

Adverse Drug Reaction Reporting among Healthcare Professionals in Private Health Facilities in Mbarara City, Uganda: A Cross-sectional Study

Calvin Cherotin

2020pha098@std.must.ac.ug

Mbarara University of Science and Technology

Moses Ocen

Mbarara University of Science and Technology

Steven Okumu

Mbarara University of Science and Technology

Micheal Mpeirwebyoona

Mbarara University of Science and Technology

Amos Oyuru

Mbarara University of Science and Technology

Alrazi Eisa Shogar

Kampala International University

Tadele Mekuriya Yadesa

Kampala International University

Julius Kyomya

Mbarara University of Science and Technology

Research Article

Keywords: ADR Reporting, Pharmacovigilance, Private Health Facilities, Health Care professionals, Patient Safety

Posted Date: October 19th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-10871288/v1>

License:   This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Additional Declarations: No competing interests reported.

Abstract

Background

Adverse drug reactions (ADRs) are an important cause of morbidity and mortality worldwide. Uganda's National Drug Authority (NDA) has strengthened pharmacovigilance in recent years, but reporting remains concentrated in government facilities. The private sector delivers a substantial share of care in Uganda, and its contribution to national ADR reporting is unclear. We assessed ADR reporting and its associated factors among healthcare professionals (HCPs) in private health facilities in Mbarara City.

Methods

We conducted a cross-sectional study in private health facilities in Mbarara City in March 2026. Facilities were stratified into hospitals and clinics, and the six hospitals and 68 clinics that granted permission were enrolled. Eligible HCPs within each facility were recruited consecutively. A structured, self-administered questionnaire was used to obtain sociodemographic characteristics, ADR reporting practice, knowledge, attitude, and perceived barriers and facilitators. The outcome variable was formal submission of at least one suspected ADR report to the NDA in the preceding 12 months. Data was analyzed in STATA version 17 using bivariate and multivariable logistic regression, with significance set at $p < 0.05$.

Results

Of the 233 participants, 142 (60.9%) had observed at least one suspected ADR in the preceding 12 months, but only 30 (12.9%, 95% CI: 9.2–17.8) had formally reported at least one ADR to the NDA. Among those who had observed a reaction, 28 (19.7%) had reported one. Overall, 182 participants (78.1%) demonstrated good knowledge of ADR reporting, with a mean score of 5.09 (SD 1.00). The major barriers to reporting were unavailability of reporting guidelines and forms (69.1%), absence of feedback from the NDA (51.5%), and insufficient training (50.2%). ADR reporting increased with professional experience (aOR 2.47, 95% CI: 1.36–4.47) and was independently associated with previous pharmacovigilance training (aOR 2.64, 95% CI: 1.12–6.22).

Conclusion

ADR reporting among HCPs in private health facilities in Mbarara City was low, despite good knowledge and favorable attitudes towards reporting. The gap between observation and reporting appears to be driven by system-level constraints rather than by individual awareness. Strengthening private-sector pharmacovigilance will require reliable distribution of reporting tools, sustained training, and a functioning feedback loop between the NDA and frontline HCPs.

INTRODUCTION

Adverse drug reactions (ADRs) are a major cause of preventable morbidity and mortality worldwide. ADRs are defined as harmful and unintended responses to a medicine occurring at doses normally used for prophylaxis, diagnosis, or treatment (1). Globally, ADRs account for an estimated 2.5–30% of hospital admissions, depending on the setting (2). Populations such as children and older adults are particularly vulnerable to severe ADRs that result in hospitalization or death (3, 4). In sub-Saharan Africa, a systematic review estimated that 4.8% of hospital admissions are attributable to ADRs in adults (5). In Uganda, 48.9% of older adults hospitalized at Mbarara Regional Referral Hospital experienced at least one ADR, and half of these were preventable (6).

Pharmacovigilance (PV) is the science and set of activities concerned with the detection, assessment, understanding, and prevention of adverse drug effects (7). Most national pharmacovigilance systems, including Uganda, rely on spontaneous reporting in which healthcare professionals or patients voluntarily submit reports of suspected reactions (8). The effectiveness of spontaneous reporting, however, depends on healthcare professionals recognizing and reporting suspected ADRs. Consequently, underreporting remains the greatest limitation of pharmacovigilance systems worldwide (9).

In Uganda, pharmacovigilance is coordinated by the National Drug Authority through the National Pharmacovigilance Centre, which receives, validates, and analyses ADR reports to inform regulatory decision-making (10). Despite these structures, ADR reporting remains suboptimal. A national survey involving 1,345 healthcare professionals found that only half had heard of pharmacovigilance, and only 15% had reported a suspected ADR during the preceding year (11). Similarly, the NDA annual pharmacovigilance report for 2022/23 documented only 104.68 ADR reports per million population, approximately half of the World Health Organization's recommended minimum of 200 reports per million population (12). Studies from Uganda have also identified limited training and poor knowledge of reporting procedures as important barriers to ADR reporting (13).

Previous studies have shown that ADR reporting is influenced by both individual and health system factors. These include knowledge of reporting procedures, attitudes towards pharmacovigilance, previous training, availability of reporting tools, institutional support, and feedback from regulatory authorities (9, 14–16). The relative importance of these factors may differ between public and private healthcare settings, where differences in organizational structures, supervision, and access to pharmacovigilance resources can influence reporting practices.

Kiguba et al. (2014) found that ADR reporting was significantly lower among HCPs in private for-profit facilities than among their public-sector counterparts (11). The private sector provides a substantial proportion of healthcare services in Uganda and is often the first point of contact for patients seeking care (17, 18). Despite this important role, pharmacovigilance activities have largely focused on public-sector facilities, leaving the reporting practices and challenges of private facilities poorly understood. Evidence on ADR reporting among healthcare professionals working in private health facilities in southwestern Uganda remains limited.

To address this knowledge gap, we assessed ADR reporting and its associated factors among healthcare professionals in private health facilities in Mbarara City.

METHODS

Study design

This was a descriptive cross-sectional study among healthcare professionals working in private health facilities in Mbarara City, southwestern Uganda.

