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REVIEW ARTICLE

PHARMACOVIGILANCE AND REGULATORY ACTION IN EAST AFRICA WITH A FOCUS ON TANZANIA: A SCOPING REVIEW

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Abstract

Background: Pharmacovigilance (PV) detects, assesses and prevents adverse drug reactions (ADRs) and other medicine-related problems. East African countries have built national PV systems, but underreporting and the weak visibility of links between safety information and regulatory decisions persist.
Objectives: To map evidence on PV systems and regulatory action in East Africa with emphasis on Tanzania; to quantify key PV outcomes among health professionals; to identify factors associated with ADR reporting; and to describe how safety information is translated into regulatory action.
Methods: Rapid scoping review following the Arksey and O'Malley framework, Joanna Briggs Institute guidance and PRISMA-ScR reporting, with a conditional quantitative synthesis. Targeted searches of web-indexed biomedical literature, repositories and regulatory and media sources were run in October 2026.
Results: Twenty-five sources were charted: 17 research sources (Tanzania, Uganda, Kenya, Ethiopia, Rwanda and two multi-country studies) and eight regulatory, programme and media reports. In 2017/18, spontaneous reporting was 4.1 reports per million inhabitants in mainland Tanzania, 6.7 in Ethiopia and 35.0 in Kenya, and no more than 1% of facilities submitted reports. Nine surveys of health professionals (n=3,091) gave a pooled ADR-reporting proportion of 30.3% (95% CI 19.1–44.4%; I^2=97.9%; 95% prediction interval 4.3–81.0%).
Conclusions: PV structures have advanced and reporting can be raised sharply by training and stimulated reporting, but low and uneven reporting, training gaps and limited visibility of locally triggered regulatory action constrain medicine safety.
Keywords: adverse drug reaction, East Africa, medicine safety, meta-analysis, pharmacovigilance, regulatory action, Tanzania.

INTRODUCTION

Medicines are authorized on the basis of trials that are limited in size, duration and population diversity. Rare, delayed and population-specific harms therefore often emerge only in routine use, which is why pharmacovigilance, defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem, is central to patient safety[1].

Access to medicines in Africa has improved through global health initiatives and national commitments to HIV, tuberculosis and neglected tropical disease programmes, but this expansion has not been matched by regulators' capacity to monitor safety[1]. In East Africa, policy and legal frameworks for PV now exist, although capacity and performance differ between countries[1]. Tanzania was the first of four East African countries assessed in a regional comparison to join the WHO Programme for International Drug Monitoring, in 1993, followed by Ethiopia (2008), Kenya (2010) and Rwanda (2013)[1]. Uganda established its national PV centre in 2005 and joined the programme in 2007[2]. Tanzania's regulator, formerly the Tanzania Food and Drugs Authority and now the Tanzania Medicines and Medical Devices Authority (TMDA), was reported to have reached WHO Global Benchmarking Tool Maturity Level 3 in 2018, an assessment that examined regulatory structures and functions rather than the volume of reports from facilities[1].

Studies from the region describe limited awareness of national reporting channels, lack of training, unavailable forms, time pressure and uncertainty about what to report[3-5]. A second question is whether PV outputs lead to action: do signals and case reports translate into label changes, safety communications, restrictions, recalls or withdrawals? Evidence on this

step is scattered across journals, regulatory documents and media reports, and has not been brought together for the region. A scoping review suits this question because the evidence is heterogeneous (surveys, system assessments, intervention evaluations, qualitative work, regulatory sources) and the aim is to map what is known and what is missing[6,7]. We nested a conditional quantitative synthesis within the review to estimate the magnitude of key PV indicators, namely reporting, awareness, training and knowledge, and their associations, where published data allowed.

The review addressed four questions. The first (RQ1) asked what evidence exists on the structure, functioning and performance of PV systems and on regulatory action in East Africa, particularly Tanzania. The second (RQ2) asked about the magnitude of key PV outcomes among health professionals, namely awareness, training, knowledge and ADR reporting. The third (RQ3) examined which factors are associated with ADR reporting and PV practice, and the fourth (RQ4) asked how PV evidence is translated into regulatory action.

METHODS

Design and reporting

The review followed the Arksey and O'Malley framework as refined by Levac and colleagues and by the Joanna Briggs Institute (JBI)[6-8], and is reported according to PRISMA-ScR[9]. Because the search was targeted rather than an exhaustive multi-database search, the review is best described as a rapid scoping review. The quantitative synthesis was specified as conditional: where sufficient methodological and clinical homogeneity existed, data were pooled by random-effects meta-analysis; otherwise findings were synthesized descriptively. No protocol was registered.

Eligibility criteria (Population–Concept–Context)

Eligibility was defined using the Population–Concept–Context framework. The population comprised health professionals (including community pharmacy staff), patients, PV and regulatory staff, and national PV systems as units of analysis. The concept covered PV system structure and performance; ADR reporting; PV knowledge, awareness, practice and training; determinants and barriers; signal detection. The context was East African countries, namely Tanzania, Kenya, Uganda, Rwanda and Ethiopia, and multi-country sources were included where country-specific data were extractable. Eligible sources were primary research (quantitative, qualitative or mixed methods), system assessments, intervention evaluations, preprints, theses, conference abstracts, regulator bulletins, and official or media reports of regulatory actions. Excluded were sources without an East African component, opinion pieces without data, veterinary PV, a withdrawn conference abstract, and duplicate reports of the same dataset.

