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Global Inequalities in Pharmacovigilance: A Critical Review and Methodological Framework for Inclusive Pharmacoepidemiology

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Abstract:
Post-marketing drug safety surveillance relies overwhelmingly on data from high-income countries (HICs), creating a critical evidentiary blind spot for global health. Although low- and middle-income countries (LMICs) represent over 80% of the world's population, they contribute less than 1% of individual case safety reports to global databases such as WHO VigiBase. Current pharmacovigilance paradigms depend heavily on electronic health records, specialist clinician verification, and standardised diagnostic coding infrastructure rarely present in low-resource settings. Consequently, non-clinical harms, context-specific drug-drug interactions, and adverse events in underrepresented populations are routinely missed or dismissed as statistical noise. This paper critically reviews the structural, technical, and governance disparities inherent in modern post-marketing surveillance and introduces the Inclusive Pharmacoepidemiology Framework (IPF). The IPF re-engineers the evidence pipeline across seven core dimensions: incorporating non-traditional data sources (e.g., community health worker logs, mobile reporting), expanding outcomes to include socio-economic harms, applying socio-structurally disaggregated Bayesian signal detection, embedding participatory co-design, mandating reflexive data governance, establishing rapid reciprocal data feedback, and integrating reflexive data feedback, and integrating non-standard real-world evidence into regulatory decision making. By shifting from HIC-centric administrative expansion to methodological reorientation, the IPF transforms global drug safety surveillance into a proactive, equitable instrument for global health justice.

Keywords:
Pharmacoepidemiology, Pharmacovigilance, Global Health Equity, Signal Detection, VigiBase, Real-World Evidence, Health Disparities.

Key Points:

1. Global Asymmetry: Current pharmacovigilance is heavily biased toward high-income countries, with low-and middle-income countries contributing under 1% of safety reports despite bearing over 80% of the world population.
2. Methodological Limitation: Hyper-standardised clinical data pipelines filter out context-rich community observations and socio-economic harms critical in low-resource settings.
3. Systemic Solution: The Inclusive Pharmacoepidemiology Framework (IPF) reengineers the evidence pipeline from frontline data generation to regulatory action.
4. Technical Innovation: IPF incorporates non-traditional data (community health worker logs), disaggregated Bayesian signal detection, and multi-criteria decision-making.
5. Equity and Governance: IPF mandates reflexive governance and rapid reciprocal data sharing to ensure safety findings directly benefit originating LMIC communities.

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1. Introduction

1.1 Why Global Pharmacovigilance Matters

Pharmacovigilance and Pharmacoepidemiology serve as the critical final safeguards in the production of a pharmaceutical product, tasked with identifying, assessing, understanding and preventing adverse drug reactions (ADRs) and medicine-related problems once therapies transition from controlled clinical trials to general populations (1,15). In an increasingly interconnected global health landscape, post-marketing safety surveillance is essential not only for refining individual risk-benefit ratios but also for safeguarding public trust in health systems, directing regulatory action, and mitigating preventable morbidity and mortality worldwide (2,16).

The stakes of post-marketing surveillance are particularly high in low- and middle-income countries (LMICs), where disease burdens are often severe, health system infrastructure is stretched, and populations frequently encounter unique therapeutic challenges (3,17). These challenges include high rates of polypharmacy for co-occurring infectious and non-communicable diseases, varying nutritional profiles, genetic polymorphisms influencing drug metabolism, and widespread exposure to substandard or falsified medical products (18,19). Consequently, robust global pharmacovigilance is not an administrative luxury; it is an indispensable pillar of universal health coverage and global health security (4,6).

1.2 Systemic Inequities in Evidence Generation

Despite the universal necessity of drug safety monitoring, contemporary pharmacoepidemiology remains marked by profound geographic, structural, and methodological inequities (3,10). The institutional architecture of modern pharmacovigilance, formulated primarily in response to historical therapeutic disasters in Europe and North America, such as the thalidomide tragedy, was built around the assumptions and capacities of high-income health systems (2,15). Centralised surveillance infrastructures, such as the United States Food and Drug Administration (USFDA) Adverse Event Reporting System (FAERS) and the World Health Organisation (WHO) Uppsala Monitoring Centre (UMC) VigiBase, depend heavily on mature electronic health records (EHR) networks, high clinician-to-patient ratios, and standardised diagnostic taxonomies (7,10).

