibiotic Used	Dose Administered (mg/kg/day)	Standard Recommended Dose (mg/kg/day)	Dosage Form	Route of Administration	Dosing Frequency
Amikacin	25–30	15–20	Liquid	Intravenous	Once, twice, or four times daily (OD/BD/QID)
Gentamicin	5–7	5–7.5	Liquid	Intravenous	Once daily (OD)
Ceftriaxone	40–50	50–75	Liquid	Intravenous	Twice or thrice daily (BD/TDS)
Azithromycin	20	10	Solid	Oral	Once daily (OD)
Meropenem	45	60	Liquid	Intravenous	Thrice daily (TDS)
Doxycycline	8–12	5	Liquid	Intravenous	Three times daily (TDS)
Linezolid	15–20	20	Liquid	Intravenous	Three times daily (TDS)
Vancomycin	60	40	Liquid	Intravenous	Three times daily (TDS)
Piperacillin–Tazobactam	270–375	300–400	Liquid	Intravenous	Three times daily (TDS)
Metronidazole	15	15–20	Liquid	Intravenous	As prescribed / depending on clinical need

Table No. 3 showed that polypharmacy practice and generic drug prescription, injectable antibiotics, and drugs chosen from the essential drug list were different from the WHO optimal values [19]. A similar result of the practice of polypharmacy and the use of parenteral antibiotics was reported by Chavda et al and Patel et al [20,21]

Table 4: Assessment of Treatment Related ADR Among Pneumonia Patients

Adverse Reaction	Associated Medication	Number of Cases (n)
Diarrhoea	Ceftriaxone	10
	Vancomycin	2
	Piperacillin–Tazobactam	2
	Linezolid	2
Vomiting	Vancomycin	2
	Linezolid	1
Constipation	Meropenem	2
Skin Rash	Ceftriaxone	1
Itching	Piperacillin–Tazobactam	3

In the table no 4, it was found most ADRs were gastrointestinal, like diarrhoea, vomiting, and constipation, primarily caused by Ceftriaxone, Vancomycin, and Meropenem. Rash was also common with ceftriaxone.

- *Clinical Presentation and Physical Examination Findings in Pneumonia*

People with pneumonia usually experience general symptoms such as fever with chills, feeling tired, loss of appetite, and muscle aches. These are often more noticeable in viral pneumonia than in bacterial pneumonia. Some patients may also have confusion, stomach pain, chest pain, or other body-wide symptoms.

Lung-related symptoms include coughing, which may or may not produce mucus. In bacterial pneumonia, the mucus is often thick and sometimes blood-streaked, while in viral pneumonia, it is usually watery or slightly thick. Some patients may also feel chest pain due to inflammation of the lining around the lungs. Shortness of breath and a feeling of heaviness in the chest can also occur.

During a physical check-up, common signs include:

- Fast breathing (tachypnoea)
- Fast heartbeat (tachycardia)
- Fever, with or without chills
- Reduced or abnormal breath sounds
- Changes in voice sounds or vibrations over the lungs, suggesting lung tissue is filled (consolidation)
- Crackling sounds in the lungs when breathing
- Dullness when tapping on the chest

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IV. RESULTS

Out of the total hospital admissions observed during the study period, a group of patients was diagnosed with pneumonia and included in the pharmacovigilance assessment. The condition was more common in elderly individuals and children under five years of age.

Many patients had comorbid conditions such as asthma, COPD, hypertension, and diabetes, which increased the risk of adverse drug reactions (ADRs).

The most frequently prescribed antibiotics were Ceftriaxone, Amikacin, Piperacillin–Tazobactam, Linezolid, and Vancomycin, mostly administered through the intravenous route. Dosing patterns were generally within the recommended range, though minor dose adjustments were made in patients with kidney-related issues.

- *Observed ADRs:*

The most common ADRs reported were gastrointestinal disturbances (mainly diarrhoea and vomiting), followed by skin reactions like itching and rash. A few cases of constipation and mild nephrotoxicity were also noted. Most ADRs were mild and resolved with dose modification or discontinuation of the suspected drug. No serious or fatal reactions occurred.

Elderly patients were more prone to ADRs related to renal and gastrointestinal systems, while younger patients showed more allergic-type reactions. Polypharmacy and intravenous drug use were found to be key factors contributing to ADR occurrence.

V. DISCUSSION

This study highlights the importance of pharmacovigilance in improving drug safety among pneumonia patients. The findings show that antibiotic therapy, though essential for treatment, is often associated with adverse drug reactions, especially when broad-spectrum agents are used.

The results are in line with previously published studies that report gastrointestinal and skin-related ADRs as the most frequent outcomes during pneumonia therapy. Drugs such as Ceftriaxone and Piperacillin–Tazobactam have been commonly associated with diarrhoea, itching, and rashes in both national and international reports.

In elderly patients, the higher frequency of ADRs may be linked to polypharmacy and decreased drug clearance, while in children, hypersensitivity reactions are more frequent due to developing immune systems.

This emphasizes the need for careful dose monitoring, individualized antibiotic selection, and active ADR reporting by healthcare professionals. Strengthening hospital-based pharmacovigilance and linking it to national reporting systems such as the Pharmacovigilance Programme of India (PvPI) will enhance patient safety and promote rational drug use.

VI. CONCLUSION

This review shows that pneumonia treatment often requires the use of strong antibiotics, and because of this, many patients may experience some form of adverse drug reaction. Most of the reactions observed in our hospital study were mild and improved after adjusting the dose or changing the medicine. Elderly patients and those with other health problems were more likely to develop side effects, while children mainly showed allergy-type reactions.

Our findings highlight that careful selection of antibiotics, regular monitoring, and early reporting of any unusual symptoms can greatly improve patient safety. Pharmacovigilance plays an important role in identifying these reactions early and preventing them from becoming serious. By following proper prescribing guidelines and maintaining good reporting practices, healthcare workers can provide safer and more effective treatment for pneumonia patients.

Overall, this study supports the need for continuous monitoring and awareness of drug safety so that pneumonia can be treated effectively while keeping patients protected from avoidable side effects.

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