Study setting and period

The study was conducted in private health facilities in Mbarara City, southwestern Uganda, during March 2026. Mbarara City is one of Uganda's fastest growing urban centres, comprising six administrative divisions with a population of 264,425 (19). The private health sector in the city is rapidly expanding, with eleven major private hospitals, 134 registered lower-level private facilities, and 84 licensed private pharmacies. Mbarara city contributes a large share of national pharmacovigilance activity. In 2022/23, Mbarara district submitted 661 adverse drug reaction and adverse event reports to the National Pharmacovigilance Centre, second only to Kampala. Additionally, Mbarara Regional Referral Hospital was the highest reporting regional referral hospital nationally (20). Despite this recognized pharmacovigilance activity, the contribution of private health facilities to ADR reporting in the region remains unclear. This makes Mbarara City an appropriate setting in which to examine ADR reporting in the private sector.

Study population and eligibility

The study population comprised healthcare professionals working in private hospitals and clinics within the geographical boundaries of Mbarara City.

Facilities were eligible if they were located within Mbarara City and employed at least one healthcare professional involved in prescribing, dispensing, administering medicines, or providing direct patient care.

Healthcare professionals were eligible if they were registered or licensed, were employed at an eligible facility, and had worked at that facility for at least three months before data collection. We excluded temporary, locum, and rotating staff not permanently attached to the facility, and staff holding exclusively administrative or managerial roles without involvement in direct patient care or medication-related activities.

Sample size

The sample size was calculated using the Cochran formula for cross-sectional studies, with an expected proportion of 16.6% based on ADR reporting among healthcare workers at Mulago National Referral Hospital (13) a 95% confidence level, and a 5% margin of error. This gave 213 participants. After adding a 10% non-response rate the final sample size was 234 participants.

Sampling and participant enrolment

Private health facilities were stratified into hospitals and clinics. Introductory letters describing the study were delivered to facilities in each stratum. Nine hospitals and 106 clinics were approached. The first six hospitals and 68 clinics that granted written permission were enrolled. Within participating facilities, all healthcare professionals present during the data collection period who met the eligibility criteria were approached consecutively and invited to participate. Each participant received a detailed explanation of the study, including its risks and benefits. Only those who gave informed consent were enrolled.

Data collection tools and procedures

Data was collected using a structured, self-administered questionnaire developed for this study (supplementary file). The questionnaire was developed following a review of the literature on ADR reporting and pharmacovigilance practice. To establish content validity and contextual appropriateness, the draft questionnaire was reviewed by pharmacovigilance experts at the National Drug Authority Western Regional Office in Mbarara. Reviewer feedback was incorporated, including refinement of ambiguous items, alignment with Uganda's national pharmacovigilance framework, and conversion of open-ended numerical items to categorical ranges. The revised questionnaire was pretested among five healthcare professionals in private facilities outside the sampling frame to assess clarity, comprehension, and administration time, and was further modified in response. The questionnaire was offered in both paper and Google Forms format to accommodate participants' preferences and access. It covered four domains: sociodemographic and professional characteristics; ADR reporting practice; knowledge and attitudes towards ADR reporting; and perceived barriers and facilitators to ADR reporting.

Written consent was obtained for the paper version and electronic consent for the online version. Paper questionnaires were checked for completeness before collection. In the online version, all items were set as required fields, so incomplete forms could not be submitted.

Questionnaires with errors or omissions were corrected by revisiting the participant where possible. Paper questionnaires were double entered, and discrepancies were resolved by reference to the original forms. Data was cleaned for outliers, logical inconsistencies, and missing values before analysis.

Outcome and study variables

The primary outcome was formal submission of at least one suspected ADR report to the National Drug Authority in the 12 months preceding data collection. This was self-reported and analyzed as a binary

variable.

Independent variables were sex, age group, professional cadre, education level, years of professional experience, facility type, previous pharmacovigilance training in the past five years, and dual practice in both private and public facilities. Knowledge and attitude measures, and endorsed barriers and facilitators, were also examined in relation to the outcome.

Knowledge was assessed using six multiple-choice items, each scored as correct or incorrect, giving a total of 0 to 6. Knowledge was categorized using Bloom's cut-off points as good ($\geq 80\%$, score 5 to 6), moderate (60 to 79%, score 4), and poor ($< 60\%$, score 0 to 3). Attitude was measured using seven items on a five-point Likert scale. Two negatively worded items were reverse scored. Barriers and facilitators were assessed as multiple-response items.

Data analysis

Data was entered in Microsoft Excel 2016 and analyzed in STATA version 17. Sociodemographic characteristics were summarized as frequencies and percentages. The proportion of participants who had reported at least one ADR was presented with a 95% confidence interval. Reporting channels, barriers, and facilitators were summarized as multiple-response frequencies. Internal consistency of the attitude items was assessed using Cronbach's alpha.

Associations between the independent variables and the binary outcome were examined using logistic regression. Bivariate logistic regression was performed for each independent variable, and variables with $p < 0.20$ were considered for the multivariable model. With 30 outcome events, the multivariable model was restricted to three estimated parameters to maintain approximately ten events per parameter. Three variables that met the screening threshold were not retained because they contained categories with very small numbers of participants yielding unstable estimates. These included age (nine participants aged 40 to 59 years), education level (six participants holding a master's degree or PhD), and dual practice (eleven participants). Years of professional experience was retained in preference to age as the more direct measure of professional exposure to pharmacovigilance practice. Years of experience was modelled as a linear trend across the four ordered categories, giving an odds ratio for each successive category rather than per year since the categories were of unequal width. Modelling the years of experience variable as a trend also avoided the unstable estimates produced by a categorical specification, in which the lowest experience category contained a single outcome event. Results are reported as crude and adjusted odds ratios with 95% confidence intervals. Statistical significance was set at $p < 0.05$. Model fit was assessed using the Hosmer-Lemeshow goodness-of-fit test, and discrimination using the area under the receiver operating characteristic curve.

RESULTS

Social demographics and characteristics of healthcare professionals in private healthcare facilities within Mbarara city.

A total of 244 healthcare professionals were approached and 233 completed the questionnaire, giving a response rate of 95.5%.

Over half of the participants (129, 55.4%) were female. Most participants had age range between 18 to 39 years (224, 96.1%) and majority (149, 64%) had between 1–5 years of practice experience. Most of the private healthcare workers in this study were nurses (128, 54.9%). Nearly half of the participants (49.4%, n = 115) reported to have received pharmacovigilance training in the last five years (Table 1).