Search strategy

Searches were run between 7 and 14 October 2026 using a web search interface that indexes biomedical literature (including PubMed Central), journal sites, institutional repositories and news sources. Targeted queries combined PV terms, ADR reporting, health-professional and country terms, for example "pharmacovigilance Tanzania healthcare professionals knowledge attitude practice adverse drug reaction reporting" and "Kenya healthcare workers adverse drug reaction reporting knowledge practice", together with queries on regulators (TMDA, PPB, NDA, Rwanda FDA), recalls and safety alerts, and on the named studies encountered (Appendix A). Full texts, abstract pages or regulator documents were retrieved for all included sources, with the exception noted in section 2.4. Reference lists of the regional assessment and an Ethiopian systematic review were used to identify further studies. Searches of Scopus, Web of Science, Embase, CINAHL, African Journals Online and African Index Medicus were not run, and several PubMed Central full texts could not be opened; this is acknowledged as a limitation.

Selection and data charting

Sources were screened on title and abstract and then full text against the criteria above. For each source we charted country, design, setting, population, sample size, PV domains and quantitative data (numerator, denominator, percentage, effect estimates with 95% confidence intervals). Where a source reported a percentage and a sample size but no numerator, the numerator was derived and flagged. No values were estimated where data were not reported. Denominators were checked against full-text tables where available; one reported percentage (Rwandan notification forms) was found to refer to a subset and was recalculated against the whole sample. One source (a conference abstract from Gondar, Ethiopia) had internally inconsistent confidence intervals, which were not used; only its counts were charted. Because the search was targeted, the numbers of records identified and screened were not tracked in a way that supports a complete PRISMA-ScR flow diagram, and none is presented.

Synthesis

Descriptive mapping covered PV system components (law and regulation, structures, reporting tools, training, signal detection, communication and regulatory decision-making). Four proportion outcomes were pooled where at least three studies reported a comparable measure: ADR reporting by health professionals, awareness of the national reporting system or centre, receipt of PV or ADR-reporting training, and good or adequate PV knowledge as defined by each study. Study-level proportions were pooled with DerSimonian–Laird random-effects models on the logit scale, with I^2, τ^2 and Cochran's Q for heterogeneity and a 95% prediction interval for outcomes with at least three studies. For ADR reporting we also ran leave-one-out analyses, a sensitivity analysis restricted to peer-reviewed articles, and a sensitivity analysis substituting an alternative Rwandan outcome definition. Subgroup analyses compared Tanzanian with other studies and compared countries, using between-subgroup Q tests. For three exposure–outcome pairs measured in two studies each (training, knowledge, and awareness of where to report, each against reporting), odds ratios were

converted to the log scale, standard errors were recovered from 95% confidence intervals, and two-study random-effects pooled odds ratios were calculated, to be read as exploratory. Where a study reported the odds of poor practice for lack of an exposure, the reciprocal exposure–outcome contrast (odds of good practice for presence of the exposure) has the same odds ratio and was used. Funnel-plot asymmetry tests were not performed because fewer than 10 studies contributed to any outcome; the funnel plot is shown for visual inspection only. Regulatory-action data were tabulated, counted by signal source and issue type, and analyzed descriptively. Calculations were done in Python (SciPy).

RESULTS

Sources charted

Twenty-five sources were charted: 17 research sources and eight regulatory, programme and media reports. Of the research sources, 14 were peer-reviewed articles or assessments, and three were not peer reviewed (one master's dissertation, one conference abstract and one preprint). Seven research sources were from Tanzania only, three from Ethiopia, two each from Uganda and Kenya, one from Rwanda, and two covered several countries. Designs were predominantly cross-sectional and facility-based, with one qualitative study, one quasi-experimental evaluation, one training programme evaluation and one regulator-level system assessment. The eight regulatory, programme and media reports are described in sections 3.6 and 3.7.

Among the research sources, a cross-sectional comparative assessment of national PV systems in Ethiopia, Kenya, Rwanda and Tanzania (July–December 2018) examined system structures, report volumes and regulatory actions[1]. In Uganda, a survey of 1,345 health professionals in public and private facilities examined recognition and reporting of ADRs[2], and a cross-sectional survey at Mulago National Referral Hospital (January–March 2010) examined ADR reporting and associated factors[3]. The Tanzanian sources comprised a cross-sectional survey of 63 HIV-service providers at Kilimanjaro Christian Medical Centre (June–July 2016) on antiretroviral ADR reporting and training[4]; qualitative interviews with providers in zonal and regional referral hospitals in 2022[5]; a survey of 792 patients at Mbeya Zonal Referral Hospital (January–August 2022) on awareness and actions[10]; a quasi-experimental evaluation of structured stimulated reporting in seven tertiary hospitals, comparing the 18 months before and after its introduction[11]; a multicentre cross-sectional survey of 380 professionals in five regions (2021) on knowledge, attitudes and practice relating to herbal-medicine PV[12]; a cross-sectional survey of 169 facilities and 192 professionals on private-sector PV participation (December 2017–June 2018; preprint); and a cross-sectional survey of 330 workers at regional referral hospitals in Dar es Salaam (master's dissertation, 2020). The PAVIA blended e-learning PV programme, with 827 registered and 421 completing learners and an analysis of case reports, covered Tanzania, Eswatini, Nigeria and Ethiopia[13]. In Kenya, a survey of 215 providers in four hospitals in Kirinyaga County examined ADR reporting to the Pharmacy and Poisons Board and its determinants, and a survey of retail chemists in Nairobi County (May–June 2018) examined determinants of reporting[14]. In Ethiopia, cross-sectional surveys covered 307 professionals at Ayder hospital, Tigray (January–March 2019)[15], 295 professionals at Hiwot Fana hospital, Harar (February–March 2015)[16], and 215 community pharmacy professionals in Gondar (June–August 2021; conference abstract). In Rwanda, a survey of 147 nurses and midwives at a teaching hospital in Kigali (April–June 2020) examined awareness and practice[17].

