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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

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ABSTRACT

Background: Preventable adverse drug reactions (ADR) and adverse events following immunization (AEFI) are more prevalent in patients of low- and middle-income nations compared to high-income countries. Sub-Saharan Africa (SSA) experiences more ADR and AEFI for many reasons, including poor quality control of drug products, extensive use of substandard traditional and herbal medicines, environmental influences, and genetic factors. This scoping review aimed to explore the challenges to ADR and AEFI reporting by healthcare providers in SSA and strategies that can be used to address these challenges.

Methods: In this scoping review, articles reporting on primary research conducted in SSA to identify challenges to ADR and AEFI reporting and strategies to address these challenges, and published in English, were retrieved from three databases (Google Scholar, ScienceDirect, and PubMed). The quality of the selected quantitative studies was evaluated utilizing the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) 22-item checklist. In contrast, qualitative studies were evaluated for credibility, confirmability, dependability, and transferability. The guidelines specified in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement were followed in this scoping review.

Results: This review revealed several challenges to ADR and AEFI reporting in SSA. The challenges were categorized into healthcare provider-related, work-related, material/tools-related, and national pharmacovigilance activities-related challenges. Several strategies to address the challenges were also revealed and categorized into healthcare providers, reporting material/tools and mechanisms strategies, national or institutional pharmacovigilance, and community engagement strategies.

Conclusion: Countries in SSA face several challenges to ADR and AEFI reporting. Strategies identified to improve the reporting of ADR and AEFI should be prioritized so that unnecessary morbidity and mortality are avoided in the region.

1. Introduction

Preventable adverse drug reactions (ADR) and adverse events following immunization (AEFI) are more prevalent in patients of low- and middle-income countries compared to high-income countries (Angamo et al., 2016). This has been attributed to several factors. LMICs have a lofty incidence of anemia and undernourishment, more people on antitubercular (anti-TB) and antiretroviral therapy (ART), and an elevated incidence of concomitant anti-TB and ART with overlapping side effects (Angamo et al., 2016). Since there are only a few reliable and operational local pharmaceutical firms in SSA, most medications must be imported from other continents. There is complexity and a lack of efficiency in the distribution networks. Moreover, procurement is inefficient, with insufficient space to store goods. Substandard and fake medications can enter the countries in the region due to the lenient border and customs entrance points (Adebisi et al., 2022).

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Although countries in SSA have National Medicines Regulatory Authorities, none of these authorities can undertake the full range of regulatory functions such as product assessment and registration, licensing manufacturers, inspection of distribution channels, quality management systems, and market and safety surveillance (Ndomondo-Sigonda et al., 2017). Poor drug registration occurs in some countries in SSA due to weak regulatory frameworks. Many countries in SSA lack facilities for drug quality control as well. Traditional medications and herbal remedies are also widely used, but their contents are frequently unknown and, in some cases, contain a dangerous combination of ingredients (Kiguba et al., 2023). Self-medication practices are highly prevalent, with easy access to prescription medicines. The other factor that might contribute to more ADR and AEFI in SSA is that data are principally derived from high-income countries with firm pharmacovigilance practices. Yet, the safety profile of several drugs can vary between settings because of environmental and genetic influences (Kiguba et al., 2023). What is worrying is that the novel medicines being created for use mainly in SSA, such as vaccines for malaria and Ebola virus disease, will rely on the current suboptimal systems of the nations in the region to provide the safety profiles of the new medicines in the post-marketing period.

Globally, up to 27% of all admissions in intensive care units are a result of ADR, with an associated mortality rate of up to 28% (Jolivot et al., 2014). It is estimated that the incidence of AEFI in sub-Saharan Africa (SSA) may be as high as 34% (Laryea et al., 2022). Apart from high rates of ADR and AEFI, SSA has also experienced several morbidities and mortalities as a result of contaminated drugs. In 2009, 13 children developed acute renal failure at a hospital in Lagos, Nigeria. It was reported that this resulted from an acetaminophen-based teething medicine contaminated with diethylene glycol that the children had used (Abubakar et al., 2009). In 2022, 66 children in the Gambia died after taking some cough syrups. Laboratory testing revealed that each implicated cough syrup had unsafe concentrations of ethylene and diethylene glycol contaminants (Tarntray et al., 2023). Had initial symptoms been reported early, more deaths could have been avoided.

The reporting of ADR remains very low in SSA. By 2015, only 0.88% of the individual case safety reports presented to VigiBase were from Africa. Furthermore, of all the individual case safety reports reported to VigiBase from African countries by the end of September 2015, 50% were from three nations, namely Nigeria, South Africa, and Morocco (Ampadu et al., 2016). Low reporting of AEFI has also been reported among countries in SSA, and this has been attributed to a lack of guidelines and AEFI review committees, the absence of robust AEFI reporting systems, a lack of trained personnel, and weak collaboration among different stakeholders (Akanmori et al., 2018). Considering the challenges that SSA faces concerning pharmacovigilance, ADR, and AEFI reporting, we explore the challenges of reporting ADR and AEFI by healthcare providers (HCPs) in SSA and the strategies that can be used to address these challenges.

