SORT IT
Improving health systems through research

May 2022

A Wake-Up Call to Improve Country-Wide Reporting of Adverse Drug Reactions in Sierra Leone [1]

[1] Thomas, F.; Abiri, O.T.; Komeh, J.P.; Conteh, T.A.; Bah, A.J.; Kanu, J.S.; Terry, R.; Abrahamyan, A.; Thekkur, P.; Zachariah, R. Inconsistent Country-Wide Reporting of Adverse Drug Reactions to Antimicrobials in Sierra Leone (2017–2021): A Wake-Up Call to Improve Reporting. Int. J. Environ. Res. Public Health 2022, 19, 3264. https://doi.org/10.3390/ijerph19063264

e-mail: fthomas@pharmacyboard.gov.sl

An adverse drug reaction (ADR) is defined as "any response to a drug which is noxious and unintended that occurs at doses normally used in human beings for prophylaxis, diagnosis, therapy of disease, or for the modification of physiological functions

Key Messages

- This first country-wide assessment of the Adverse Drug Reporting (ADR) in Sierra Leone shows inconsistent reporting, with delays and incomplete data. This implies that ADRs are being underreported which can compromise clinical care and drug safety.
- 90% of all reports were from active reporting from mass drug administration campaigns, while 10% came from voluntary (passive) reporting from health facilities.
- This is a wake-up call for improving monitoring by introducing compulsory (active) reporting and setting performance targets for completeness and timeliness of ADR data as part of national pharmacovigilance guidelines.

What is the problem and why is it important?

The World Health Organization (WHO) advocates for vigilant monitoring of adverse drug reactions (ADRs) to antimicrobials as they can cause life-threatening illness, permanent disabilities, and death.

Since 2007, Sierra Leone established a national database for monitoring ADRs (VigiFlow). However, there is insufficient insight into the quality of these data and 'what works and what needs to be improved. This compromises data utility in terms of clinical practice, drug safety and setting up drug regulation systems.

How did we measure it?

We assessed countrywide ADR reporting on antimicrobials using individual case safety reports (ICSRs) entered into VigiFlow during 2017–2021.

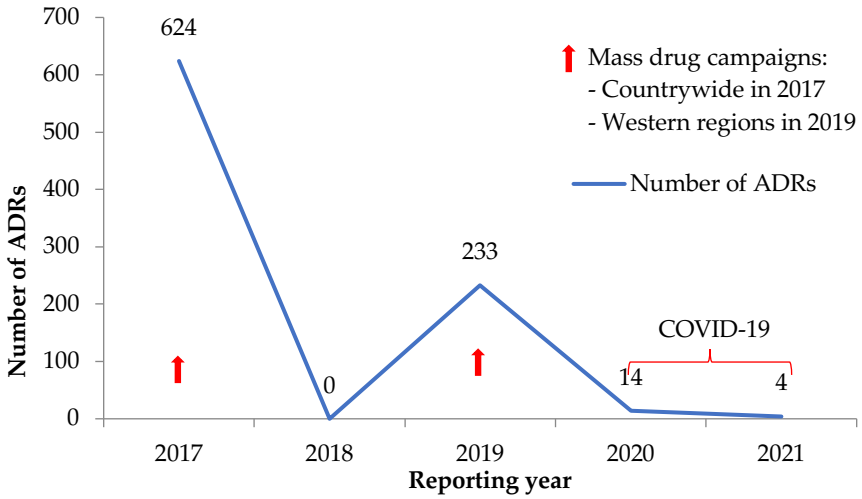
VigiFlow is a country-level pharmacovigilance database established by WHO.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

Data was incomplete, with 57% of reports having variables not filled.

What did we find?

- Of 566 ICSRs, inconsistent reporting was seen, with peaks in 2017 and 2019 (mass drug campaigns for deworming), zero reporting in 2018 (reasons unknown), and only a handful in 2020 and 2021 (since COVID-19).



- 90% of all reports were from active reporting from mass drug administration campaigns, while 10% came from voluntary (passive) reporting from health facilities.
- There were reporting delays, with 90% of reports taking over 30 days to be entered into VigiFlow (maximum threshold = 30 days).
- Data was incomplete, with 57% of reports having variables not filled.
- Final patient outcomes in 36% of reports were not available.

Implications

- This first country-wide study from Sierra Leone shows inconsistent reporting with delays and incomplete data that can be improved.

- Possible ways forwards to improve monitoring include:

1. Introduction of active compulsory ADR reporting at all health facilities.
2. Enforcing performance targets for monitoring, including:
   - Serious ADRs are reported within 7 days and other ADRs within 30 days.
   - All key variables to be filling in ADR forms.
3. Optimizing the use of the already existing online electronic ADR reporting system using mobile phones and/or computers.

- Improved monitoring and reporting of ADR data will have major benefits for the clinical management of patients, which in turn could prevent life-threatening illness, permanent disabilities, and death.