PV systems and structures (RQ1)

All four countries in the regional assessment had national PV programmes supported by acts, regulations or policies, with standard operating procedures for receiving, processing and communicating suspected adverse-event reports[1]. Differences were marked.

Tanzania was the only country with a consumer reporting form, available in Swahili. Full-time-equivalent PV staffing was 12 in Tanzania (5 at headquarters and 7 zonal), 5 in Kenya, 10 in Ethiopia (6 for clinical trials and 4 for PV) and 2 in Rwanda. In 2017/18 the national authorities received 4.1 individual case safety reports (ICSRs) per million inhabitants in Tanzania, 35.0 in Kenya and 6.7 in Ethiopia, and Rwanda received none; cumulative ICSRs submitted to VigiBase to December 2018 total 1,899 for Tanzania, 11,373 for Kenya, 1,331 for Ethiopia and 30 for Rwanda. Pre-service PV training for students was absent in Tanzania, Kenya and Rwanda, and Ethiopia had developed a curriculum that had not been implemented[1].

Only Kenya and Tanzania had both a designated PV budget and an electronic reporting system, and none of the four national systems had access to drug-utilisation data[1]. In Tanzania, 97% of ICSRs received in the assessed year underwent causality assessment, compared with 2.0% in Ethiopia and 5.5% in Kenya, although Tanzania had the lowest VigiGrade completeness score of the three countries with data (0.57, versus 0.72 in Kenya and 0.87 in Ethiopia)[1]. Tanzania introduced an online reporting system in October 2016[10]. In 2018, no more than 1% of health facilities in Ethiopia, Kenya and Tanzania had submitted ICSRs[1].

Magnitude of PV outcomes among health professionals (RQ2)

Seventeen surveys and related sources gave quantitative data on reporting, awareness, training or knowledge (Table 1). Outcome definitions differed between studies, so the table lists each definition as reported. Reporting varied more than fourfold between settings. In Kilimanjaro, 32 of 63 providers (50.8%) had never completed an ADR report form[4]. At Mulago hospital, lack of training was cited as the main deterrent to reporting (56.5%)[3]. In Kirinyaga County, Kenya, 74% of providers had not reported to the PPB in the previous three months and 90.2% had never been trained. In Tigray, Ethiopia, 74.9% of professionals had met an ADR in the preceding 12 months but only

32.1% reported; 58.3% had poor knowledge and 31.9% knew where to report[15]. In Harar, 60.7% reported ever having reported an ADR, with physicians (77.3%) above the average, and 53.9% cited an unavailable form as a reason for not reporting[16]. Among community pharmacy professionals in Gondar, 86 of 115 (74.8%) who saw an ADR reported it, but only 26% felt adequately trained. In Dar es Salaam, 36.4% of 330 workers had excellent reporting knowledge and 49.7% had ever submitted a report. Among Nairobi retail chemists, 61% reported general knowledge of PV, 51% had never read a PPB publication on PV and 60% said the PPB did not engage them as stakeholders[14]. A Tanzanian multicentre survey found that 65.8% of professionals scored low on PV knowledge[12]. In the Tanzanian private-sector survey, 89.7% of facilities had no system for monitoring and reporting PV activities, and although 55.7% of respondents had observed ADRs.

Table 1: Pooled estimates (random-effects).

Outcome	k	N	Pooled % (95% CI)	I^2 (%)	95% prediction interval
ADR reporting, all studies	9	3,091	30.3 (19.1–44.4)	97.9	4.3–81.0
Peer-reviewed articles only	7	2,546	26.6 (14.8–42.9)	97.9	–
Tanzania	2	393	49.6 (44.7–54.5)	0.0	–
Uganda, Kenya, Ethiopia, Rwanda	7	2,698	25.7 (14.7–40.9)	98.0	3.1–66.3
By country: Uganda	2	1,519	15.0 (13.2–16.8)	0.0	–
By country: Ethiopia	3	817	44.1 (27.8–61.8)	96.0	–
By country: Kenya; Rwanda (one study each)	1; 1	215; 147	26.0 (20.6–32.3); 8.2	–	–
Aware of national reporting system / centre	6	2,327	42.6 (31.3–54.7)	95.8	11.2–81.3
Received PV / ADR-reporting training	4	800	29.8 (15.2–50.2)	96.0	0.7–96.4
Good / adequate PV knowledge	3	1,017	37.3 (33.1–41.7)	52.3	8.0–80.2
Associations (odds ratio, 95% CI)					
Training → reporting [18,17]	2	522	OR 5.71 (2.80–11.66)	41.5	–
Knowledge → reporting [18,17]	2	522	OR 2.66 (1.54–4.61)	40.7	–
Awareness of where to report → reporting [3,4]	2	1,519	OR 3.22 (0.82–12.65)	87.8	–