Table 1
Socio-demographics and characteristics of healthcare professionals
in private healthcare facilities within Mbarara city, March 2026

Characteristic	Frequency	Percent (%)
Sex		
Female	129	55.4
Male	104	44.6
Age group (years)		
18–39	224	96.1
40–59	9	3.9
Professional cadre		
Nurse	128	54.9
Clinical officer	43	18.5
Medical doctor	19	8.2
Pharmacist	4	1.7
Pharmacy technician	9	3.9
Others*	30	12.9
Education level		
Certificate	80	34.3
Diploma	101	43.3
Bachelor's	46	19.7
Master's / PhD	6	2.6
Years of experience		
<1 year	21	9.0
1–5 years	149	64.0
6–10 years	53	22.7
>10 years	10	4.3
Facility type		
Clinic	131	56.2
Hospital	101	43.3

Characteristic	Frequency	Percent (%)
Sex		
Medical center	1	0.4
Received PV training (past 5 years)		
Yes	115	49.4
No	118	50.6
Dual practice (private & government)		
Yes	11	4.7
No	222	95.3

Key: PV-Pharmacovigilance *others: midwife, laboratory technicians, dentists and laboratory assistants.

Prevalence of ADR reporting among study participants

Of the 233 participants, 142 (60.9%) had observed or managed at least one suspected ADR in the preceding 12 months. Among these 142, most had observed between one and five ADRs (126, 88.7%), while 10 (7.0%) had observed six to ten and 6 (4.2%) more than ten.

In contrast, only 30 participants (12.9%, 95% CI: 9.2–17.8) had formally reported at least one suspected ADR to the NDA during the same period. Among the 142 participants who had observed an ADR, 28 (19.7%) had reported one, meaning that four in five clinicians who encountered a suspected ADR did not report it.

Among the 30 participants who had reported an ADR to the NDA, the channels used were phone calls (17, 56.7%), physical forms (16, 53.3%), the Med Safety app (4, 13.3%), WhatsApp (3, 10.0%) and email (2, 6.7%).

Knowledge and attitude of healthcare professionals towards ADR reporting

Overall, 182 participants (78.1%) demonstrated good knowledge of ADR reporting, with a mean score of 5.09 (SD 1.00) out of a possible 6. A further 31 (13.3%) had moderate knowledge and 20 (8.6%) had poor knowledge, based on Bloom's cut-off points.

Performance was high on most individual items. Almost all participants correctly identified that all healthcare professionals are responsible for reporting ADRs (229, 98.3%). Most knew when an ADR should be reported (206, 88.4%), correctly defined an ADR (201, 86.3%), and knew where completed reports should be submitted (193, 82.8%). Fewer correctly identified which types of reaction should be

reported (184, 79.0%), and the lowest-scoring item was recognizing which information is not required in an ADR report (172, 73.8%) (Fig. 1).

Participants agreed strongly that ADR reporting is a professional obligation (mean 4.64, SD 0.60) and that their reports contribute to patient safety and medication management (mean 4.64, SD 0.51). There was also strong agreement that reporting remains important for well-known drugs (mean 4.15, SD 0.88), and a high level of personal motivation to report (mean 4.07, SD 0.92). Few regarded reporting as futile, with participants largely disagreeing that it is a waste of time (mean 1.45, SD 0.75).

Concern that reporting could lead to legal or other negative consequences was below average but the most variable of any item (mean 2.31, SD 1.11, range 1 to 5). Perceptions of the reporting system's usability were intermediate (mean 3.16, SD 0.95). Internal consistency across the seven items was low (Cronbach's $\alpha = 0.43$), with item-rest correlations ranging from 0.04 to 0.35, indicating that the items did not measure a single underlying construct. Attitude was therefore analyzed at item level rather than as a composite score (Table 2).

Table 2
Attitude of healthcare professionals working in private healthcare facilities within Mbarara city towards ADR reporting.

Attitude statement (1 = SD, 5 = SA)	Mean	SD	Min	Max
ADR reporting is professional obligation	4.64	0.60	2	5
Reporting is waste of time	1.45	0.75	1	5
Reports contribute to patient safety and medication management	4.64	0.51	3	5
Personally motivated to report	4.07	0.92	1	5
System is user-friendly	3.16	0.95	1	5
Could lead to legal issues	2.31	1.11	1	5
Important even for well-known drugs	4.15	0.88	1	5

Items scored on 5-point Likert scale (1 = Strongly Disagree, 5 = Strongly Agree). Items Q2 and Q6 are negatively worded; reverse-scored for total computation. Cronbach's $\alpha = 0.43$.

Barriers and Facilitators to ADR reporting

The most reported barriers to ADR reporting were lack of clear reporting guidelines and reporting forms (161, 69.1%), absence of feedback from NDA (120, 51.5%), and insufficient training or knowledge of the reporting process (117, 50.2%). Less frequently reported barriers included heavy workload (77, 33.0%), difficulty assessing causality (65, 27.9%), fear of litigation or blame (63, 27.0%), concerns about patient confidentiality (49, 21.0%), and the perception that the adverse reaction was too minor or already well known to report (47, 20.2%) (Fig. 2A)

The most frequently identified facilitators of ADR reporting were regular pharmacovigilance training (132, 56.7%), access to up-to-date drug information resources (129, 55.4%), readily available reporting tools (126, 54.1%), and supportive facility management (118, 50.6%). Other facilitators included timely feedback from the NDA (109, 46.8%) and designated pharmacovigilance personnel (104, 44.6%). Encouragement from colleagues (87, 37.3%) and incentives or recognition for reporting (56, 24.0%) were reported less frequently (Fig. 2B).

Factors associated with ADR reporting

At bivariate level of regression analysis, ADR reporting was associated with age 40 to 59 years, bachelor's level of education, dual practice, previous pharmacovigilance training, and citing patient confidentiality as a barrier. ADR reporting also increased across categories of professional experience when modelled as a trend (cOR 2.29, 95% CI 1.32 to 3.97).

In the multivariable model, the odds of reporting an ADR increased with each successive category of professional experience (aOR 2.47, 95% CI: 1.36–4.47, $p = 0.003$). Previous pharmacovigilance training was also independently associated with ADR reporting (aOR 2.64, 95% CI: 1.12–6.22, $p = 0.026$). Participants who cited patient confidentiality as a barrier had higher odds of reporting an ADR (aOR 2.40, 95% CI: 1.01–5.69, $p = 0.046$). The model showed adequate fit (Hosmer-Lemeshow $\chi^2 = 4.22$, $df = 5$, $p = 0.518$) and acceptable discrimination (area under the ROC curve 0.70) (Table 3).

