

# Assessment of the vaccine safety monitoring systems within the national immunization programs in Ethiopia, Kenya, Rwanda, and Tanzania

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## Conclusions

The immunization programs in Ethiopia, Kenya, Rwanda and Tanzania have started to integrated vaccine safety monitoring. Underreporting AEFIs is a challenge within the immunization programs in all four countries. A specific budget for pharmacovigilance activities, functional collaboration between the immunization programs and the respective pharmacovigilance centres, mechanisms to disseminate pharmacovigilance information and standard operating procedures for risk management and communication should be in place for appropriate safety monitoring of vaccines in the four countries.

## Introduction

Immunization is effective for preventing infectious diseases to improve public health. In the last decade, there has been considerable progress in developing new vaccines and expanding use of existing vaccines, therefore there is a need to monitor the safety and occurrence of adverse events following immunizations (AEFIs). In Africa, safety monitoring of vaccines is not given much prominence due to limited resources.

## Results

- All the four immunization programs included pharmacovigilance activities in their strategic plans.
- 61, 9, 3 and 0 AEFIs were submitted to VigiBase by Kenya, Tanzania, Ethiopia and Rwanda respectively in 2017/2018.
- There was no/limited functional collaboration between the four immunization programs and their respective national pharmacovigilance centre (National Medicines Regulatory Authorities).

## Aim

To assess the pharmacovigilance systems for AEFI monitoring within the respective national immunization programs in Ethiopia, Kenya, Rwanda and Tanzania, Rwanda, thereby identifying the limitations/gaps for targeted interventions to further strengthen vaccine safety monitoring within the immunization programs in the four countries.

## Method

Staff of the national immunization programs were interviewed using the East African Community Harmonized Pharmacovigilance Indicators tool for Public Health Programmes in 2018. Data on four components of safety monitoring were collected and data was analyzed.



Fig.1 AEFI surveillance cycle

Source: <https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/health-professionals-info/aefi>

Country	Systems, Structures, and Stakeholder Coordination				Signal Generation and Data Management		Risk Assessment and Evaluation		Risk Management and Communication	
	PV activities included within the strategic/operational plans and treatment guidelines	Mechanism to disseminate PV information	Budget for PV	Website	Training That Included PV Sensitization	Use the national AEFI reporting form	Number of AEFIs submitted to VigiBase in 2018	Collaboration between NIP and NMRA	Existence of a program-related newsletter that features vaccine safety information	Average time lag between identification of safety signal and communication to health care workers and the public
Ethiopia	✓	X	X	X	✓	✓	3	Limited functional collaboration	X	Unknown
Kenya	✓	✓	X	X	✓	✓	61	Limited functional collaboration	X	Unknown
Rwanda	✓	✓	✓	X	✓	X	0	No functional collaboration	X	Unknown
Tanzania	✓	X	X	X	✓	X	9	No functional collaboration	X	Unknown

✓ = present; X = missing/ not available

AEFI Adverse event following immunization, NIP National Immunization Programme, NMRA National Medicines Regulatory Authority, PV Pharmacovigilance



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