2. Methodology

2.1. Study design

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement was loosely used as a reference for this scoping review. We chose a scoping review since it would help us identify the body of literature on challenges of ADR and AEFI reporting by HCPs in SSA and strategies that can be used to address these challenges. Additionally, this scoping review would be used as a precursor to a systematic review on the same subject.

2.2. Research question and study eligibility

The problem-interest-context (PICo) framework was utilized to establish the requirements for qualifying for the review question. This framework identified the problem (P) as ADR and AEFI reporting, the HCPs as the subject of interest (I), and the SSA as the context (Co). The purpose of this review was to address the following research questions:

i. What are the challenges of ADR and AEFI reporting by HCPs in SSA?

ii. What strategies can be used to address the challenges of ADR and AEFI reporting by HCPs in SSA?

2.3. Inclusion criteria

Studies were considered eligible if they were original qualitative and quantitative research that were conducted in SSA and reported on the challenges HCPs have when reporting ADRs and AEFI, and strategies that can be used to address the challenges. They were also supposed to have been published in English between 2017 and 2022.

2.4. Exclusion criteria

Editorials, letters to the editor, systematic reviews, meta-analyses, and review articles were all excluded from this review.

2.5. Literature sources and search strategy

We looked for peer-reviewed English-language publications from 2017 to 2022 in the Google Scholar, ScienceDirect, and PubMed databases. The keywords we used for the literature search were 'adverse drug reaction reporting', 'adverse drug events reporting', 'adverse events following immunization reporting', 'sub-Saharan Africa', 'challenges', and 'strategies.' Boolean operators 'AND' and 'OR' were used to find articles that contained either one of the terms or both terms. The full-text versions of all studies that potentially satisfied the inclusion criteria were retrieved and evaluated. We looked through the reference lists of every article we found for any more relevant publications that database searches had missed. Two reviewers independently assessed each paper's title and abstract before comparing their results. Where discrepancies were discovered, they were resolved by dialogue or judgment by a third reviewer.

2.6. Data extraction

The authors' data extraction form included fields for the names of the authors, publication year, country, study design, major results on the challenges HCPs have in reporting ADRs and AEFI, and possible solutions. We then provided a narrative description of the major findings from the included articles after extraction.

3. Findings

Six hundred articles were obtained from the primary search of all databases. After eliminating the 250 duplicates, 100 articles remained. After the initial round of title screening, 82 abstracts were considered for abstract screening. The authors performed a conceptual screening to determine if the retrieved publications addressed the challenges of ADR and AEFI reporting by HCPs and the strategies used to overcome these difficulties in SSA. The reviewers also looked at when the articles were published and whether or not they presented new findings. After the initial conceptual screening, 53 papers were eliminated, leaving 29 for full-text review. Six articles failed to pass the full-text screening because they did not address the challenges of ADR and AEFI reporting by HCPs. In total, this review includes 23 articles (Fig. 1).

3.1. Characteristics of included studies

Twenty-three articles published in different journals were considered for this review. To assess the quality of the included quantitative studies, the authors used the Strengthening the Reporting of Observational