In a sensitivity analysis including education level as a binary variable, degree-level qualification was not independently associated with reporting (aOR 2.29, 95% CI: 0.95–5.53, $p = 0.065$), and the estimate for years of experience was unchanged (aOR 2.47, 95% CI: 1.35–4.50).

Table 3

Bivariate and multivariable logistic regression of factors associated with adverse drug reaction reporting among healthcare professionals in private health facilities in Mbarara City (n = 233).

Variable	Reported an ADR, n/N (%)	cOR (95% CI)	p-value	aOR (95% CI)	p-value
Sex					
Female	17/129 (13.2)	Ref			
Male	13/104 (12.5)	0.94 (0.43–2.04)	0.878		
Age group					
18–39	25/224 (11.2)	Ref			
40–59	5/9 (55.6)	9.95 (2.51–39.51)	0.001*		
Education level					
Certificate	7/80 (8.8)	Ref			
Diploma	12/101 (11.9)	1.41 (0.53–3.75)	0.496		
Bachelor's	10/46 (21.7)	2.90 (1.02–8.24)	0.046*		
Master's / PhD ^a	1/3 (33.3)	5.21 (0.42–64.98)	0.199		
Years of experience					
<1 year	1/21 (4.8)	Ref			
1–5 years	16/149 (10.7)	2.41 (0.30–19.15)	0.407		
6–10 years	8/53 (15.1)	3.56 (0.42–30.36)	0.246		
>10 years	5/10 (50.0)	20.00 (1.89–211.84)	0.013		
Per successive category ^b		2.29 (1.32–3.97)	0.003*	2.47 (1.36–4.47)	0.003*
Facility type					
Clinic	18/131 (13.7)	Ref			
Hospital	12/101 (11.9)	0.85 (0.39–1.85)	0.675		

Variable	Reported an ADR, n/N (%)	cOR (95% CI)	p-value	aOR (95% CI)	p-value
Sex					
PV training					
No	10/118 (8.5)	Ref		Ref	
Yes	20/115 (17.4)	2.27 (1.01–5.10)	0.046*	2.64 (1.12–6.22)	0.026*
Dual practice					
No	26/222 (11.7)	Ref			
Yes	4/11 (36.4)	4.31 (1.18–15.72)	0.027*		
Knowledge level					
Knowledge score (per point)		0.79 (0.55–1.13)	0.199		
Barriers cited					
Patient confidentiality		2.51 (1.10–5.72)	0.028	2.40 (1.01–5.69)	0.046*
ADR too minor/well-known		2.24 (0.97–5.19)	0.059		
Lack of guidelines or forms		0.54 (0.24–1.17)	0.118		
No feedback from NDA		1.74 (0.79–3.85)	0.168		
Facilitators cited					
Management support		1.81 (0.82–4.01)	0.140		

^a Omitted due to perfect prediction (zero cell). ^b Experience modelled as a linear trend across the four ordered categories; a likelihood ratio test showed no significant difference in fit compared with a categorical specification ($p = 0.54$). Multivariable model: $LR \chi^2(3) = 17.70$, $p = 0.0005$; pseudo $R^2 = 0.099$; Hosmer-Lemeshow $\chi^2(5) = 4.22$, $p = 0.518$; area under ROC curve = 0.70.

DISCUSSION

This study examined ADR reporting practices and their determinants among healthcare professionals working in private health facilities in Mbarara City. ADR reporting among healthcare professionals in private health facilities was low despite frequent encounters with suspected ADRs in routine practice.

Although most participants had observed a suspected ADR during the preceding year, only a small proportion had reported one to the National Drug Authority indicating substantial under-reporting. This occurred despite generally good knowledge of ADR reporting and positive attitudes towards reporting. The most identified barriers were lack of reporting guidelines and forms, absence of feedback from the NDA, and insufficient pharmacovigilance training, while regular training, access to reporting tools and drug information resources, supportive management, and regulatory feedback were the most frequently identified facilitators. ADR reporting increased with professional experience and was independently associated with previous pharmacovigilance training.

The 12.9% prevalence of ADR reporting observed in this study is similar to the 15% reported earlier by Kiguba et al (2014) across public and private facilities in Uganda (11). Our finding also aligns with rates documented in comparable sub-Saharan African primary care settings, 16.0% in Tshwane South Africa (21) and 17.3% in Ghana (22). This suggests that underreporting remains a persistent challenge across sub-Saharan Africa despite differences in health systems and practice settings. In this study, three in five participants had encountered a suspected ADR during the preceding year, yet only one in eight had submitted a report to the NDA. Among those who had observed a reaction, fewer than one in five had reported it. This indicates a substantial gap in translating recognition of suspected ADRs into formal reporting. The barriers identified in this study provide insight into this reporting gap and suggest that improving ADR reporting in private facilities requires strengthening the systems that support reporting.

The most frequently cited barrier was the lack of clear reporting guidelines and forms (69.1%). This is consistent with KAP studies elsewhere in sub-Saharan Africa, where unavailability of reporting forms has repeatedly emerged as a primary structural barrier to HCP reporting (23, 24). In Uganda, Kiguba et al. (2014) reported that only one-third of HCPs at Mulago National Referral Hospital were aware of national ADR reporting forms within their own facility (11). The persistence of this barrier in the private sector suggests that challenges may relate more to inadequate distribution and accessibility of reporting tools than to lack of awareness alone. The second major barrier was the absence of feedback from NDA following report submission (51.5%). Failure to close the reporting loop may lead HCPs to perceive their contributions as having limited value thereby reducing sustained engagement with pharmacovigilance activities (25). Fear of litigation or blame was reported by 27% of the participants. Although less frequently cited, this concern likely reflects the limited institutional and legal protections available to clinicians in private practice, where formal PV committees are uncommon. Without protective policy frameworks, fear may continue to suppress reporting in this sector even among knowledgeable HCPs. Addressing these system-level barriers through improved access to reporting tools, routine feedback mechanisms, and supportive reporting environments may enhance participation of private-sector HCPs in Uganda's pharmacovigilance system.