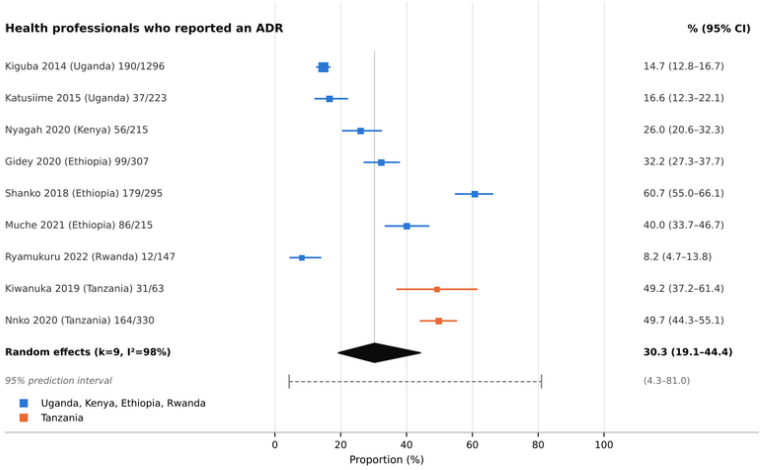


Figure 1: Forest plot of the proportion of health professionals who reported an ADR (random-effects, logit scale; I^2 = 97.9%, τ^2 = 0.83). Square size reflects sample size. Orange: Tanzania; blue: other countries.

In the Tanzanian private-sector survey, 89.7% of facilities had no system for monitoring and reporting PV activities, and although 55.7% of respondents had observed ADRs, none had sent a report to the national PV centre; this source is a preprint and was not peer reviewed.

Pooled estimates

Nine surveys (n=3,091) contributed to the pooled ADR-reporting proportion, which was 30.3% (95% CI 19.1–44.4%; I^2=97.9%; τ^2=0.83), with a 95% prediction interval of 4.3–81.0% (Table 2, Figure 1). Leave-one-out estimates ranged from 27.0% (omitting the Harar survey) to 34.3% (omitting the Rwandan survey). Restricting to the seven peer-reviewed articles gave 26.6% (95% CI 14.8–42.9%), and replacing the Rwandan outcome with "filled any report form" (81/147) gave 36.5% (95% CI 24.1–50.9%). Pooled awareness of the national reporting system or centre was 42.6% (95% CI 31.3–54.7%; six studies, n=2,327), pooled training coverage was 29.8% (95% CI 15.2–50.2%; four studies, n=800) and pooled good or adequate PV knowledge was 37.3% (95% CI 33.1–41.7%; three studies, n=1,017; Figure 2). Knowledge was the only outcome with moderate heterogeneity (I^2=52%); the three knowledge studies used different instruments and cut-offs but gave similar results (34–42%). The very high heterogeneity in the reporting outcome reflects different definitions ("ever", "past year", "last three months", "any form", "national centre"), different professional mixes and settings, and study years from 2010 to 2022.

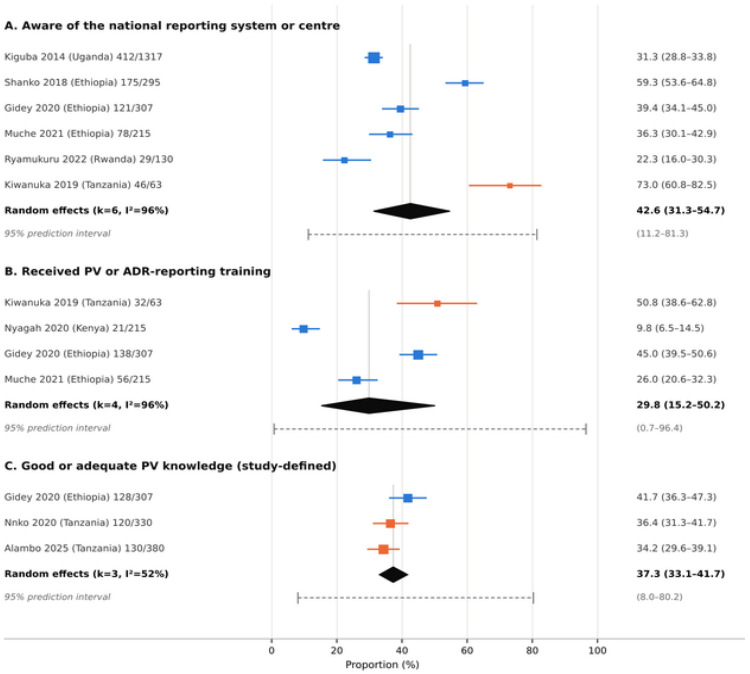


Figure 2: Forest plots of (A) awareness of the national reporting system or centre, (B) PV training and (C) good or adequate PV knowledge.