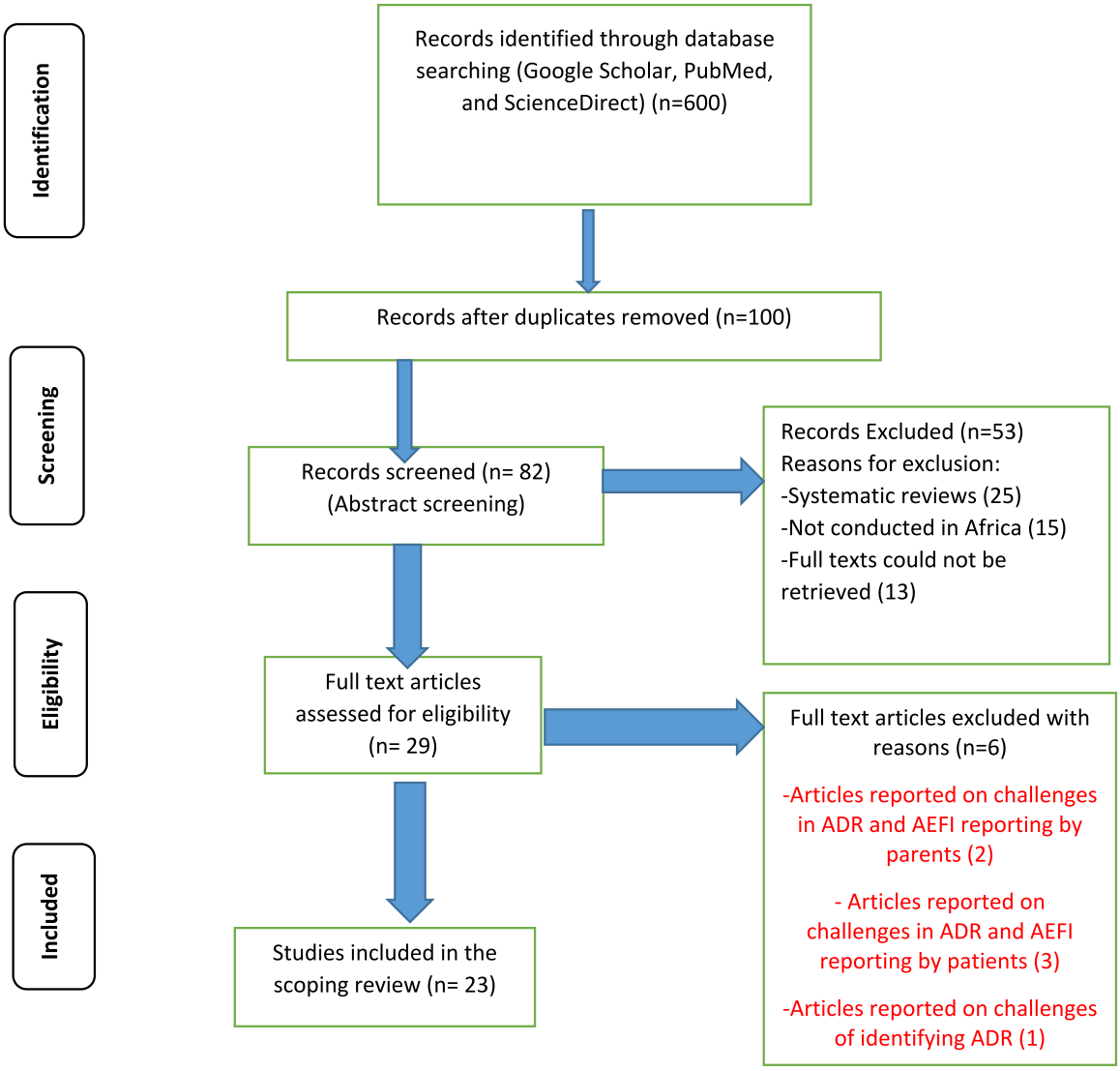

Fig. 1. PRISMA Flowchart.

Studies in Epidemiology (STROBE) 22-item checklist (Cuschieri 2019). Comparatively, the credibility, reliability, confirmability, and transferability of qualitative studies were evaluated (Stenfors et al., 2020). According to both reviewers, all the included articles were of good quality. Four studies were conducted in Ghana (Aborigo et al., 2022; Adu-Gyamfi et al., 2022; Gidudu et al., 2020; Osei et al., 2021), three studies in South Africa (Bogolubova, et al., 2018; Gordhon & Padayachee, 2020; Terblanche et al., 2017), two each in Ethiopia (Gidey et al., 2020; Nadew et al., 2020), Kenya (Malande et al., 2021; Nyagah et al., 2020), and Sudan (Babiker Osman & Mohamed Awad, 2021; Saeed, et al., 2021), and one each in Zimbabwe (Mugauri et al., 2018), Zambia (Prashar et al., 2019), Tanzania (Kiwanuka et al., 2019), Namibia (Adenuga et al., 2020a, 2020b), Rwanda (Ryamukuru et al., 2022), Malawi (Jusot et al., 2020), Nigeria (Opadeyi et al., 2018), Uganda (Kiguba et al., 2020), Eritrea (Abdu et al., 2022), and one multinational (Stegmann et al., 2022). Sixteen of the studies (Abdu et al., 2022; Adenuga et al., 2020a, 2020b; Adu-Gyamfi et al., 2022; Babiker Osman & Mohamed Awad, 2021; Bogolubova et al., 2018; Gidey et al., 2020; Gidudu et al., 2020; Gordan & Bangalee, 2022; Kiguba et al., 2020; Kiwanuka et al., 2019; Nyagah et al., 2020; Osei et al., 2021; Prashar et al., 2019; Ryamukuru et al., 2022; Saeed et al., 2021; Terblanche et al., 2017) used a cross-sectional study design, four (Malande et al., 2021; Mugauri et al., 2018; Nadew et al., 2020; Opadeyi et al., 2018) a mixed methods design, two (Jusot et al., 2020; Stegmann et al., 2022) an implementation research design, and one a qualitative exploratory descriptive study design (Aborigo et al., 2022). More details are presented in Table 1.

3.2. *Review findings*

The findings of this scoping review are presented below. More details are presented in Table 2.

