



Community-Embedded Pharmacovigilance: An Evaluation of Adverse Drug Reaction Reporting in Khayelitsha, South Africa

Thandiwe Ndlovu¹, Lungile Botha^{2,3}, Nokwanda Mkhize^{3,4}, Pieter van der Merwe^{4,5}

¹ SA Medical Research Council (SAMRC)

² Department of Internal Medicine, North-West University

³ Agricultural Research Council (ARC)

⁴ University of the Witwatersrand

⁵ Department of Clinical Research, Agricultural Research Council (ARC)

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Correspondence: tndlovu@outlook.com

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Author notes

Thandiwe Ndlovu is affiliated with SA Medical Research Council (SAMRC) and focuses on Medicine research in Africa.

Lungile Botha is affiliated with Department of Internal Medicine, North-West University and focuses on Medicine research in Africa.

Nokwanda Mkhize is affiliated with University of the Witwatersrand and focuses on Medicine research in Africa.

Pieter van der Merwe is affiliated with University of the Witwatersrand and focuses on Medicine research in Africa.

Abstract

Pharmacovigilance systems in low-resource settings frequently experience under-reporting of adverse drug reactions (ADRs), especially from community level. South Africa's public health system lacks formal mechanisms for community-based ADR surveillance, creating a gap in post-marketing drug safety data. This study evaluated the implementation and initial outcomes of a pilot community-embedded pharmacovigilance system in Khayelitsha, South Africa. Its objectives were to assess the system's feasibility, describe the characteristics of ADRs reported, and identify barriers and facilitators to community-level reporting. A mixed-methods, observational study was conducted. Quantitative data from ADR reports were analysed descriptively. Qualitative data were gathered through focus group discussions with community health workers and semi-structured interviews with clinic nurses and participating community members, followed by thematic analysis. During the study, 147 ADR reports were submitted, representing a substantial increase compared to routine passive surveillance in the preceding period. Antiretroviral and anti-tuberculosis drugs accounted for 68% of reported ADRs. Trust in community health workers and simplified reporting tools were key facilitators. Systemic delays in feedback and a perceived lack of action were major demotivators for reporters. The community-embedded model proved feasible and markedly improved ADR reporting rates in a high-burden, resource-constrained setting. It successfully engaged the community in medicine safety monitoring. Integrate community-embedded pharmacovigilance into national health policy. Strengthen feedback mechanisms to reporters to sustain engagement. Expand the model to include other medicine classes and replicate it in similar settings. pharmacovigilance, adverse drug reaction reporting, community health workers, South Africa, community engagement This study provides evidence for a practical model to strengthen pharmacovigilance in resource-constrained communities, highlighting the critical role of community health workers in bridging the reporting gap.

Keywords: *pharmacovigilance, adverse drug reaction reporting, community health workers, South Africa, health systems evaluation, under-reporting, low-resource settings*

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