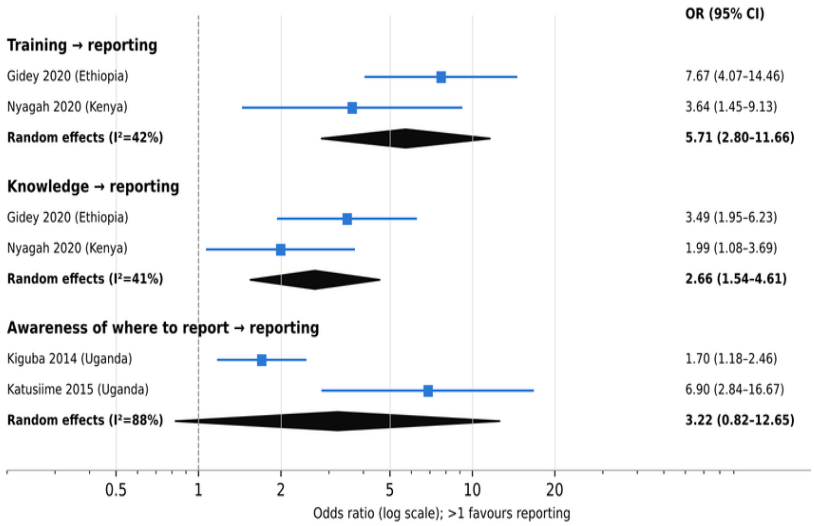


Figure 3: Forest plots of odds ratios for reporting by training, knowledge and awareness of where to report (random-effects, two studies each).

Odds ratios where the source gave odds of poor practice for absence of the exposure were inverted to odds of reporting for presence of the exposure.

The pooled figure is therefore a summary of a heterogeneous literature, not a single regional prevalence, and the prediction interval, which spans 4% to 81%, is the more honest description of what a new study in this region might find.

About six of the nine reporting numerators and six of the thirteen training, awareness and knowledge numerators were derived from reported percentages (flagged with asterisks in Appendix B).

Factors associated with ADR reporting (RQ3): Three exposure outcome pairs could be pooled, each from two studies (Table 2, Figure 3). Professionals who had received ADR-reporting training had about six times the odds of reporting (pooled OR 5.71, 95% CI 2.80–11.66; I²=42%), based on an unadjusted OR of 7.67 (95% CI 4.07–14.46) from Ethiopia[15] and a crude OR of 3.64 (95% CI 1.45–9.13) from Kenya. Good knowledge was associated with higher odds of reporting (pooled OR 2.66, 95% CI 1.54–4.61; I²=41%), from Ethiopia (unadjusted OR 3.49, 95% CI 1.95–6.23)[15] and Kenya (crude OR 1.99, 95% CI 1.08–3.69, for knowledge of the reporting guidelines). Awareness of where or to whom to report showed a positive but imprecise association (pooled OR 3.22, 95% CI 0.82–12.65; I²=88%), combining an OR of 1.7 (95% CI 1.18–2.46) for knowing to whom to report in the Ugandan multi-facility survey[2] with an OR of about 6.9 (95% CI 2.8–16.7) for awareness of the national PV centre at Mulago hospital[3]. All pooled estimates are crude associations from cross-sectional surveys and combine slightly different exposure definitions. After adjustment in the Ethiopian study, the odds ratios were

7.31 (95% CI 3.42–15.62) for lack of training and 2.63 (95% CI 1.26–5.45) for poor knowledge, so both remained independent predictors[15].

Other associations were reported descriptively:

Training and knowledge (not pooled): In Kilimanjaro, PV training had a positive influence on reporting, although no effect estimate was reported[4]; in Rwanda, practice was associated with having heard about PV (p=0.004) and knowing the hospital's reporting system (p=0.005)[17]. In Kenya, 11 of 21 trained providers (52.4%) had reported in the previous three months compared with 45 of 194 untrained (23.2%). In Uganda, not understanding the concept of ADR reporting was associated with lower odds of reporting (unadjusted OR 0.16, 95% CI 0.046–0.561)[3].

Profession: In Kenya, 12 of 18 pharmacy staff (66.7%) had reported, compared with 25 of 129 nurses (19.4%), 10 of 39 clinical officers (25.6%) and 9 of 29 medical officers or consultants (31.0%) (p=0.001). At Mulago, nurses had lower unadjusted odds of reporting than doctors (OR 0.28, 95% CI 0.12–0.65)[3]; in Ethiopia the nursing profession was associated with poor practice (unadjusted OR 2.11, 95% CI 1.06–4.20)[15] and physicians were more likely to have reported in Harar[16].

Age, experience and workplace: In Kenya, reporting rose from 9.3% in those aged 18–25 years to 25.4% at 26–35 and 42.0% above 35 years (p=0.001). Work experience of 10 years or more was associated with better practice in Ethiopia (adjusted OR for poor practice 0.36, 95% CI 0.13–0.97)[15]. In the Ugandan multi-facility survey, hospital staff reported more (OR 1.9, 95% CI 1.18–3.10), private for-profit facilities less (OR 0.5, 95% CI 0.28–0.77), and professionals who had encountered a fatal ADR more (OR 2.9, 95% CI 1.94–4.25)[2]. Age showed an inconsistent association in Uganda: lower odds in the multi-facility survey (OR 0.6, 95% CI 0.43–0.91)[2] and higher odds at Mulago (OR 3.07 for 36–65 vs 21–35 years)[3].

Barriers: Lack of motivation, uncertainty about how to report, lack of time and unavailable forms were the main barriers in Kilimanjaro[4]. Inadequate training, delayed feedback, not knowing where or to whom to report, lack of a PV centre in the county and inadequate access to forms and guidelines were the main barriers in Kenya. In Harar, 53.9% cited an unavailable form, 51.9% uncertainty about how to report and 41% lack of feedback[16]; in Tigray, 64.8% agreed that reporting creates additional workload[15]. Qualitative work in the Tanzanian southern highlands found that providers had adequate knowledge but perceived reporting as laborious and believed that not all ADRs needed reporting[5]. In Rwanda, the commonest barrier was the absence of a reporting system in the hospital (21.4%), followed by considering the reaction a normal side effect (12.2%) and heavy workload (11.2%)[17]. In the Tanzanian private sector, lack of PV tools (60.9%) and poor knowledge of reporting procedures (69.8%) were reported, with lack of feedback from the TMDA cited by 93.3%.