3.2.1. *Challenges of ADR and AEFI reporting*

Eighteen of the included studies reported on the challenges of ADR reporting (Adenuga et al., 2020a, 2020b; Adu-Gyamfi et al., 2022; Babiker Osman & Mohamed Awad, 2021; Bogolubova et al., 2018; Gidey et al., 2020; Gordan & Bangalee, 2022; Jusot et al., 2020; Kiguba et al., 2020; Kiwanuka et al., 2019; Mugauri et al., 2018; Nadew et al., 2020; Nyagah et al., 2020; Opadeyi et al., 2018; Osei et al., 2021; Prashar et al., 2019; Ryamukuru et al., 2022; Saeed et al., 2021; Terblanche et al., 2017), four reported on the challenges of AEFI reporting (Abdu et al., 2022; Aborigo et al., 2022; Gidudu et al., 2020; Malande et al., 2021), while one reported on both ADR and AEFI (Stegmann et al., 2022). We categorized the challenges into healthcare provider-related, work-related, material/tools-related, and national pharmacovigilance

Table 1
Characteristics of included studies.

Authors, Publication year	Reference	Country where the study was conducted	Study design
Abdu N, Mosazghi A, Yehdego T, Tesfamariam EH, Russom M., 2022	(Abdu, et al., 2022)	Eritrea	Cross-sectional study
Aborigo RA, Welaga P, Oduro A, Shaum A, Opare J, Dodoo A, et al., 2022	(Aborigo, et al., 2022)	Ghana	Qualitative exploratory descriptive study
Adenuga BA, Kibuule D, Rennie TW, 2020	(Adenuga, et al., 2020)	Namibia	Cross-sectional study
Adu-Gyamfi PK, Mensah KB, Ocansey J, Moomin A, Danso BO, Agyapong F, et al. 2022.	(Adu-Gyamfi, et al., 2022)	Ghana	Cross-sectional study
Babiker Osman AM, Mohamed Awad M, 2021	(Babiker Osman & Mohamed Awad, 2021)	Sudan	Cross-sectional study
Bogolubova S, Padayachee N, Schellack N, 2018	(Bogolubova, et al., 2018)	South Africa	Cross-sectional survey
Gidey K, Seifu M, Hailu BY, Asgedom SW, Niriayo YL, 2020	(Gidey, et al., 2020)	Ethiopia	Cross-sectional study
Gidudu JF, Shaum A, Dodoo A, Bosomprah S, Bonsu G, Amponsa-Achiano K, et al. 2020	(Gidudu, et al., 2020)	Ghana	Cross-sectional study
Gordan A, Bangalee V, 2022	(Gordan & Bangalee, 2022)	South Africa	Cross-sectional study
Jusot V, Chimimba F, Dzabalala N, Menang O, Cole J, Gardiner G, et al., 2020	(Jusot, et al., 2020)	Malawi	Implementation research
Kiguba R, Ndagije HB, Nambasa V, Manirakiza L, Kirabira E, Serwanga A, et al., 2020	(Kiguba, et al., 2020)	Uganda	Cross-sectional study
Kiwanuka M, Muro FJ, Alloyce PJ, Muro EP, 2019	(Kiwanuka, et al., 2019)	Tanzania	Cross-sectional study
Malande OO, Munube D, Afaayo RN, Chemweno C, Nzoka M, Kipsang J, et al., 2021	(Malande, et al., 2021)	Kenya	Mixed-methods study
Mugauri H, Tshimanga M, Mugurungi O, Juru T, Gombe N, Shambira G, 2018	(Mugauri, et al., 2018)	Zimbabwe	Mixed-methods study
Nadew SS, Beyene KG, Beza SW, 2020	(Nadew, et al., 2020)	Ethiopia	Mixed-methods study
Nyagah DM, Mokaya D, Karanja SM, 2020	(Nyagah, et al., 2020)	Kenya	Cross-sectional study
Opadeyi AO, Fourrier-Réglat A, Isah AO, 2018	(Opadeyi, et al., 2018)	Nigeria	Mixed-methods study
Osei JY, Nortey PA, Bandoh DA, Kenu E, Addo-Lartey AA, 2021	(Osei, et al., 2021)	Ghana	Cross-sectional study
Prashar L, Jere E, Kalungia CA, 2019	(Prashar, et al., 2019)	Zambia	Cross-sectional study
Ryamukuru D, Mukantwari J, Munyaneza E, Twahirwa TS, Bagweneza V, Nzamukosha A, et al., 2022	(Ryamukuru, et al., 2022)	Rwanda	Cross-sectional study
Saeed AA, Umballi O, Ahmed N, Ali S, Alfaki A, 2021	(Saeed, et al., 2021)	Sudan	Cross-sectional study
Stegmann JU, Jusot V, Menang O, Gardiner G, Vesce S, Volpe S, et al., 2022	(Stegmann, et al., 2022)	Malawi, Côte d'Ivoire, and Democratic Republic of Congo (DRC)	Implementation research
Terblanche A, Meyer JC, Godman B, Summers RS, 2017	(Terblanche, et al., 2017)	South Africa	Cross-sectional study

