The Impact of Adverse Drug Reactions:
The Need for Global Drug Safety Surveillance

Exploring the Importance of Pharmacovigilance with PrimeVigilance

The World Health Organization defines adverse drug reactions (ADRs) as unintended, harmful reactions to medicines. ADRs pose a significant challenge to global health systems and are a leading cause of death globally.[1]

Drug safety systems and robust ADR reporting are essential for understanding the impact of ADRs and identifying the additional health inequalities they reveal. This can lead to improvements such as increased diversity of clinical trials, better packaging, clearer packaging inserts, digital monitoring systems, increasingly accessible reporting structures, and more.

Indeed, the lack of robust pharmacovigilance in low- and middle-income countries creates its own health inequality.[2]

PrimeVigilance offers holistic, top-quality, cost-effective, innovative pharmacovigilance solutions to help pharmaceutical companies deliver safer and better patient outcomes. With a team of 1,500 pharmacovigilance professionals on three continents and an extensive network of local QPPVs spanning 160 countries, PrimeVigilance has the scale, capacity, and global footprint to meet all program needs.

1,500
pharmacovigilance professionals

160
countries with an extensive network of local QPPVs spanning

Below, we highlight the need for effective drug safety surveillance programs, including the link between ADRs and urgent hospitalizations, their economic impact, and their role in revealing health inequalities.

Section 1 — Adverse Drug Reactions: a Global Health Challenge Highlighting Health Inequalities

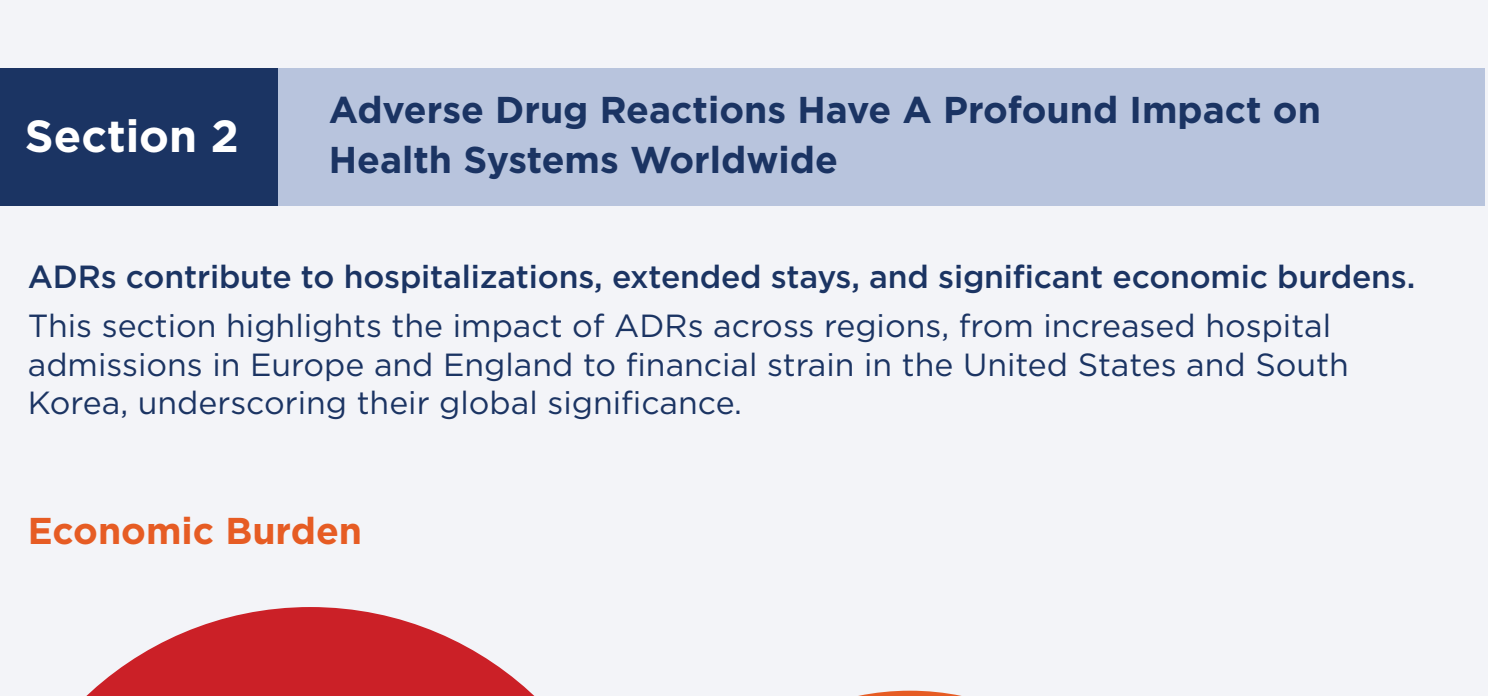
Adverse Drug Reactions (ADRs) pose a significant challenge to global health systems. They impact patient safety, increase hospital admissions, and place a substantial economic burden on healthcare providers worldwide. Understanding the incidence and severity of ADRs is crucial for improving drug safety programs and addressing health inequalities.