Patients and herbal medicines: Among 792 patients in Mbeya, 14.1% were aware that an ADR is an unexpected harm after medication use and 21.6% had previously experienced an ADR[10]. Among Tanzanian health professionals, 70.8% perceived herbal medicines as safer than conventional medicines[12].

Tanzania compared with other countries: In the subgroup analysis, pooled reporting was 49.6% (95% CI 44.7–54.5%; I^2=0%) in the two Tanzanian surveys[4] and 25.7% (95% CI 14.7–40.9%; I^2=98.0%) in the seven surveys from Uganda, Kenya, Ethiopia and Rwanda[2,3,15-17]; the test for subgroup difference was significant (Q=8.09, p=0.004). Comparing countries, pooled reporting was lowest in Uganda (15.0%) and Rwanda (8.2%), intermediate in Kenya (26.0%) and highest in Ethiopia (44.1%) and Tanzania (49.6%) (Table 1). This should not be read as evidence that Tanzanian professionals report more. The two Tanzanian estimates are strikingly consistent with each other (49.2% and 49.7%) but come from 393 respondents in a tertiary HIV and dermatology setting with dedicated reporting forms and in regional referral hospitals in a single city, one of them from an unpublished master's dissertation. Outcome definitions also differ: the Tanzanian surveys asked about ever having submitted a report or form, whereas the Ugandan and Kenyan surveys used shorter reference periods. The Ethiopian studies, which also used "ever".

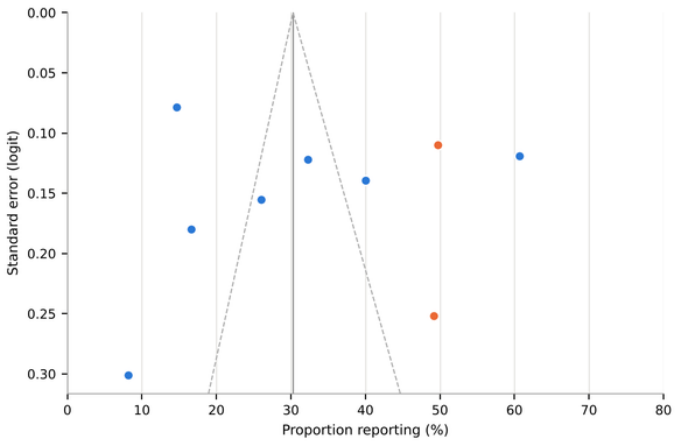


Figure 4: Funnel plot of the nine ADR-reporting proportions (logit scale standard error against proportion). Orange: Tanzania.

Evidence of impact: structured stimulated reporting and training in Tanzania: A structured stimulated spontaneous safety monitoring programme, combining training with follow-up phone calls to patients, was piloted in seven tertiary hospitals and evaluated by comparing reports for 18 months before (July 2017–December 2018) and after (January 2019–June 2020) its introduction[11]. Reports rose from 20 to 11,637 in Dar es Salaam, from 49 to 316 in Kilimanjaro, and from 17 to 77 in Mbeya, and the national reporting ratio rose from 2 to 85 reports per million inhabitants between 2018 and 2019[11]. In total, 16,557 adverse drug events were recorded, of which 16,332 (98.6%) followed the start of the programme. The programme also identified novel ADEs linked to a newly introduced antiretroviral regimen and a cluster of cases tied to an antibiotic at one site, which was addressed by retraining health workers on correct administration; these are locally detected signals, although the sources do not describe any resulting regulatory action. An evaluation of the PAVIA blended e-learning PV training programme, in which 827 learners registered and 421 completed the programme, likewise reported a substantial increase in case reports after training in Tanzania, Eswatini and Nigeria[13]. These are before–after comparisons without concurrent controls, so secular trends and other initiatives cannot be excluded, and report quality was not examined in the sources reviewed.

Regulatory action and the signal-to-action pathway (RQ4): The 2018 regional assessment documented regulatory outputs as follows[1]. In Tanzania, signals were identified on average five times a year over five years, with regulatory actions taken; two withdrawals occurred in the last calendar year, the time from suspected problem to action was days to weeks, and safety issues reported from abroad were acted on. In Kenya, 30 quality signals and one safety signal were identified in the last year, 13 recalls (voluntary and regulatory) were carried out, the time to action ranged from 7 days to 3 months, and five safety issues reported from abroad were acted on in the last year. In Ethiopia, 31 PV-related actions were recorded over eight years, including four withdrawals in the last calendar year, the time to action was 2–3 months, and no action was initiated on safety issues reported from abroad. Rwanda had received no reports, and no signals or actions were recorded. Most recalls and restrictive actions in the region were linked to product quality, and Ethiopian actions were generally based on poor quality identified through reports of adverse reactions[1].

The assessors interpreted the predominance of quality-related actions as an indication that very low ICSR volumes do not capture all medicine-related harm, including preventable harms such as medication errors[1].

