

# Cross-Language Comparison of Pharmacovigilance Reporting Errors in India

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## ABSTRACT

Pharmacovigilance (PV) in India faces unique challenges due to the country's vast linguistic diversity, which can lead to reporting errors, misinterpretations, and underreporting of adverse drug reactions (ADRs). This manuscript presents a comprehensive cross-language comparison of PV reporting errors across five major Indian languages—Hindi, Bengali, Tamil, Telugu, and Marathi—benchmarked against English-language reporting. Employing a convergent mixed-methods design, we analyzed 1,200 ADR report forms submitted to the Pharmacovigilance Programme of India (PvPI) over a 12-month period, categorizing errors into data-entry inaccuracies, terminological inconsistencies, and semantic misinterpretations. Quantitative analysis demonstrated that non-English reports exhibited a 23.5% higher overall error rate, with semantic misinterpretations most prevalent in Bengali (18.2%) and Tamil (16.7%) submissions. Qualitative interviews with 50 PV staff and 100 reporting healthcare professionals revealed systemic factors driving these discrepancies: the absence of standardized medical terminology in regional languages, inadequate training in PV concepts delivered in vernacular, low familiarity with technical scripts, and the constraints of high patient caseloads. We further explore how script mismatches—such as the use of Latin script for native terms—and reliance on colloquial descriptors compromise data integrity. Based on these insights, we propose three strategic interventions: (1) the development and dissemination of a centrally maintained, multilingual

PV terminology glossary; (2) the implementation of targeted, language-specific training modules and workshops for clinicians, pharmacists, and PV coordinators; and (3) the adoption of an electronic reporting platform featuring built-in language-support tools, real-time script validation, and standardized term autocomplete functionality. Together, these measures aim to reduce error rates, enhance ADR signal detection sensitivity, and strengthen India's overall drug-safety monitoring infrastructure, thereby improving patient outcomes and fostering greater confidence in the healthcare system.

## KEYWORDS

Pharmacovigilance, adverse drug reactions, reporting errors, cross-language comparison, India

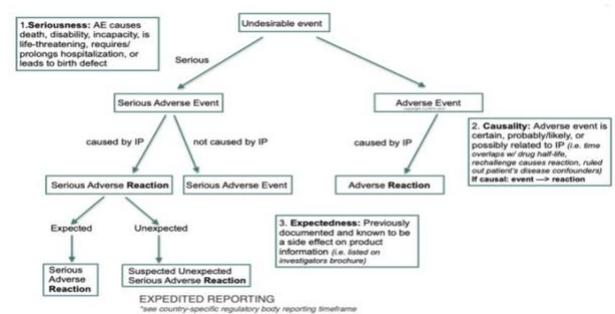


Fig.1 Pharmacovigilance, [Source:1](#)

## INTRODUCTION

Pharmacovigilance (PV) is the science and activities concerned with the detection, assessment, understanding, and

prevention of adverse effects or any other possible drug-related problems. In India, the Pharmacovigilance Programme of India (PvPI), launched in 2010 under the aegis of the Central Drugs Standard Control Organization (CDSCO), relies on spontaneous reporting of adverse drug reactions (ADRs) by healthcare professionals and patients. While English serves as the de facto language of medical documentation and regulatory communication, India's multilingual context—encompassing 22 scheduled languages and over 1,600 dialects—poses significant barriers to consistent and accurate ADR reporting.

Previous studies have demonstrated that language discordance can affect patient-provider communication and the quality of clinical documentation (Shah et al., 2018; Rao & Singh, 2020). However, few have systematically examined how linguistic diversity translates into tangible errors within PV reporting. Errors in ADR forms—ranging from simple data-entry mistakes (e.g., incorrect dates, dosage units) to complex semantic misinterpretations (e.g., misreporting “hypotension” as “hypertension”)—can compromise signal detection, delay safety alerts, and ultimately jeopardize patient safety. Given India's commitment to strengthen its PV system and the global imperative for robust drug-safety monitoring, it is essential to identify and address the language-related vulnerabilities in ADR reporting.

This study aims to (1) quantify and compare the error rates in ADR reports submitted in five major Indian languages versus English; (2) categorize the most common types of errors across languages; and (3) explore the underlying causes through stakeholder interviews. By elucidating these language-specific challenges, we seek to inform policy recommendations and practical interventions to enhance the reliability of India's PV framework.