activities-related challenges. The healthcare provider-related challenges that were revealed in the study include negative perceptions among healthcare providers toward ADR reporting (Gidey et al., 2020; Saeed et al., 2021; Srisuriyachanchai et al., 2022), low awareness of reporting procedures (Adenuga et al., 2020a, 2020b; Adu-Gyamfi et al., 2022; Aborigo et al., 2022; Bogolubova et al., 2018; Gordan & Bangalee, 2022; Jusot et al., 2020; Kiguba et al., 2020; Kiwanuka et al., 2019; Nadew et al., 2020; Nyagah et al., 2020; Prashar et al., 2019; Ryamukuru et al., 2022; Terblanche et al., 2017), and complacency (Aborigo et al., 2022; Gordan & Bangalee, 2022; Kiwanuka et al., 2019; Kiguba et al., 2020; Nadew et al., 2020). In addition, other healthcare provider-related challenges were a low clinical knowledge of ADR and AEFI (Babiker Osman & Mohamed Awad, 2021; Gidey et al., 2020; Gidudu et al., 2020; Gordan & Bangalee, 2022; Malande et al., 2021; Mugauri et al., 2018; Osei et al., 2021; Prashar et al., 2019), uncertainty about the outcome of reporting (Terblanche et al., 2017), a lack of confidence to discuss ADR (Terblanche et al., 2017), a lack of appreciation of the importance of ADR and AEFI reporting (Abdu et al., 2022; Gidudu et al., 2020; Mugauri et al., 2018; Prashar et al., 2019;), fear of blame and litigation (Abdu et al., 2022; Aborigo et al., 2022; Adu-Gyamfi et al., 2022; Gidudu et al., 2020; Malande et al., 2021; Nadew et al., 2020; Ryamukuru et al., 2022;), and poor documentation and record keeping of ADR (Opadeyi et al., 2018). The work-related challenges that were identified in the included studies were additional work associated with ADR and AEFI reporting (Abdu et al., 2022; Aborigo et al., 2022; Adu-Gyamfi et al., 2022; Gidey et al., 2020; Gidudu et al., 2020; Gordan & Bangalee, 2022; Kiguba et al., 2020; Kiwanuka et al., 2019; Malande et al., 2021; Mugauri et al., 2018; Prashar et al., 2019; Ryamukuru et al., 2022; Terblanche et al., 2017), and lack of training on ADR and AEFI reporting (Aborigo et al., 2022; Adenuga et al., 2020a, 2020b; Adu-Gyamfi et al., 2022; Gidey et al., 2020; Gidudu et al., 2020; Nyagah et al., 2020; Saeed et al., 2021). Materials/tools-related challenges identified in the study include the unavailability of ADR and AEFI reporting forms (Aborigo et al., 2022; Adu-Gyamfi et al., 2022; Bogolubova et al., 2018; Gidudu et al., 2020; Jusot et al., 2020; Kiguba et al., 2020; Kiwanuka et al., 2019; Mugauri et al., 2018; Nadew et al., 2020; Nyagah et al., 2020; Osei et al., 2021; Saeed et al., 2021; Terblanche et al., 2017), and the ADR reporting forms not being user-friendly (Saeed et al., 2021; Stegmann et al., 2022). The national pharmacovigilance activities-related challenges revealed in the study include a shortage of personnel (Stegmann et al., 2022), an inadequate budget for pharmacovigilance (Opadeyi et al., 2018), a lack of a national pharmacovigilance centre (Nyagah

Table 2
Findings from included studies.