The Global Incidence of Adverse Drug Reactions (ADRs) Varies Significantly

However, reporting discrepancies also arise from differing national requirements and system effectiveness worldwide.[3]

Developed countries report more ADRs due to established drug safety programs.[3]

Low- and middle-income countries often face underreporting because they lack robust safety systems.[2]



ICSRs per million inhabitants
Individual case safety reports (ICSRs) received in VigiBase from 01-07-2017 to 30-06-2022 (average to compensate for year-to-year fluctuations), divided per million inhabitants (World Bank 2021)

Section 2 — Adverse Drug Reactions Have A Profound Impact on Health Systems Worldwide

ADRs contribute to hospitalizations, extended stays, and significant economic burdens.
This section highlights the impact of ADRs across regions, from increased hospital admissions in Europe and England to financial strain in the United States and South Korea, underscoring their global significance.

Economic Burden

Total societal cost: €79 billion per year[5] — European Union

ADRs may cost up to $30.1 billion annually[6] — United States

£380 million is the estimated annual cost to the NHS[4] — England

England

Hospital Impact

ADRs account for 4 out of every 100 hospital bed days[4]

This is equivalent to operating 15–20 hospitals with 400 beds each solely for ADR patients[4]

European Union

Health Impact

5% of all hospital admissions are due to ADRs[5]

5th most common cause of hospital deaths by ADRs[5]

approximately 197,000 deaths annually[5]

United States

Healthcare Strain

Increased hospitalization and prolonged hospital stay

Additional clinical investigations in severe cases[6]

Prescription Cascades

New medications prescribed to address ADRs caused by other drugs are often unrecognized[6]

Australia

Hospitalization Effects

ADRs lead to increased length of hospital stays[7]

Associated with higher risks of readmission and in-hospital mortality

South Korea

Financial Impact

ADRs increase the burden on health insurance systems[8]

This leads to higher out-of-pocket costs for patients due to hospitalization expenses.

Section 3 — ADR Reporting Reveals Significant Health Inequalities

Adverse Drug Reactions (ADRs) can disproportionately affect specific populations, highlighting significant health inequalities.
This section explores how ethnicity, gender, age, and socio-economic status influence the likelihood and severity of ADRs. Understanding these disparities is essential for improving drug safety and addressing health inequities.

Ethnicity

Black Patients

x3 more likely to experience angioedema from ACE inhibitors[9]

x1.5 higher risk of intracranial hemorrhage with thrombolytic therapy

East Asian Patients

x2.7 higher risk of cough from ACE inhibitors compared to white patients[9]

Gender

Women

Nearly 2x as likely to suffer an ADR as men[11]

Females 20.6 ADRs vs Males 12.9 ADRs per 10,000 patient-months

Socio-Economic Status & Pediatrics

Latino Children

Experience higher rates of adverse events (AEs) in hospitals.

Latino Children 30.1 AEs vs Non-Latino White children 16.9 AEs per 1,000 patient days[10]

Insurance Disparities

Publicly insured children have **higher rates of preventable AEs** compared to privately insured children.

Public 12.1 AEs vs Private 8.5 AEs per 1,000 patient days; P = .02

Elderly Populations

Community Settings

Ireland

78% of people over 70 experienced at least one adverse drug event over six months[12]

Hospital Admissions

Netherlands

24% of patients over 70 were admitted due to ADRs

Italy

6% of patients over 65 admitted due to ADRs

Residential Care

Massachusetts, USA

14% of long-term care residents experienced ADRs over a year

Conclusion

Effective drug safety systems and robust ADR reporting are essential for identifying and addressing health inequalities. ADR data reveals disparities based on ethnicity, socioeconomic status, gender, and age. By enhancing reporting mechanisms and focusing on diverse populations, healthcare systems can develop targeted interventions to reduce ADRs. Strengthening global pharmacovigilance efforts can improve patient outcomes and alleviate the economic burden on health systems.

Partner with PrimeVigilance for their expertise in establishing global drug safety surveillance programs that address the nuances across Asia-Pacific, Africa, and Latin America.

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Sources

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