Rwanda after 2018: Rwanda, which had received no ICSRs in the assessed year[1], published its first medicines safety bulletin in June 2021 covering November 2018 to December 2020. It recorded 1,427 ADR reports in about 26 months, two thirds of them (950, 66.6%) for paracetamol (520) and amoxicillin (430), issued 11 safety communications, and recalled 75 batches (59 human, 16 veterinary). The bulletin did not link individual alerts or recalls to specific signal sources. It also recorded 235 reports of suspected poor-quality products, 158 medicine samples tested of which 8 (5.1%) failed standards, and 18 medication-error reports analyzed.

Dated regulatory actions: We identified six dated actions in Uganda, Tanzania and Kenya from media reports (Figure 5). Three were triggered by international alerts or foreign laboratory findings and three by local complaints or national testing. In Uganda in October 2016, the NDA withdrew six products, including a multivitamin, hydralazine injection and nalidixic acid tablets, because of capsules sticking to packaging, powder that did not dissolve and mould, after laboratory tests and complaints. In Tanzania in July 2018, the TFDA recalled valsartan combination products through a 14-day process after a US FDA alert on an NDMA impurity with carcinogenic risk, and in November 2019 the TMDA suspended the use and prescribing of all ranitidine-containing medicines for the same impurity after alerts from the EMA, US FDA, TGA and Swissmedic. In Kenya in September 2023, the PPB ordered a mandatory recall of Tamedol paracetamol oral solution for children, which had failed market-authorization requirements, after customer complaints about batch quality.

In April 2024, a recall of one batch of a children's cough syrup in Kenya, Tanzania and Rwanda followed a high-toxicity finding on testing by Nigeria's regulator. In October 2025, the NDA recalled all batches of the bupivacaine product Bupitroy Heavy after multiple complaints from health facilities over an extended period, including life-threatening and fatal reactions.

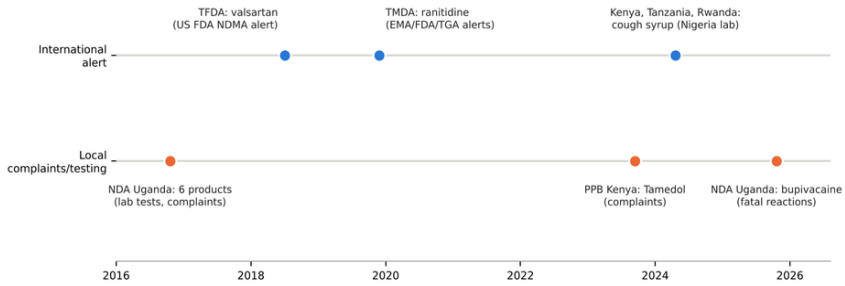


Figure 5: Dated regulatory actions in East Africa by signal source (Table 7).
Blue: triggered by an international alert or foreign laboratory finding; orange: triggered by local complaints or national testing.

By issue, three actions concerned impurities or contamination (valsartan, ranitidine, cough syrup), two concerned manufacturing or product-quality defects (the 2016 withdrawals and the 2023 recall) and one concerned adverse reactions and treatment failure (bupivacaine). All six were recalls, withdrawals or suspensions; we found none that was a label change or a restriction on use. Only the 2025 Ugandan recall explicitly cited local adverse-reaction reports. These six actions are illustrative, not a systematic census. A formal quantitative analysis of regulatory actions by year, therapeutic class and signal source was not possible because regulatory actions are not consolidated in a published, analyzable dataset in the sources reviewed, and TMDA safety communications could not be retrieved.

DISCUSSION

Principal findings

East African PV systems have legal and structural foundations but limited engagement from reporters. In 2017/18, reporting was 4 to 35 reports per million inhabitants in the three countries with data and no more than 1% of facilities submitted reports[1]. Across nine surveys in five countries, about three in ten health professionals reported an ADR (30.3%), but the estimate was extremely heterogeneous and the range of plausible values in a new setting was wide (4–81%). Awareness of the national reporting system was modest (42.6%), training was reported by under one third (29.8%) and about two in five had good knowledge (37.3%). Training and knowledge were each associated with several-fold higher odds of reporting, documented regulatory actions in the region were mostly quality-related, and half of the actions we found followed international alerts or foreign testing.

Systems versus performance

Tanzania illustrates the gap between institutional maturity and reporting performance. Its regulator reached WHO Maturity Level 3, has a designated PV budget, an electronic reporting system, a consumer form in Swahili and a technical committee, yet it received 4.1 reports per million inhabitants in 2017/18. The regional assessors noted that benchmarking examined structures and functions and did not reflect low reporting caused by limited engagement from providers, public health programmes, marketing-authorization holders and consumers[1]. Our synthesis supports that interpretation: system indicators should be complemented by outcome indicators such as reporting rates, facility participation and report quality. Rwanda shows how quickly volumes can change once systems are active, from none in the assessed year to 1,427 reports in about 26 months[1], although the concentration of reports on two common medicines suggests that volume alone does not equal signal-detection capacity.