Authors, Publication year	Reference	Findings	
		Challenges faced	**Strategies to address the challenges**
Abdu N, Mosazghi A, Yehdego T, Tesfamariam EH, Russom M., 2022.	(Abdu, et al., 2022)	– Perception that AEFI were not serious. – No motivation to report AEFI. – No knowledge of reporting. – Time constraints. – Fear of blame – Not seeing the importance of reporting	– Training of HCPs on AEFI reporting
Aborigo RA, Welaga P, Oduro A, Shaum A, Opare J, Dodoo A, et al., 2022.	(Aborigo, et al., 2022)	– Difficulty in recognizing the adverse events. – Not knowing the reporting requirements and processes. – Lack of training on AEFI. – Heavy workload – Unavailability of AEFI reporting forms. – Fear of blame – Lack of motivation for reporting	– Educating HCPs on AEFI reporting. – Effective supportive supervision to encourage AEFI reporting. – Simplifying the AEFI reporting system. – Improve the availability of AEFI forms. – Providing incentives to HCPs reporting AEFI. – Providing adequate funds for AEFI reporting. – Standardizing the reporting procedures. – Reviewing reportable AEFI to reduce workload.
Adenuga BA, Kibuule D, Rennie TW, 2020	(Adenuga, et al., 2020)	– Lack of training in pharmacovigilance – Lack of knowledge on reporting ADR	– HCP training on pharmacovigilance, how to complete ADR forms, and how to detect ADR in practice. – Use of electronic ADR reporting system – Decentralization of pharmacovigilance /ADR reporting system – Community engagement – Feedback from the pharmacovigilance centre
Adu-Gyamfi PK, Mensah KB, Ocansey J, Moomin A, Danso BO, Agyapong F, et al. 2022	(Adu-Gyamfi, et al., 2022)	– Inadequate knowledge of pharmacovigilance – Inadequate knowledge of reporting procedures – Fear that reporting ADR may be wrong – Lack of training on pharmacovigilance – Lack of time and heavy workload – Non-availability of reporting forms.	– PV training for nurses – Making ADR reporting forms more accessible – Allowing for online submission of ADR reporting forms. – Integrating electronic reporting – Giving encouragement and feedback to those who report ADR.
Babiker Osman AM, Mohamed Awad M, 2021	(Babiker Osman & Mohamed Awad, 2021)	– Lack of knowledge of drug safety-related aspects of some specific drugs	– Training of HCPs on pharmacovigilance
Bogolubova S, Padayachee N, Schellack N, 2018	(Bogolubova, et al., 2018)	– Lack of awareness with respect to the process of ADR reporting – Lack of access to ADR reporting forms	– Training regarding ADR reporting
Gidey K, Seifu M, Hailu BY, Asgedom SW, Niriayo YL, 2020	(Gidey, et al., 2020)	– Lack of training on ADR reporting – Poor knowledge of ADR – Negative attitude – Reporting thought to create an additional workload	– Training of HCPs on pharmacovigilance – Increasing awareness of existing pharmacovigilance systems
Gidudu JF, Shaum A, Dodoo A, Bosomprah S, Bonsu G, Amponsa-Achiano K, et al. 2020.	(Gidudu, et al., 2020)	– Fear of personal consequences. – Lack of knowledge/training. – Work pressure/forgetfulness. – Perception that AEFI was not serious. – No forms available. – Late/No supervision feedback	– Supervision. – Training on AEFI.
Gordan A, Bangalee V, 2022	(Gordan & Bangalee, 2022)	– Low awareness of reporting procedures – Low clinical knowledge of ADR – Time constraints – Additional work associated with reporting – Complacency by HCPs	– Training of HCPs
Jusot V, Chimimba F, Dzabalala N, Menang O, Cole J, Gardiner G, et al., 2020	(Jusot, et al., 2020)	– No clear mechanism for reporting and transmission of ADR forms – Lack of awareness of the availability and use of reporting forms – ADR forms not readily available to HCPs	– Pharmacovigilance training – Pharmacovigilance mentoring of HCPs

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Table 2 (*continued*)