These conditions rarely reflect the healthcare delivery environments of LMICs (4,17). As a result, global safety databases exhibit stark structural asymmetries (10,11). Although LMICs represent more than 80% of the world's population and bear the vast majority of the global disease burden, their contribution to global individual case safety reports (ICSRs) remains negligible (3,10). According to recent analyses of VigiBase, high-income countries contribute over 81% of all ICSRs, whereas low-income countries account for approximately 0.2% to 0.5% of cumulative reports (10,11). When safety data from LMICs do enter global pipelines, they are frequently decontextualised, stripped of socio-structural variables, and evaluated against baseline parameters established in Northern populations (3,12). LMICs are thus relegated to data peripheries, frequently recruited as trial sites for transnational clinical trials, but routinely excluded from safety agenda-setting, methodological design, and global risk evaluation (3,14).

1.3 Why Methodological Reform is Needed

Standard approaches to resolving these disparities have historically relied on capacity-building initiatives that import Northern regulatory templates, technical standards (such as International Council for Harmonisation [ICH] guidelines), and standardised software platforms into LMIC settings (2,20). However, these technical fixes fail to address the core problem: current pharmacoepidemiologic methods themselves encode restrictive assumptions about what counts as valid scientific evidence and who possesses the authority to define therapeutic harm (3,12).

Current evidence hierarchies prioritise quantitative, hyper-standardised, clinician-verified reports while dismissing qualitative narratives, community-level observations, and non-clinical harms (e.g., loss of daily wages, caregiving disruptions, functional mobility impacts) as anecdotal or methodologically invalid statistical "noise" (1,8). This hyper-standardisation creates an evidentiary paradox: systems optimised for algorithmic causality in high-resource settings actively filter out the context-rich data necessary to detect safety signals in low-resource settings (3,8).

To build a truly globally representative drug safety ecosystem, pharmacoepidemiology requires more than administrative expansion or technical harmonisation; it demands a fundamental methodological

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reorientation (5,14). This paper presents the Inclusive Pharmacoepidemiology framework, a conceptual and practical toolkit designed to bridge global safety gaps by integrating participatory data design, intersectional risk stratification, narrative pharmacovigilance, and reflexive data governance into mainstream epidemiological practice (5,6).

2. Current Global Pharmacovigilance Systems

Modern post-marketing surveillance relies on a network of national and international databases designed to collect, process, and analyse Individual Case Safety Reports (ICSRs) (1,2). These systems vary significantly in structural architecture, technological maturity, and regulatory authority.