The most frequently cited facilitator was regular pharmacovigilance training (56.7%), followed by access to up-to-date drug information (55.4%) and availability of reporting forms (54.1%). These findings are consistent with evidence from Uganda and elsewhere in sub-Saharan Africa showing that training improves ADR recognition and reporting practices among healthcare professionals. Katusiime et al

(2015) demonstrated that PV training improved ADR reporting among HCPs at Mulago Hospital (13), while evidence from Malawi similarly identified training as a key enabler of pharmacovigilance participation (15). Regular training may help translate PV from a regulatory requirement into a routine clinical practice by strengthening confidence in ADR identification, documentation, and reporting. However, training alone may be insufficient if supportive reporting systems are lacking. Digital approaches may complement these educational interventions by addressing several structural barriers identified in this study. Recent evidence from Uganda further suggests that digital tools can amplify these gains. In a cluster-randomized trial conducted in HIV clinics in Uganda, the Med Safety mobile application increased ADR reporting rates by 73% compared with existing reporting approaches (26). Earlier qualitative work also demonstrated healthcare workers' willingness to adopt the application, although concerns related to smartphone access and connectivity were noted (27). By reducing reliance on paper-based forms, facilitating feedback, and simplifying report submission, digital PV tools such as Med Safety could help address key reporting bottlenecks. Integrating such tools into private-sector healthcare settings alongside continuous PV training may therefore strengthen ADR reporting and improve participation of private facilities in Uganda's pharmacovigilance system.

Participants with greater professional experience had higher odds of ADR reporting compared with those in lower experience categories. This finding is consistent with evidence from Shanko and Abdela (2018), who reported that more experienced healthcare professionals were more likely to have awareness of the national ADR reporting system (28). The observed association may be explained by cumulative exposure to clinical practice, which may increase opportunities to encounter suspected ADRs and familiarity with pharmacovigilance processes. More experienced professionals may also have greater confidence in assessing suspected ADRs, documenting clinical information, and engaging with reporting systems. These findings suggest that less experienced healthcare professionals may benefit from targeted mentorship and supportive supervision to build confidence in ADR reporting.

Previous pharmacovigilance training was also independently associated with ADR reporting. This finding aligns with studies from Ghana, where trained healthcare professionals were more likely to report ADRs (22), and Malawi, where in-service training improved pharmacovigilance practices (15). Training may enhance reporting by improving recognition of suspected ADRs, increasing familiarity with reporting procedures, and reducing uncertainty regarding what constitutes a reportable event. Integrating PV training into routine continuing professional development activities for private-sector healthcare professionals may therefore strengthen reporting capacity when combined with improvements in the reporting environment.

Limitations

This study has some limitations that should be considered in the interpretation of its findings. The study was conducted in a single urban setting, which may limit generalizability to rural private facilities and to other regions of Uganda. The cross-sectional design limits the ability to establish temporal relationships or causal inferences between factors such as PV training, professional experience, and ADR reporting

behavior. Additionally, ADR reporting was self-reported and may have been affected by recall bias and social desirability bias. The internal consistency of the attitude scale was low (Cronbach's $\alpha = 0.43$), limiting confidence in interpreting attitude as a single composite construct. Therefore, individual attitude items presented in Table 2 provide more meaningful insight than the overall attitude score classification.

Despite these limitations, the study provides important insights into ADR reporting practices and the system-level barriers and facilitators influencing pharmacovigilance participation among private-sector healthcare professionals in Uganda.

Conclusion

The findings of this study demonstrate that ADR reporting among healthcare professionals in private health facilities in Mbarara City remains low. Despite generally good knowledge of ADR reporting and favorable attitudes towards pharmacovigilance, a substantial gap remained between recognition of suspected ADRs and actual reporting. This suggests that underreporting in private facilities is driven largely by health-system constraints rather than inadequate awareness among healthcare professionals. The main barriers identified were limited access to reporting guidelines and forms, inadequate feedback from the regulator, and insufficient pharmacovigilance training. Reporting practices were higher among professionals with greater experience and those who had previously received PV training. Improving private-sector pharmacovigilance in Uganda will require a coordinated approach that ensures reliable access to reporting tools, strengthens feedback mechanisms between the National Drug Authority and healthcare professionals, and embeds continuous PV training within routine professional development.

Abbreviations

- ADR
adverse drug reaction
- aOR
adjusted odds ratio
- AUC
area under the curve
- CI
confidence interval
- cOR
crude odds ratio
- HCP
healthcare professional
- MRRH
Mbarara Regional Referral Hospital
- MUST
Mbarara University of Science and Technology

NDA
National Drug Authority
NPC
National Pharmacovigilance Centre
PV
pharmacovigilance
ROC
receiver operating characteristic
SD
standard deviation
SSA
sub-Saharan Africa
UBOS
Uganda Bureau of Statistics
WHO
World Health Organization

Declarations

Ethics approval and consent to participate

Ethical approval to conduct this study was granted by the department of pharmacy institutional research committee (IREC) at Mbarara University of Science and Technology, which reviews and approves undergraduate research protocols within the Faculty of Health Sciences. Permission to conduct the study was obtained from the management of each participating health facility. All participants received a detailed explanation of the study's purpose, procedures, risks, and benefits before enrolment. Written informed consent was obtained from participants completing the paper questionnaire, and electronic informed consent from those completing the online version. Participation was voluntary, and participants were free to decline or withdraw at any point without consequence. Neither participant names nor facility names were recorded. Only unique identifiers were used throughout the study. The study was conducted in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable

Availability of data and materials

The data that supports the findings of this study are available from the corresponding author upon reasonable request.

Competing interests

Data and materials used in this study are available from the corresponding author upon request.

Funding:

Not applicable.

Authors' contributions

All the authors named in this manuscript have contributed greatly to this work and meet the criteria for authorship. CC, MO, SO, MM, and JK conceptualized and designed the study. CC, MO, SO, and MM collected the data under the supervision of JK. AO, AES, and JK analyzed the data. CC, JK, and TMY drafted the manuscript. AO, JK, AES, and TMY substantively revised the manuscript. All authors read and approved of the final manuscript.

Acknowledgments

The authors thank the healthcare professionals from private health facilities in Mbarara City who participated in this study and generously shared their experiences and perspectives on adverse drug reaction reporting. We also acknowledge the support provided by the management and staff of the participating health facilities during data collection.