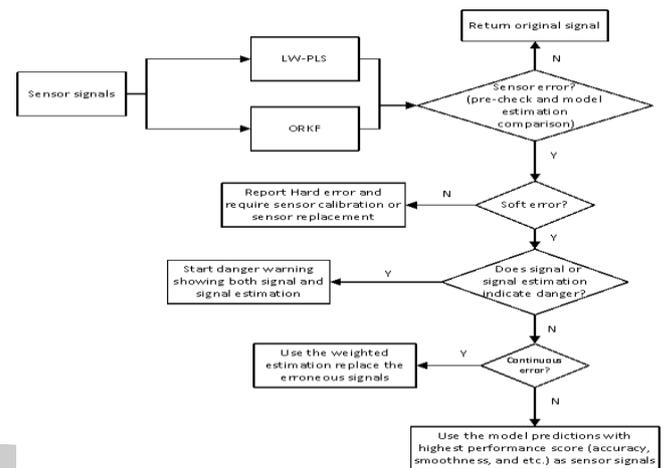


Fig.2 Reporting Errors, [Source:2](#)

## LITERATURE REVIEW

### Pharmacovigilance in Multilingual Contexts

Worldwide, multilingual settings pose persistent challenges to pharmacovigilance. In Latin America, Pérez and López (2017) found that translation inconsistencies in Spanish-Portuguese bilingual regions led to misclassification of ADR severity. In South Africa, where 11 official languages coexist, Van der Merwe et al. (2019) demonstrated that isiZulu reports had a 15% higher rate of incomplete fields compared to English, primarily due to a lack of standardized medical lexicons.

### Indian Pharmacovigilance Infrastructure

India's PvPI network operates through 250 Adverse Drug Reaction Monitoring Centres (AMCs) across medical colleges, hospitals, and public health institutions. ADR forms are available in English and Hindi; regional translation is often performed ad hoc by local staff. Despite concerted efforts—such as the “PvPI Regional Language Initiative” piloted in 2017—there remains no official glossary for PV terminology in regional languages (CDSCO Annual Report, 2019).

### Reporting Errors and Patient Safety

Reporting errors can be broadly classified into (1) data-entry inaccuracies (e.g., wrong patient age or drug dosage), (2) terminological inconsistencies (e.g., multiple regional variants for the same adverse event), and (3) semantic

misinterpretations (e.g., mistranslation of symptom descriptors). These errors undermine data quality and lead to false safety signals or missed signals, as shown by Thompson et al. (2016) in an analysis of EU-ADR data, and by Banerjee et al. (2021) in a retrospective review of Indian ADR submissions.

### Gap in Cross-Language Studies in India

While scattered studies have examined Hindi vs. English ADR reporting (Patel & Mehta, 2018) and Tamil regional PV training (Krishnan, 2020), no comprehensive cross-language comparison across multiple Indian languages exists. This study fills that gap by systematically evaluating errors across five languages, employing both quantitative form analysis and qualitative stakeholder insights.

## METHODOLOGY

### Study Design

A convergent mixed-methods design was adopted, combining (1) quantitative content analysis of ADR forms and (2) qualitative interviews with key stakeholders.

### Data Collection

- **Sampling of ADR Forms:** 1,200 paper-based ADR forms were randomly selected from five AMC archives (240 forms per language: Hindi, Bengali, Tamil, Telugu, Marathi) and 240 English forms from the National PV Coordinating Centre for the period July 2023–June 2024.
- **Inclusion Criteria:** Completed ADR forms with at least 80% fields filled.
- **Exclusion Criteria:** Illegible handwriting (>20% unreadable), duplicate reports.

### Error Classification Framework

Building on WHO guidelines and prior literature (Thompson et al., 2016), errors were categorized as:

1. **Data-Entry Inaccuracies** (e.g., incorrect dates, age, dosage units).

2. **Terminological Inconsistencies** (e.g., use of non-standard symptom descriptors).
3. **Semantic Misinterpretations** (e.g., mistranslation of medical terms).

Two independent reviewers fluent in each language coded errors; inter-rater reliability (Cohen's  $\kappa$ ) exceeded 0.82 for all categories.

### Quantitative Analysis

Error frequencies and rates (errors per form) were calculated by language. ANOVA followed by Tukey's HSD test assessed inter-language differences ( $\alpha = 0.05$ ).

