The Burden of Adverse Drug Reactions: Challenges and Opportunities

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Background:

Health systems aim to reduce the costs that are directly triggered by adverse drug reactions (ADRs). We elaborate on the quantifiable and unquantifiable costs of ADRs for marketing authorisation holder (MAH), regulators, academia, patients, and health systems.

Methods:

Literature search and landscape analysis.

Results:

→ Safety concerns remain the main reason for drug attrition in early phases prior to marketing authorization application (MAA), causing high costs for drug development (1)

→ Estimates show an ADR prevalence of **5.1%** (2), **6.5%** (3), and **6.5%** (4)

→ Data suggests that hospital admissions due to ADRs cost the National Health System in the UK up to **£466 million** (€706M, $847M) per year (3)

→ As much as **72 %** of all ADRs were classified as either definitely or possibly avoidable (3)

The burden for patients, regulatory workload, additional pharmacovigilance activities, research setback, as well as the consequence on availability and affordability were not quantifiable.

Discussion:

Utilization of innovative approaches in the field of drug response prediction and prevention:

- **Real-world evidence** (5)
- **OMICS** (6)
- **Artificial Intelligence** (7)

MAH:	→ develop and produce safe and effective medications → monitor drug safety of medications on the market	**High costs for drug development, pharmacovigilance activities**
Regulators:	→ approve and withdraw medications → ensure positive benefit-risk ratio of drugs	**Regulatory workload**
Academia:	→ advance knowledge, understanding in various fields → research, teaching, collaboration	**Research setback**
Patients:	→ receive safe and effective medications	**Impairment, decreased well-being**
Health Systems:	→ promote and protect public health and well-being → ensure access to quality healthcare services	**Costs for treatments of ADRs, less availability and affordability**

Conclusion:

Reducing the impact of ADR is of societal interest. Addressing this challenge demands collaborative efforts among key stakeholders, including marketing authorization holders (MAHs), regulators, academia, patients and health systems. Investment in research and technological innovation will be needed to achieve improvements.

Acknowledgement:

I (Amélie) would like to express my heartfelt gratitude to my academic mentors at the University of Freiburg, Prof. Andreas Bechthold, Prof. Stefan Günther for their unwavering support and insightful guidance. I also would like to sincerely thank Dr. Anja Langeneckert, who has played a pivotal role in the completion of this research poster.

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