References

1. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. *Lancet*. 2000;356(9237):1255–9. 10.1016/S0140-6736(00)02799-9 PubMed PMID: 11072960.
2. Sultana J, Cutroneo P, Trifirò G. Clinical and economic burden of adverse drug reactions. *J Pharmacol Pharmacother*. 2013;4(1suppl):S73–7. 10.4103/0976-500X.120957.
3. Impicciatore P, Choonara I, Clarkson A, Provasi D, Pandolfini C, Bonati M. Incidence of adverse drug reactions in paediatric in/out-patients: a systematic review and meta-analysis of prospective studies. *Br J Clin Pharmacol*. 2001;52(1):77–83. 10.1046/j.0306-5251.2001.01407.x PubMed PMID: 11453893; PubMed Central PMCID: PMC2014499.
4. Cosgrave N, Frydenlund J, Beirne F, Lee S, Faez I, Cahir C, et al. Hospital admissions due to adverse drug reactions and adverse drug events in older adults: a systematic review. *Age Ageing*. 2025;54(8):afaf231. 10.1093/ageing/afaf231.
5. Mouton JP, Jobanputra N, Tatz G, Cohen K. Serious adverse drug reactions in sub-Saharan Africa in the era of antiretroviral treatment: A systematic review. *Pharmacol Res Perspect*. 2021;9(6):e00875. 10.1002/prp2.875.
6. Yadesa TM, Kitutu FE, Tamukong R, Alele PE. Prevalence, incidence, and characteristics of adverse drug reactions among older adults hospitalized at mbarara regional referral hospital, Uganda: A prospective cohort study. *Clin Interv Aging*. 2021;16:1705–21. 10.2147./CIA.S332251 PubMed PMID: 34588772.

7. World Health Organization. The importance of pharmacovigilance [Internet]. 2002 [cited 2026 Jul 29]. Available from: <https://www.who.int/publications/i/item/10665-42493>
8. Bailey C, Peddie D, Wickham ME, Badke K, Small SS, Doyle-Waters MM, et al. Adverse drug event reporting systems: a systematic review. *Br J Clin Pharmacol*. 2016;82(1):17–29. 10.1111/bcp.12944.
9. García-Abeijon P, Costa C, Taracido M, Herdeiro MT, Torre C, Figueiras A. Factors Associated with Underreporting of Adverse Drug Reactions by Health Care Professionals: A Systematic Review Update. *Drug Saf*. 2023;46(7):625–36. 10.1007/s40264-023-01302-7.
10. National Drug Authority. Professional Guidelines on Detecting and Reporting Adverse Drug Reactions in Uganda [Professional Guidelines] [Internet]. Kampala, Uganda: National Drug Authority; 2019 Oct. Professional Guidelines DPS/GDL/013, Revision 1. Available from: <https://www.nda.or.ug/wp-content/uploads/2022/02/GUIDELINES-detecting-and-reporting-ADR.pdf>
11. Kiguba R, Karamagi C, Waako P, Ndagije HB, Bird SM. Recognition and reporting of suspected adverse drug reactions by surveyed healthcare professionals in Uganda: key determinants. *BMJ Open*. 2014;4(11):e005869. 10.1136/bmjopen-2014-005869 . PubMed PMID: 25421337.
12. National Drug Authority. ANNUAL PHARMACOVIGILANCE REPORT 2022-23 [Internet]. Kampala, Uganda: National Drug Authority. 2023. Available from: https://www.nda.or.ug/wp-content/uploads/2023/12/ANNUAL-PHARMACOVIGILANCE-REPORT-2022_23-1-1.pdf
13. Katusiime B, Semakula D, Lubinga SJ. Adverse drug reaction reporting among health care workers at Mulago National Referral and Teaching hospital in Uganda. *Afr Health Sci*. 2015;15(4):1308–17. 10.4314/ahs.v15i4. 34 PubMed PMID: 26958036; PubMed Central PMCID: PMC4765406.
14. Moyo E, Moyo P, Mangoya D, Imran M, Dzinamarira T. Adverse drug reaction reporting by healthcare providers in sub-Saharan Africa: A scoping review of the challenges faced and the strategies to address the challenges. *Int J Afr Nurs Sci*. 2023;19:100639. 10.1016/j.ijans.2023.100639.
15. Chiumia F, Dzabala N, Ndalama A, Sambakunsi C, Raguenaud ME, Merle C, et al. Impact of in-service training on the knowledge, attitude, and practice of pharmacovigilance in Malawi: a cross-sectional mixed methods study. *Malawi Med J J Med Assoc Malawi*. 2024;36(3):163–9. 10.4314/mmj.v36i3. 2 PubMed PMID: 40018398; PubMed Central PMCID: PMC11862858.
16. N IO, R KPS JR. Barriers to and facilitators of healthcare professionals in ADR reporting in a tertiary care hospital in India. *BMC Health Serv Res*. 2025;25(1):166. 10.1186/s12913-024-12139-w.
17. Basu S, Andrews J, Kishore S, Panjabi R, Stuckler D. Comparative Performance of Private and Public Healthcare Systems in Low- and Middle-Income Countries: A Systematic Review. *PLOS Med*. 2012;9(6):e1001244. 10.1371/journal.pmed.1001244.
18. Turyamureba M, Yawe BL, Oryema JB. Factors influencing public and private healthcare utilisation in Uganda. *Afr Health Sci*. 2023;23(3):724–31. 10.4314/ahs.v23i3.83 . PubMed PMID: 38357188; PubMed Central PMCID: PMC10862578.
19. Uganda Bureau of Statistics. The National Population and Housing Census 2024 – Final Report, Volume 1 (Main) [Internet]. Kampala, Uganda: Uganda Bureau of Statistics. 2024. Available from:

- <https://www.ubos.org/wp-content/uploads/2024/12/National-Population-and-Housing-Census-2024-Final-Report-Volume-1-Main.pdf>
20. Annual-Pharmacovigilance-Report NDAN. -2023-2024 [Internet]. 2024. Available from: https://www.nda.or.ug/wp-content/uploads/2024/10/Annual-Pharmacovigilance-Report-2023-2024_compressed.pdf&ved=2ahUKEwiYss-KrouRAxUWXEEAHRJ901AQFnoECCAQAQ&usg=AOvVaw3jascq-rM6wKNjv2z8rz39
 21. Haines HM, Meyer JC, Summers RS, Godman BB. Knowledge, attitudes and practices of health care professionals towards adverse drug reaction reporting in public sector primary health care facilities in a South African district. *Eur J Clin Pharmacol*. 2020;76(7):991–1001. 10.1007/s00228-020-02862-8 . PubMed PMID: 32296857; PubMed Central PMCID: PMC7306046.
 22. Asiamah M, Akuffo KO, Nortey P, Donkor N, Danso-Appiah A. Spontaneous reporting of adverse drug reaction among health professionals in Ghana. *Arch Public Health*. 2022;80(1):33. 10.1186/s13690-021-00783-1.
 23. Adisa R, Omitogun TI. Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in Ibadan, southwestern Nigeria. *BMC Health Serv Res*. 2019;19(1):926. 10.1186/s12913-019-4775-9 . PubMed PMID: 31796034; PubMed Central PMCID: PMC6889459.
 24. Polile R, Maja L, Mautsoe R, Mokonyana M, Shelile M, Mabuzela M. Healthcare Professionals' Knowledge, Attitudes and Practices Towards Pharmacovigilance and Adverse Drug Reaction Reporting in Public Hospitals in Lesotho: DOI: <https://dx.doi.org/10.4314/ajhs.v38i2.10>. *Afr J Health Sci* [Internet]. 2025 Dec 19 [cited 2026 May 18];38(2). Available from: <https://ojs.ajhsjournal.or.ke/index.php/home/article/view/704>
 25. Mwakawanga DL, Kilonzi M, Philipo EG, Martine A, Mbilinyi T, Kileo NF et al. Pharmacovigilance and Adverse Drug Reactions Reporting: Healthcare Providers' Experiences from Southern Highland Tanzania. Dar AA, editor. *Adv Pharmacol Pharm Sci*. 2023;2023:1–10. 10.1155/2023/5537592
 26. Kiguba R, Ndagije HB, Mwebaza N, Ssenyonga R, Giibwa L, Isabirye G, et al. Adverse drug reaction reporting with the Med Safety app in Uganda: a cluster-randomised, controlled trial. *Lancet Glob Health*. 2025;13(10):e1761–70. 10.1016/S2214-109X. (25)00299-2 PubMed PMID: 40975083; PubMed Central PMCID: PMC12446902.
 27. Kiguba R, Zakumumpa H, Ndagije HB, Mwebaza N, Ssenyonga R, Tregunno P, et al. Facilitators and Barriers to Uptake of the Med Safety Mobile App for Adverse Drug Reaction Reporting by Health Workers in Uganda: A Qualitative Study. *Drug Saf*. 2023;46(6):565–74. 10.1007/s40264-023-01303-6.
 28. Shanko H, Abdela J, Knowledge. Attitudes, and Practices of Health Care Professionals Toward Adverse Drug Reaction Reporting in Hiwot Fana Specialized University Hospital, Harar, Eastern Ethiopia: A Cross-sectional Study. *Hosp Pharm*. 2018;53(3):177–87. 10.1177/0018578717737430.

Figures

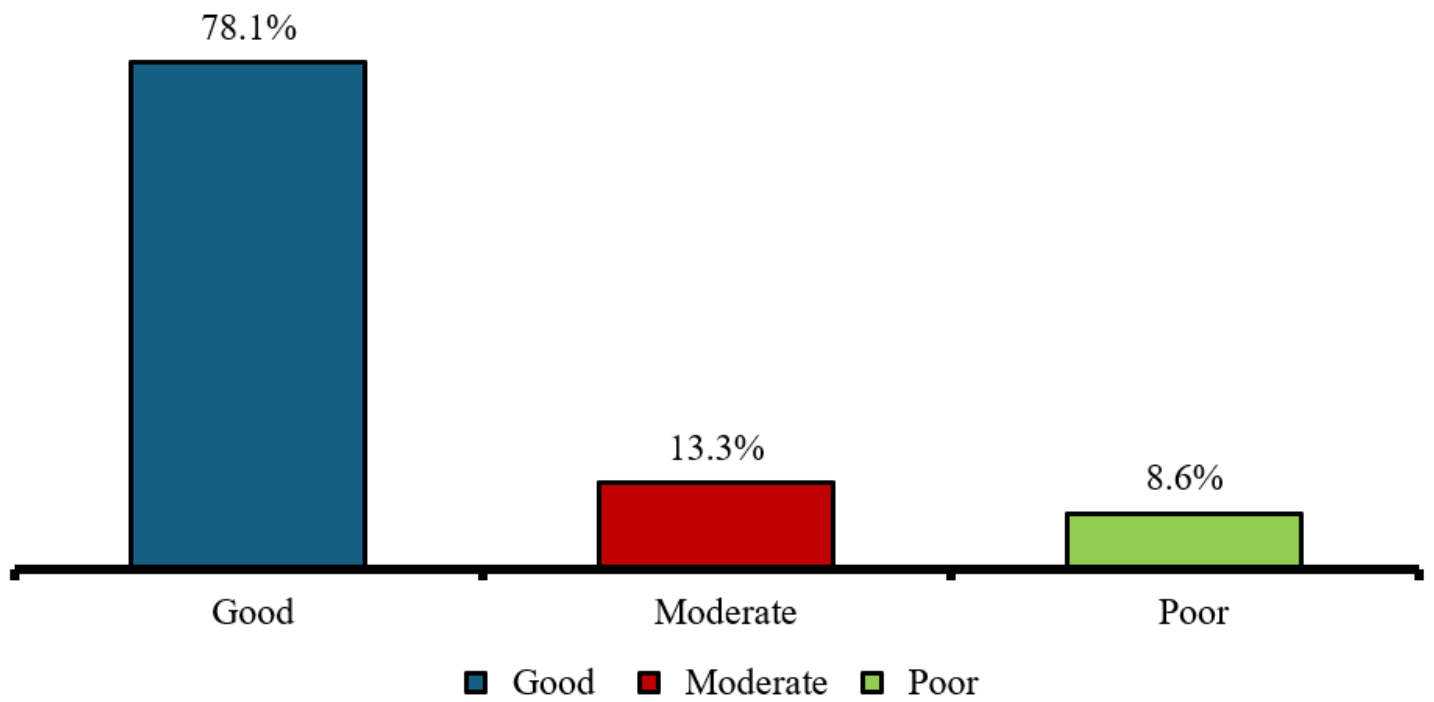
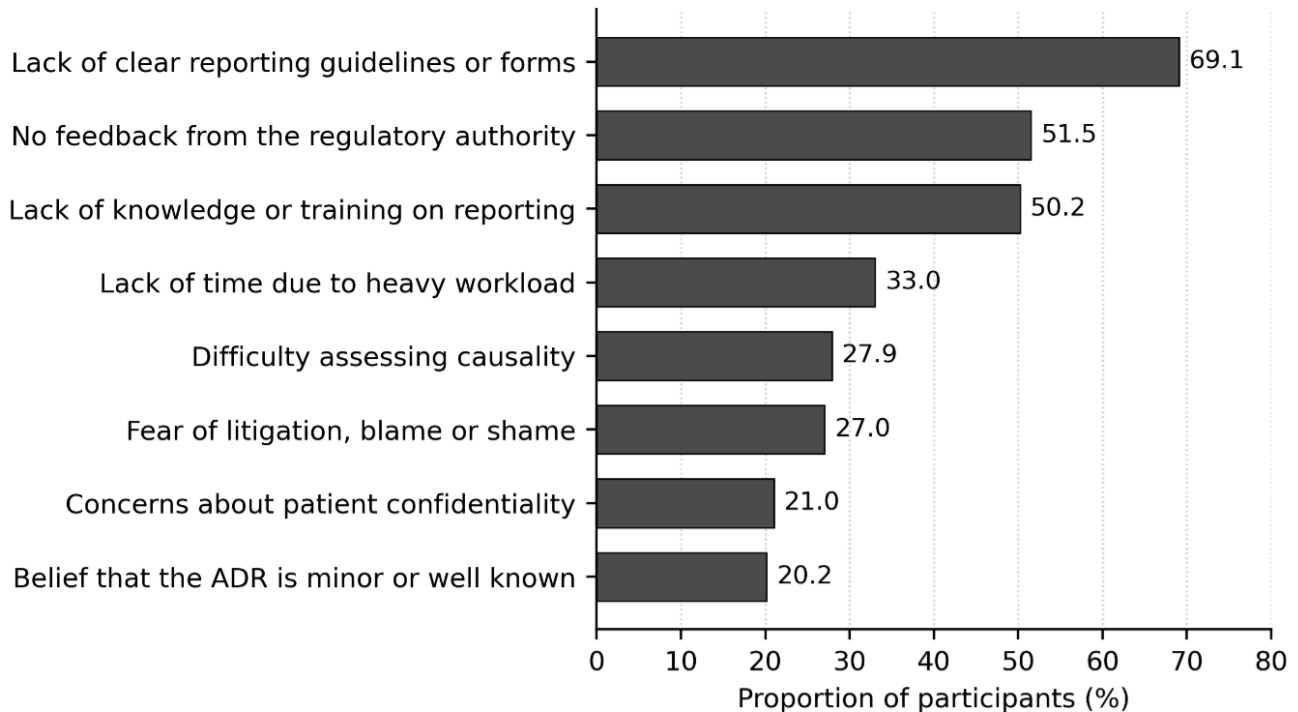