Authors, Publication year	Reference	Findings	
		Challenges faced	**Strategies to address the challenges**
Kiguba R, Ndagije HB, Nambasa V, Manirakiza L, Kirabira E, Serwanga A, et al., 2020	(Kiguba, et al., 2020)	– Unavailability of reporting procedures – Poor feedback from and/or no follow-up of treated patients – Absence of reporting tools such as forms or registers – Lack of knowledge about where to report ADR – Patient overload/lack of time to report – Lack of motivation	– Feedback from National Pharmacovigilance Centre – Training of HCPs and the public – A dedicated toll-free telephone line for reporting ADR
Kiwanuka M, Muro FJ, Alloyce PJ, Muro EP, 2019	(Kiwanuka, et al., 2019)	– Lack of motivation – Uncertainty about reporting procedures – Lack of time – Unavailability of reporting forms – Ignorance	– Training HCPs on pharmacovigilance – Posters at conspicuous locations in healthcare facilities to serve as a constant reminder – Establishment of an ADR monitoring centre with a specified focal person in every hospital – Creating awareness and promoting self-reporting among patients
Malande OO, Munube D, Afaayo RN, Chemweno C, Nzoka M, Kipsang J, et al., 2021	(Malande, et al., 2021)	– Fear of blame. – Lack of knowledge – Completing the forms requires a lot of time.	– Training of HCPs on AEFI reporting
Mugauri H, Tshimanga M, Mugurungi O, Juru T, Gombe N, Shambira G, 2018	(Mugauri, et al., 2018)	– Lack of ADR knowledge by HCPs – Weak incident detection strategies – Unavailability of ADR reporting forms – HCWs overwhelmed by other responsibilities – Lack of appreciation of the importance of ADR reporting – Nonresponse by the Medicines Control Authority of Zimbabwe to reported ADR	– Improve feedback and communication from the Medicines Control Authority of Zimbabwe. – Training of HCPs
Nadew SS, Beyene KG, Beza SW, 2020	(Nadew, et al., 2020)	– Poor awareness and training on the risk of under-reporting – feeling that reporting is minor – An absence of appropriate reporting tools – delay and/or absence of feedback on reported ADR – overly burdened doctors – negligence – fear of legal liability	– improving access to ADR reporting forms – decentralise the safety monitoring system – conducting awareness training on ADR reporting
Nyagah DM, Mokaya D, Karaaja SM, 2020	(Nyagah, et al., 2020)	– inadequate training, delayed feedback – not knowing where or to whom to report – lack of a pharmacovigilance centre in the county – inadequate access to ADR forms and guidelines.	– HCP training – Promotion of ADR reporting tools
Opadeyi AO, Fourrier-Réglat A, Isah AO, 2018	(Opadeyi, et al., 2018)	– Poor budgeting for pharmacovigilance – Lack of awareness of measuring indices to monitor and evaluate pharmacovigilance. – Poor record keeping – Poor documentation of ADR	– Capacity building – Provision of training – Feedback – Information dissemination
Osei JY, Nortey PA, Bandoh DA, Kenu E, Addo-Lartey AA, 2021	(Osei, et al., 2021)	– Unavailability of reporting forms. – Uncertainty about a causal relationship between the drug and the suspected ADR.	– Improve availability of ADR forms in facilities – Making HCPs and communities aware of the online reporting system. – Training of HCPs on pharmacovigilance.
Prashar L, Jere E, Kalungia CA, 2019	(Prashar, et al., 2019)	– Low knowledge of ADR reporting – Concern that information reported may be wrong – Lack of clinical knowledge to decide whether an ADR has occurred or not – Lack of time to complete the ADR report forms – Reporting generating extra workload – Perceived unimportance of reporting a known ADR as it will make little difference to knowledge and practice	– Training HCPs
Ryamukuru D, Mukantwari J, Munyaneza E, Twahirwa TS,	(Ryamukuru, et al., 2022)	– Inadequate practices in monitoring and reporting ADR	– Training of HCPs on ADR

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Table 2 (*continued*)

Authors, Publication year	Reference	Findings	
		Challenges faced	**Strategies to address the challenges**
Bagweneza V, Nzamukosha A, et al., 2022		– Lack of awareness of policy about PV in the hospital. – Lack of awareness about the ADR reporting system in the hospital – Lack of awareness of the national agency to which ADR are reported in Rwanda – Heavy workload – Fear of blame and punishment	– Well-functioning pharmacovigilance committees at hospitals.
Saeed AA, Umballi O, Ahmed N, Ali S, Alfaki A, 2021	(Saeed, et al., 2021)	– inadequate access to ADR forms – Lack of training on pharmacovigilance – Poor attitude about ADR and pharmacovigilance – Difficulty in communicating with the pharmacovigilance centre – Difficulty in writing the ADR reports	– Educational training and workshops
Stegmann JU, Jusot V, Menang O, Gardiner G, Vesce S, Volpe S, et al., 2022	(Stegmann, et al., 2022)	– Delayed transmission of adverse events (AE) reports from all levels of the healthcare system to the national pharmacovigilance centre – Non-delivery of posted AE reports – AE forms were not user-friendly – Negative perceptions among healthcare providers (HCPs) toward AE reporting – Coordination challenges between pharmacovigilance centre and public health programs and the expanded programme of immunisation (EPI) – Shortage of pharmacovigilance personnel	– It is beneficial to adopt a stepwise approach to pharmacovigilance training within each country, either by region or by levels of the healthcare system, depending on the gaps that exist in the pharmacovigilance system. – In-house training sessions for HCPs – Adopting electronic reporting tools that are compatible with the national database – Adoption of user-friendly suspected ADR and adverse events following immunisation (AEFI) reporting forms is likely to encourage PV as routine practice by HCPs – Have clinicians and pharmacists as pharmacovigilance focal points since they have the medical knowledge to detect and notify AEs – Adequate funding of PV activities – Establishment of national pharmacovigilance guidelines and regulations – Effective and transparent collaboration with the EPI
Terblanche A, Meyer JC, Godman B, Summers RS, 2017	(Terblanche, et al., 2017)	– Majority of HCPs were unaware of pharmacovigilance system in the hospital. – ADR forms were not available – Some HCPs did not know where to submit the completed ADR forms – Lack of time – Additional workload – Uncertainty about the outcome of reporting – Lack of confidence to discuss ADR with colleagues	– Training on ADR reporting – Implementation of systems to facilitate relevant processes

et al., 2020), difficulty in communicating with the pharmacovigilance centre (Saeed et al., 2021; Stegmann et al., 2022), non-response from the pharmacovigilance centre (Gidudu et al., 2020; Kiguba, et al., 2020; Mugauri et al., 2018; Nadew et al., 2020), unavailability of reporting procedures (Kiguba et al., 2020), and no clear mechanism of reporting and transmission of ADR and AEFI reporting forms (Jusot et al., 2020).