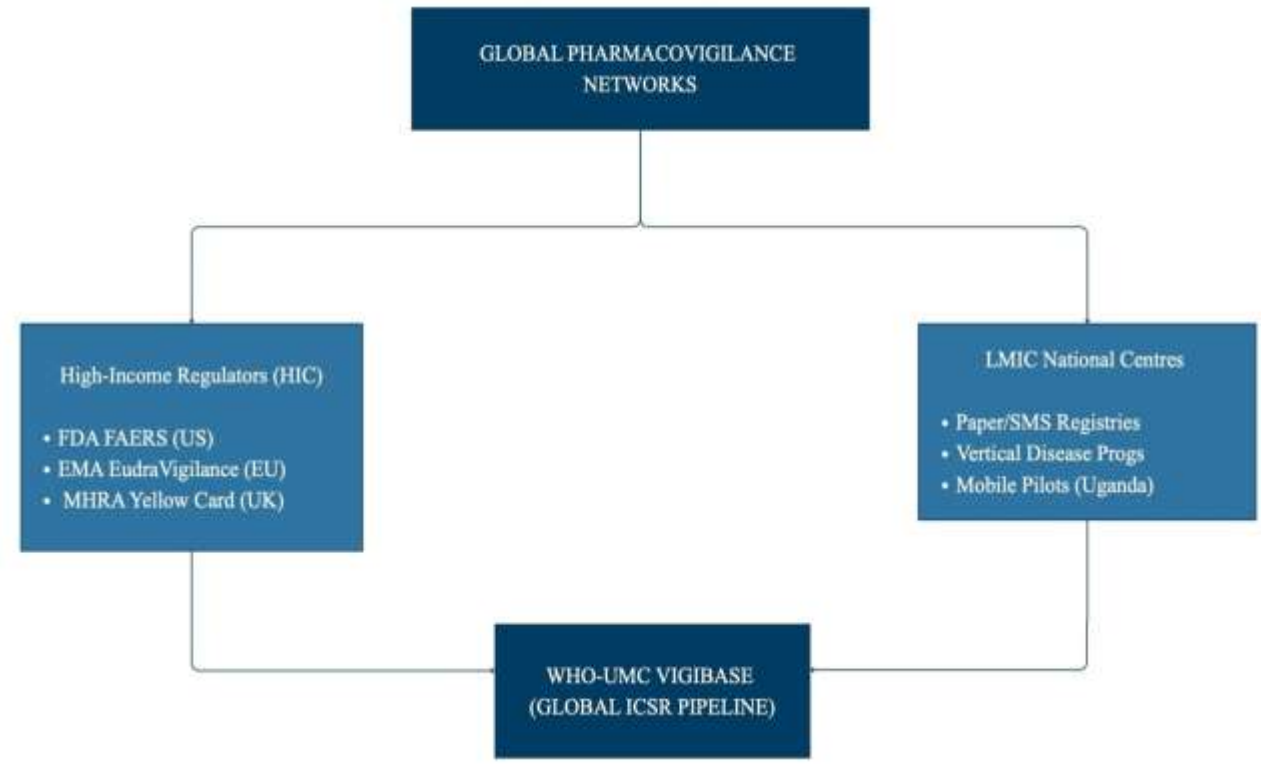

Figure 1: Structural architecture and data pipelines of Global Pharmacovigilance Networks. A schematic overview comparing post-marketing surveillance pathways in High-Income Countries (HICs) versus Low-and Middle-Income Countries (LMICs). High-income regulators utilise integrated electronic systems (e.g., FDA FAERS, EMA EudraVigilance, MHRA Yellow Card Scheme), whereas LMIC national centres rely predominantly on paper/SMS registries, vertical disease surveillance programs, and localised mobile plots. Both streams aggregate into WHO-UMC VigiBase, inheriting the structural and volume asymmetries of contributing national systems.

2.1 Centralised High-Income Regulatory Platforms

- FDA Adverse Event Reporting System (FAERS): Maintained by the U.S FDA, FAERS is one of the world's largest databases, containing tens of millions of reports (2,3). While technologically advanced and publicly searchable, its entry mechanisms rely heavily on clinician reports, pharmaceutical manufacturer submissions, and electronic health record (HER) integration (2,3).
- EudraVigilance: Operated by the European Medicines Agency (EMA), EudraVigilance enforces centralised ICSR processing across European Union member states under strict Good Pharmacovigilance Practices (GVP) Module VI standards (4,5). It relies on automated E2B gateway exchanges and standardised diagnostic taxonomies (4,5).
- MHRA Yellow Card Scheme: The UK Medicines and Healthcare products Regulatory Agency (MHRA) pioneered direct patient reporting through the Yellow Card system (6,7). Although it

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broadens patient input, its infrastructure assumes widespread digital literacy, high healthcare accessibility, and robust national health insurance coverage (6,7).

2.2 Global Consolidation: WHO VigiBase

Managed by the Uppsala Monitoring Centre (UMC), VigiBase acts as the international repository for the WHO programme for the International Drug Monitoring (PIDM), combining data from over 170 member states (1,8). Despite its global mandate, VigiBase operates as an aggregator rather than a primary collection tool, meaning its data quality and volume inherit the structural biases of contributing national pharmacovigilance centres (1,8).