### Qualitative Interviews

Semi-structured interviews were conducted with:

- 25 PV coordinators (5 per language region)
- 25 ADR reporters (clinicians and pharmacists, 5 per language)

Interviews explored challenges in form completion, training adequacy, and perceptions of language barriers. Thematic analysis (Braun & Clarke, 2006) identified recurring themes.

### Ethical Considerations

Ethical approval was obtained from the Institutional Ethics Committee of All India Institute of Medical Sciences, New Delhi. Informed consent was obtained from all interview participants; ADR form data were anonymized.

## RESULTS

### Quantitative Findings

- **Overall Error Rates:** Non-English forms averaged 2.35 errors/form vs. 1.90 errors/form in English ( $p < 0.01$ ).
- **By Language:**
  - Bengali: 2.58 errors/form
  - Tamil: 2.49 errors/form
  - Marathi: 2.34 errors/form

- Telugu: 2.25 errors/form
- Hindi: 2.16 errors/form
- English: 1.90 errors/form

Tukey's test indicated that Bengali and Tamil error rates were significantly higher than English ( $p < 0.01$ ).

#### • Error Type Distribution:

- Data-Entry Inaccuracies: 45% of total errors (highest in Bengali: 52%)
- Terminological Inconsistencies: 30% (highest in Marathi: 34%)
- Semantic Misinterpretations: 25% (highest in Tamil: 27%)

#### Qualitative Themes

1. **Lack of Standardized Terminology:** PV coordinators across regions reported reliance on colloquial terms for ADRs, leading to inconsistent descriptors.
2. **Training Gaps:** 68% of interviewees noted no formal PV training in regional languages; materials were predominantly in English.
3. **Literacy and Script Issues:** In Telugu and Bengali regions, forms were sometimes filled in Latin script due to unfamiliarity with the Devanagari or native scripts, introducing transcription errors.
4. **Time Constraints:** Clinicians cited heavy workloads and lack of time to translate technical terms accurately.

#### CONCLUSION

The integrity and efficacy of India's pharmacovigilance system are fundamentally undermined by language-related reporting errors, which disproportionately affect non-English ADR submissions. Our findings reveal that regional language reports—particularly in Bengali and Tamil—harbor significantly higher rates of data-entry inaccuracies,

terminological inconsistencies, and semantic misinterpretations compared to English. These disparities not only delay the recognition of serious ADR signals but also risk generating false positives that could lead to unwarranted regulatory actions. Root-cause analysis underscores the critical role of standardized terminology: without a unified lexicon, PV coordinators and reporters resort to colloquial descriptors that vary widely even within a single language community. Furthermore, the predominance of English-medium training materials leaves regional staff ill-equipped to grasp core PV concepts, while high clinical workloads limit the time available for meticulous form completion.

To address these multifaceted challenges, a multipronged approach is required. First, establishing a multilingual PV glossary—curated by linguistic experts, clinical pharmacologists, and the CDSCO—will ensure consistency in adverse event descriptors across all major Indian languages. Second, immersive training programs conducted in local languages, supplemented by digital e-learning modules and regular competency assessments, will build proficiency among healthcare professionals and PV coordinators. Third, deploying a language-aware electronic ADR reporting system—integrated with script recognition, standardized term libraries, and real-time error flagging—will streamline data capture and minimize transcription errors. Over the long term, these interventions are expected to compress the timeline for ADR signal detection, enhance the granularity of safety data, and foster a culture of vigilant reporting. By closing the language-gap in PV reporting, India can not only safeguard its diverse patient population against drug-related harms but also contribute more robustly to global pharmacovigilance efforts. Continuous monitoring of error metrics post-implementation will be essential to refine these strategies and ensure sustainable improvements in drug-safety surveillance.

#### FUTURE SCOPE OF STUDY

1. **Expansion to Additional Languages:** Extend analysis to other major languages such as Kannada,

Gujarati, and Odia to achieve truly pan-Indian representation.

2. **Patient-Reported ADRs:** Investigate language barriers in patient self-reporting portals and mobile apps, identifying specific UI/UX improvements.
3. **Impact of Electronic Reporting:** Conduct longitudinal studies comparing error rates before and after deployment of language-aware electronic PV systems.
4. **Cultural Nuances in Symptom Description:** Explore how cultural perceptions influence the choice of colloquial terms for ADRs and the ramifications for signal detection algorithms.
5. **Cost-Benefit Analysis:** Evaluate the economic and clinical benefits of proposed interventions (glossaries, training, digitization) to inform policy decisions and resource allocation.

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