Figure 1

Knowledge of ADR reporting among the study participants categorized using Bloom's cut-off points: Good ($\geq 80\%$), Moderate (60-79%), Poor ($< 60\%$).

A. Barriers to ADR reporting



B. Facilitators of ADR reporting

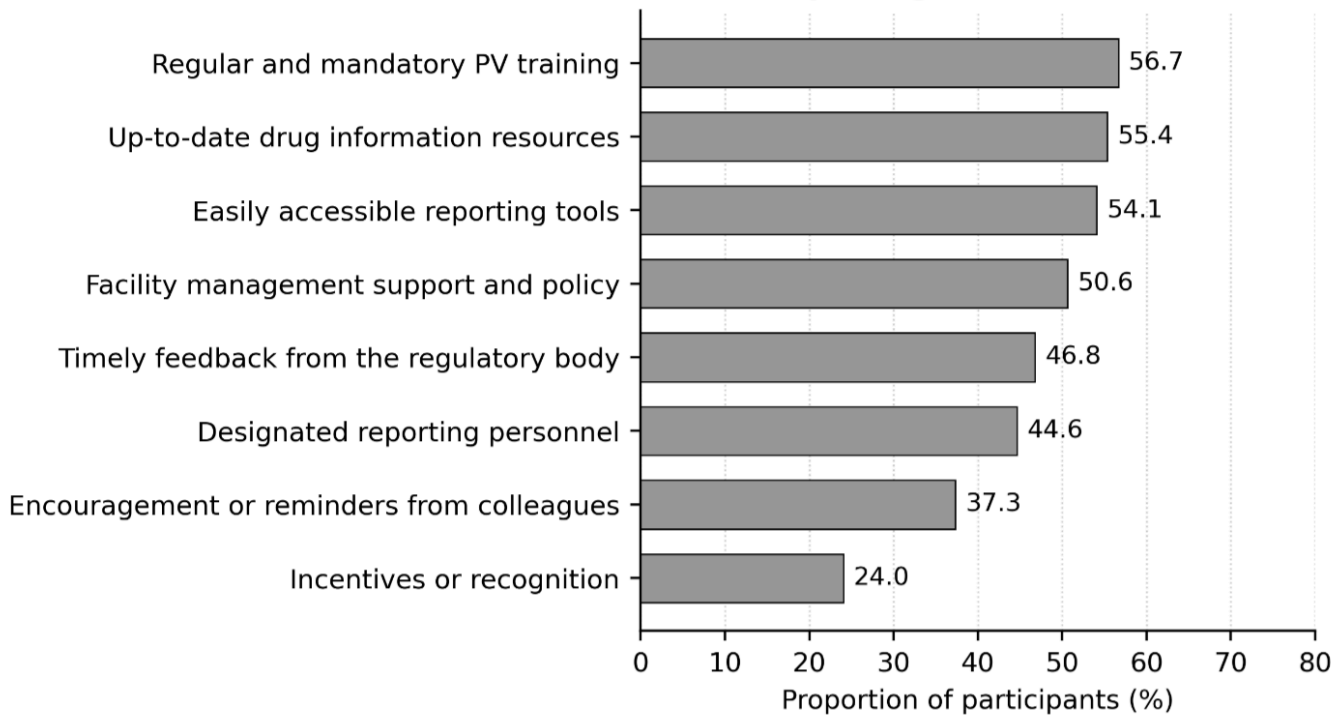


Figure 2

Barriers to and facilitators of adverse drug reaction reporting among healthcare professionals in private health facilities in Mbarara City, March 2026 (n = 233).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [DatacollectiontoolADRreporting.pdf](#)