2.3 LMIC Pharmacovigilance Infrastructure

Pharmacovigilance systems across low- and middle-income countries (LMICs) vary widely in operational capacity (9,10). Most national centres depend on paper-based spontaneous reporting or specialised surveillance embedded within vertical disease control programs (e.g., malaria, HIV, tuberculosis) (9,11). While digital and mobile reporting pilots, such as SMS-based community health worker tools in Sub-Saharan Africa, have demonstrated high diagnostic sensitivity, these decentralised streams frequently lack formal regulatory pathways for integration into national and international databases (10,12).

3. Evidence Describing Inequities In Pharmacovigilance

A synthesis of contemporary pharmacoepidemiologic literature reveals deep, systemic inequities across six core operational dimensions:

Geographic and Reporting Inequities

Empirical analyses of global safety databases highlight severe spatial bias (1,13). High- income countries account for over 80% of cumulative ICSRs in Vigibase, whereas low-income countries contribute between 0.2% and 0.5% (1,13). Sub-Saharan Africa, representing over 1.1 billion individuals, contributes less than 1% of the total global safety reports (13,14). Consequently, global disproportionality algorithms (e.g., Proportional Reporting Ratios, Information Component) detect safety signals almost exclusively from HIC clinical demographics (2,15).

Regulatory and Capacity Inequities

Under the WHO Global Benchmarking Tool (GBT), fewer than 10% of African national regulatory authorities (NRAs) have achieved Maturity Level 3 (Stable, well-functioning, and integrated regulatory systems) (16,17). Deficits in regulatory enforcement, limited laboratory capacity for drug quality testing, and chronic underfunding restrict the ability of LMIC regulators to act independently on localised safety signals (16,18).

Data Governance and Digital Infrastructure Gaps

Extraction of safety data from LMICs frequently occurs without reciprocal data sharing (19,20). Data are collected by international research consortia or donor agencies, transferred to Northern institutions, and published without returning actionable safety recommendations or therapeutic resources to local health systems (19,20). Furthermore, digital divides such as limited internet connectivity, lack of interoperable EHRs, and absence of localised MedDra translation interfaces further widen the reporting gap (10,12).

4. Critical Appraisal Of Existing Approaches

A critical appraisal of current strategies deployed to resolve global pharmacovigilance disparities demonstrates clear strengths, major operational limitations, and persistent structural gaps:

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Approach	What works	What doesn't	Remaining Gaps
Technical harmonisation (ICH E2B/E6) (4,5)	Standardises ICSR transmission; enables global data pooling across HIC databases (4,5)	Imposes rigid clinical coding that discards narrative, functional, and community-reported harms (10,21)	Fails to accommodate non-HER, low-resource, or community-based data streams (10,21).
Donor-Funded Vertical PV Pilots (9,11)	Successfully captures localised ADRs for specific therapies (e.g., antimalarials, ART) (9,11)	Fragmented; collapses when grant funding ends; creates parallel reporting structures (9,19)	Lacks long-term integration into routine national primary care surveillance (9,16).
Spontaneous Patient Reporting Platforms (6,7)	Empowers direct patient participation in high-resource settings (6,7)	Assumes high digital literacy and reliable internet access; underperforms in rural LMIC settings (6,10)	Does not capture structural barriers to care or functional/economic impacts (19,22).

Table 1: Critical Appraisal of Existing Approaches to Resolving Global Pharmacovigilance Disparities.
A comparative evaluation of contemporary strategies utilised to address global drug safety surveillance disparities. The table synthesizes the operational strengths, technical limitations and persistent structural gaps across three dominant paradigms: technical harmonisation (ICH standards), donor-funded vertical disease programs, and spontaneous patient reporting platforms. Despite localised successes, existing frameworks fail to accommodate decentralised, non-clinical, or community-based data streams essential for detecting safety signals in low-resource settings.