Knowledge, training and the reporting gap

Surveys show a recurring gap between awareness and action. Most Kilimanjaro providers (73%) knew the national system, yet half had never completed a report form[4]; most Rwandan nurses and midwives had heard of PV (88.4%) but only 8.2% had used the adverse-event notification form, although 84.4% of those who observed an ADR filled some report form, most commonly the hospital's internal incident form[17]. In Tigray three in four professionals had met an ADR in the previous year but only one in three reported it[15], and in Gondar three in four pharmacy professionals who saw an ADR reported it even though only a quarter felt adequately trained. This shows that ADRs may be recorded and escalated inside facilities without reaching the national PV centre, a pathway that is invisible to national statistics. Qualitative work in southern Tanzania found that knowledgeable providers still saw reporting as burdensome and discretionary[5]. Knowledge-only interventions are unlikely to be sufficient; workload, motivation, feedback and the availability and usability of tools matter as much. The pooled associations of training (OR 5.7) and knowledge (OR 2.7) with reporting, and the association with knowing where to report, support simple, concrete interventions such as visible reporting channels, focal persons and routine training. Because these data are cross-sectional and self-reported, they show association, not that training causes reporting, and those who report may be more likely to seek training.

Tanzania in the regional context

The Tanzanian surveys showed higher reporting than surveys in Uganda, Kenya and Rwanda, but similar to Ethiopia, and we caution against concluding that Tanzanian practice is better. Both Tanzanian estimates came from single-site hospital surveys, one from a population with a dedicated HIV reporting form, and the dissertation is not peer reviewed. System-level data point the opposite way, with Tanzania's per-capita report volume below Ethiopia's and Kenya's[1]. A more useful reading is that facilities with reporting tools, training and a reporting culture, as in the Tanzanian referral settings, can reach reporting levels around 50%, while the national

Evidence that reporting can improve

The Tanzanian structured stimulated reporting programme provides the strongest signal that reporting can rise substantially, with a reporting ratio increasing from 2 to 85 per million inhabitants in one year[11], and an e-learning programme was likewise followed by increased reports[13]. The much smaller increases in Kilimanjaro and Mbeya than in Dar es Salaam suggest that effects depend on implementation intensity and context[11]. Because these were uncontrolled before-and-after evaluations in tertiary hospitals, generalizability to primary-care and private facilities is unknown, and the quality and sustainability of the additional reports require evaluation. The programme's detection of novel ADEs linked to a new antiretroviral regimen and of an antibiotic-administration cluster shows that stimulated reporting can generate locally relevant signals, which is the missing link in the regulatory evidence below.

From reports to regulatory action

Regional regulators acted quickly once problems were identified (days to weeks in Tanzania, up to three months in Ethiopia and Kenya), which suggests that decision-making is not the main bottleneck. Half of the

dated actions we identified followed international alerts or foreign testing, consistent with the finding that Kenya and Tanzania act on safety issues reported from abroad[1]. Responding to international alerts is appropriate regulatory practice, particularly for impurities such as NDMA, but it does not demonstrate that national PV data are generating signals. The Ugandan bupivacaine recall is the clearest example in our data of local adverse-reaction reports driving action, and it took place in 2025, which may indicate that this pathway is strengthening. We found no documented label changes or restrictions, and no TMDA action attributed to a Tanzanian signal. This may reflect true absence, incomplete publication, or the limits of our media-based search. Without drug-utilization data, regulators cannot calculate reporting rates relative to use or prioritize signals by population exposure[1].

Implications

Policy and regulation: Integrate PV into pre-service curricula (absent in Tanzania, Kenya and Rwanda at the time of assessment)[1]; add reporting-rate, facility-participation and report-quality indicators to regulator performance monitoring; build access to drug-utilization data[1]; and publish regulatory decisions with the evidence source, as the Rwanda FDA bulletin begins to do.

Practice: Place reporting tools and a named focal person at the point of care, simplify reporting, give feedback to reporters, train staff, and engage community pharmacies and private facilities, where reporting appears weakest[14].

Research: Standardize outcome definitions (for example, "ever reported" versus "reported in the past year" versus "reported to the national centre"), report numerators and denominators, extend studies to primary care, community pharmacy and private facilities, and create analyzable registers of regulatory actions with signal source.

Strengths and limitations

Strengths include mapping both reporter-level and regulator-level evidence, pooling four PV indicators and three associations with prediction intervals and sensitivity analyses, a Tanzania-focused subgroup comparison, checking denominators against full-text tables (which led to correction of one misleading reported percentage), and transparent handling of derived data. The search was targeted and web-based, so eligible studies, particularly from Kenya, Ethiopia, Uganda and Burundi, and from databases not searched, are likely to have been missed (an Ethiopian systematic review located 17 studies from that country alone, of which we pooled three); several PubMed Central full texts could not be opened; the evidence base is weighted to hospital-based cross-sectional surveys with self-reported outcomes; study dates range from 2010 to 2022, and the regional assessment reflects 2018 conditions, so some indicators may have changed.

CONCLUSIONS

East African PV systems, including Tanzania's, have progressed institutionally, but reporting by professionals, facilities and consumers remains low and uneven: pooled across nine surveys, about three in ten professionals had reported an ADR, fewer than one in three had been trained, and training and knowledge were each associated with several-fold higher odds of reporting. The evidence linking locally generated safety information to regulatory action is limited, and half of the actions we identified followed international alerts or foreign testing. Pre-service and in-service training, accessible reporting channels, feedback to reporters and transparent regulatory communication are priorities.

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AUTHOR'S CONTRIBUTIONS

Barugahale LP: conceived the review and led the writing. **Lemanya SV:** data analysis, manuscript writing. **Ndetico KJ:** editing, critical review. **Mwombeki L:** data charting, critical revision. Final manuscript was checked and approved by all authors.

DATA AVAILABILITY

The related author can provide the empirical data supporting the study's conclusions upon request.

CONFLICT OF INTEREST

There are no conflicts of interest in regard to this project.

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