5. Existing Frameworks And Their Limitations

Several global health and regulatory bodies have introduced initiatives to enhance pharmacovigilance equity and real-world evidence (RWE) generation (4,116,23). However, an evaluation of these frameworks reveals critical boundaries:

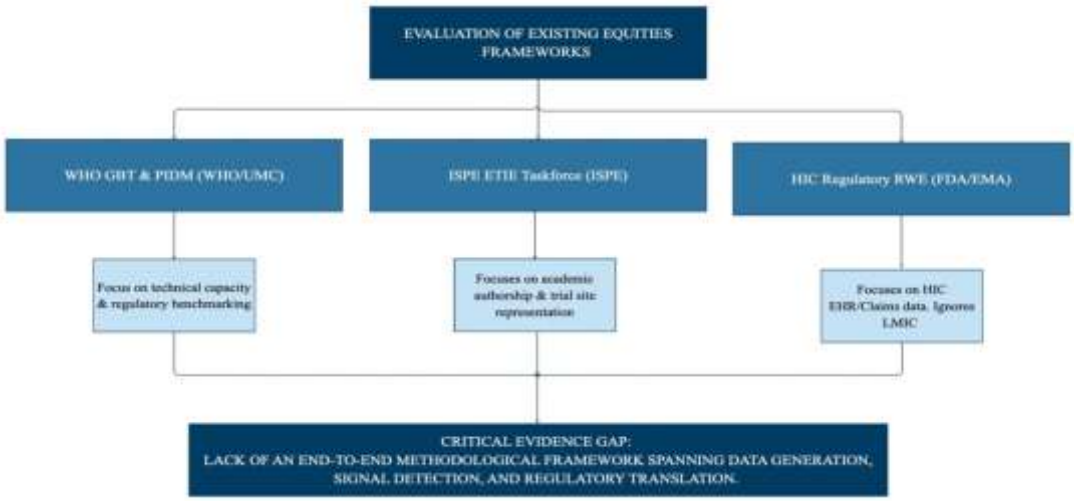

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Figure 2: Critical Evaluation and Evidence Gaps in Existing Equity Frameworks. Comparative mapping of current international initiatives addressing pharmacovigilance and real-world evidence (RWE). Existing approaches focus on administrative benchmarking (WHO GBT & PIDM), workforce and trial site representation (ISPE ETIE Taskforce), or HIC-centric electronic health record data pipelines (FDA/EMA RWE). A critical evidence gap remains due to the absence of an end-to-end methodological framework that bridges frontline data generation, disaggregated signal detection, and regulatory translation in low-resource settings.

- WHO Global Benchmarking Tool (GBT) & PIDM: Excellent for evaluating regulatory maturity and technical compliance but focuses primarily on administrative processes rather than reforming fundamental epidemiologic methods.
- ISPE Equity, Diversity, and Inclusion (ETIE) Initiatives: Strong focus on diversifying academic authorship, workforce inclusion, and clinical trial representation, but does not provide a formal mathematical or data-pipeline framework for post-marketing signal detection.
- FDA & EMA Real-World Evidence (RWE) Frameworks: Designed to incorporate observational registries and EHR claims data into regulatory decision-making. However, these frameworks assume a mature, digitised HIC healthcare infrastructure and do not translate to low-resource settings.

6. Proposed Inclusive Pharmacoepidemiology Framework (Ipf)

To resolve the systemic, pipeline-wide deficiencies identified in the literature, we introduce the Inclusive Pharmacoepidemiology Framework (IPF). Rather than operating as a passive equity checklist, the IPF re-engineers the entire drug-safety evidence pipeline, from data generation to regulatory translation.

6.1 The Inclusive Pharmacoepidemiology Framework (IPF):

1. Inclusive Data Sources: Community Health Workers, SMS/Digital Loggers, Retail/Informal Dispensers.
2. Context- Sensitive Outcome Definitions: Functional Impairment, loss of livelihood, Caregiver Burden, Psychosocial Harm.
3. Equity-aware signal detection: Disaggregated Bayesian Mining, Stratified PRR, Adjustment for Access Delays.
4. Community-Centred Pharmacovigilance: Participatory Co-Design, Pictorial ADR Cards, Local Health Worker Validation.
5. Reflexive Governance: Mandatory Positionality Statements, Power Audits, Structural Resource Sharing.
6. Reciprocal Data Sharing: Rapid Bidirectional Feedback, Community Action Alerts, Local Health System Support.
7. Implementation & Regulatory Translation: Multi-Criteria HTA Integration, Pragmatic RWE Pathways, Flexible ICSR Ingestion.

1. Inclusive Data Sources

Safety surveillance must expand beyond formal clinical encounters to include decentralised real-world data (RWD) streams. In LMIC contexts where clinical contact is sparse, incorporating frontline Community Health Worker (CHW) logs, mobile SMS reporting, and retail/informal pharmacy dispensing registries captures adverse events closer to the point of care, preventing early safety signals from being lost to clinical non-reporting.

2. Context-Sensitive Outcome Definitions

Current systems treat safety outcomes as narrow, binary clinical markers (e.g., safe/unsafe, severe/non-severe). The IPF broadens outcome criteria to encompass functional, economic, and relational harms. Indicators such as “inability to perform daily agricultural labour”, “prolonged

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fatigue impairing caregiving", or "treatment-induced economic disruption" are recognised as primary safety endpoints, capturing the true burden of pharmaceutical toxicity on marginalised populations.

3. **Equity-Aware Signal Detection**
   Standard disproportionality algorithms (PRR, ROR, IC) assume uniform reporting probabilities across populations. The IPF integrates equity-adjusted disproportionality mining. By disaggregating signal detection along socio-structural axes (gender, rurality, socioeconomic status, transport accessibility) and applying Bayesian stratification, algorithms can unmask localised safety signals that are otherwise diluted in aggregate global databases.

4. **Community-Centred Pharmacovigilance**
   Instead of treating patients as passive data subjects, the IPF embeds participatory research paradigms into pharmacovigilance. Reporting instruments such as pictorial ADR cards and localised open-text mobile interfaces are co-designed with local women's groups, CHWs and patient advocates. Frontline health workers validate and contextualise observations, ensuring high diagnostic accuracy and local relevance.

5. **Reflexive Governance**
   To dismantle colonial and extractive research hierarchies, the IPF mandates reflexive governance mechanisms. Principal investigators and regulatory sponsors must publish "Positionality and Power Statements" detailing research leadership, resource allocation, and data ownership structures, ensuring transparency and equitable credit across translational research consortia.

6. **Reciprocal Data Sharing**
   Data generation must be coupled with immediate, bidirectional information flow. Rather than extracting safety data solely for Northern registries, the IPF mandates that the analysed safety signals and actionable clinical guidance be returned rapidly to originating health facilities and community centres in accessible formats, directly supporting local patient care.

7. **Implementation and Regulatory Translation**
   The IPF creates structured translation pathways for non-standardised real-world evidence (RWE). Health Technology Assessment (HTA) bodies and national regulatory authorities (NRAs) adopt multi-criteria decision analysis (MCDA) frameworks that evaluate qualitative narratives, CHW reports, and disaggregated signal data alongside traditional clinical trials, informing context-sensitive drug labelling and local safety warnings.

6.2 Data Validation and Noise Reduction Protocols

A Primary challenge is integrating non-traditional data sources, such as Community Health Worker (CHW) digital logs, patient-reported mobile/SMS entries, and informal pharmacy dispensing notes, which can lead to unverified narratives, misclassifications, and high signal-to-noise ratios. To ensure regulatory-grade data integrity without sacrificing inclusivity, the Inclusive Pharmacoepidemiology Framework (IPF) incorporates a multi-tier data validation workflow prior to statistical signal deflection:

1. Automated Algorithmic Pre-filtering: Raw digital inputs undergo automated natural language processing (NLP) and rule-based validation to map lay descriptions of adverse events to standardised MedDRA (Medical Dictionary for Regulatory Activities) Preferred Terms (PTs), flagging incomplete or duplicate submissions(21).
2. Node-level Verification: Local clinical supervisors or trained CHW leads perform lightweight verification of flagged moderate-to-severe events, cross-referencing patient records or dispensing logs where available to confirm temporal sequence and drug exposure (24).
3. Quantitative Noise Mitigation: Disaggregated Bayesian signal detection models apply empirical Bayes shrinkage methods specifically calibrated for lower-density, noisy datasets. By adjusting background exposure frequencies and reporting probability thresholds by local health system type, the framework controls for false-positive inflation while preserving sensitivity for genuine localised signals (22).

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6.3 Real-World Case Study Vignette: Early Detection of Neurotoxicity in Artemisinin-Based Combination Therapy (ACT)

To illustrate the practical utility of the IPF over conventional passive surveillance, consider a rural district where a novel fixed-dose Artemisinin-Based Combination Therapy (ACT) is deployed for mass malaria administration (23).

Under standard pharmacovigilance, passive spontaneous reporting relies on clinical facility encounters. In this rural setting, patients experiencing transient vestibular toxicity or ataxia following treatment rarely present to regional tertiary hospitals due to high travel costs and informal care-seeking behaviours; thus, global safety databases register zero adverse drug reaction (ADR) signals over several years.

Under the IPF:

Data Generation: CHWs conducting routine post-treatment home visits record qualitative observations ("dizziness severe enough to prevent farm labour") via mobile SMS templates (24).

Disaggregated Signal Mining: Local Bayesian algorithms stratify safety signals by transport access and occupation, isolating a cluster of functional impairment reports among agricultural workers that would otherwise be obscured in aggregate national figures (25)(27).

Regulatory Action: The identified signal triggers rapid, targeted clinical follow-up, facilitating early development of dosage adjustment guidelines and safety warnings tailored to high-risk occupational groups, long before formal tertiary hospital reporting would have captured the pattern (24)(26).

Future Research aand Policy Translation

Quantitative Methodological Innovations

- Natural Language Processing (NLP) for Open-Text Narratives: Developing localized, multilingual NLP models capable of parsing unstructured, open-text patient narratives into MedDRA-mapped semantic categories without losing contextual nuance.
- Algorithmic Bias Audits: Establishing standard testing protocols to identify and correct for socioeconomic and geographic reporting biases in machine-learning signal detection tools.

Regulatory Policy Reforms

- Flexible ICSR Ingestion Standards: Re-engineering international data standards (such as ICH E2B) to allow optional contextual metadata fields (e.g., informal dispensing, economic impact indicators) without invalidating report transmission to VigiBase.
- Decentralized Regulatory Capacity: Transitioning donor funding toward direct, sustainable institutional support for LMIC National Regulatory Authorities through initiatives like the African Medicines Agency (AMA).

Conclusion

Pharmacoepidemiology can no longer operate under the assumption that its standard, HIC-centric methods are value-neutral or universally applicable. Traditional post-marketing surveillance structures systematically marginalize safety data from Low- and Middle-Income Countries, producing critical evidentiary blind spots that threaten global health equity.

By systematically reviewing the literature, this paper demonstrates that global safety disparities are rooted in the methods of data generation, signal detection, and regulatory governance. The **Inclusive Pharmacoepidemiology Framework (IPF)** offers a comprehensive, pipeline-wide solution. By integrating inclusive data sources, context-sensitive outcomes, equity-aware signal detection, participatory design, reflexive governance, reciprocal data sharing, and flexible regulatory translation, the IPF transforms pharmacovigilance from a technocratic regulatory requirement into a dynamic instrument for global health justice

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readability and clarity. The author reviewed, edited, and validated all the content, and assumes full responsibility for the integrity, accuracy, and scientific content of the final publication, and confirms that no AI tools were used for data analysis, raw literature synthesis, or theoretical concept generation.

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