3.2.2. *Strategies to address the challenges of ADR and AEFI reporting*

All the included studies in this review reported on strategies to address the challenges of ADR and/or AEFI reporting. We categorized the strategies into those aimed at HCPs, reporting material/tools and mechanisms strategies, national or institutional pharmacovigilance, and community engagement. All the studies included in this review reported that training HCPs on ADR and AEFI reporting and pharmacovigilance was important in addressing HCP-related challenges. Another HCP-related strategy mentioned was the pharmacovigilance mentoring of HCPs (Jusot et al., 2020). Reporting material/tools and mechanisms strategies revealed in the included studies include the use of electronic reporting tools (Adenuga et al., 2020a, 2020b; Adu-Gyamfi et al., 2022; Osei et al., 2021; Stegmann et al., 2022), adopting user-friendly ADR and AEFI forms (Aborigo, et al., 2022; Stegmann et al., 2022), improving access to ADR and AEFI reporting forms (Adenuga et al., 2020a, 2020b; Aborigo et al., 2022; Nadew et al., 2020; Nyagah et al., 2020), improving supervision on reporting (Aborigo et al., 2022; Gidudu et al., 2020), and providing incentives to HCPs for reporting AEFI (Aborigo et al., 2022). Strategies related to national or institutional pharmacovigilance revealed in the included studies are the establishment of national pharmacovigilance guidelines and regulations (Kiwanuka et al., 2019; Stegmann et al., 2022; Terblanche et al., 2017;), adequate funding of pharmacovigilance activities (Stegmann et al., 2022), an effective and transparent collaboration of the national pharmacovigilance centre with the expanded program of immunization (Stegmann et al., 2022) and improving feedback from the pharmacovigilance centre (Adenuga et al., 2020a, 2020b; Adu-Gyamfi et al., 2022; Kiguba et al., 2020; Mugauri et al., 2018; Opadeyi et al., 2018). Furthermore, other pharmacovigilance strategies revealed by this review include having healthcare providers as pharmacovigilance focal points (Stegmann et al., 2022), decentralizing pharmacovigilance activities (Adenuga et al., 2020a, 2020b; Nadew et al., 2020), increasing awareness of existing pharmacovigilance systems (Gidey et al., 2020), pharmacovigilance capacity building (Opadeyi et al., 2018), and establishing well-functioning pharmacovigilance committees at hospitals (Ryamukuru et al., 2022). Community engagement strategies reported in this review include creating awareness and promoting self-reporting among patients and communities (Adenuga et al., 2020a, 2020b; Kiwanuka et al., 2019; Opadeyi et al., 2018), using posters in healthcare facilities to serve as

constant reminders about adverse events (Kiwanuka et al., 2019), and establishing toll-free telephone lines for reporting adverse events (Kiguba et al., 2020).

4. Discussion

4.1. Challenges of ADR and AEFI reporting

This scoping review revealed that perceptions among HCPs about ADR and AEFI influence their reporting of ADR and AEFI. These findings concur with the results of a study conducted in Thailand which revealed that the negative perceptions about ADR reporting by the majority of the HCPs led to poor adverse events reporting (Srisuriyachanchai et al., 2022). The negative perception may be attributed to the time required to complete the ADR and AEFI forms which increase the HCPs' workload (Katusiime et al., 2015). This study also revealed that there was low awareness of ADR and AEFI reporting procedures among HCPs. Similar findings were reported from a study conducted in Pakistan, which revealed that the majority of HCPs in the study did not know how to report an ADR at their workplace (Hussain et al., 2022). These findings may be an indication that HCPs do not receive adequate training on ADR and AEFI reporting. This scoping review revealed that low clinical knowledge of ADR and AEFI among HCPs is a challenge to ADR and AEFI reporting. A study conducted in South Africa among HCPs to evaluate their knowledge, attitudes, and practices toward ADR reporting also revealed that a lack of knowledge about adverse events was a discouraging factor in reporting the events (Gordhon & Padayachee, 2020). This lack of knowledge may lead to a lack of appreciation of the importance of ADR and AEFI reporting, uncertainty about the outcome of reporting, and a lack of confidence in discussing ADR and AEFI. This scoping review revealed that fear of blame and litigation by HCPs leads to poor ADR and AEFI reporting. These findings concur with the results of a study conducted in Australia, which revealed that the fear of blame and litigation acts as a barrier to the creation of a positive ADR reporting culture (Li et al., 2022). HCPs, therefore, need to be assured that there will be no repercussions associated with ADR and AEFI reporting so that they can feel free to report them.

This study revealed that a lack of training on ADR and AEFI contributes to poor reporting. The problem of a lack of training on ADR and AEFI is not only seen in SSA. A study conducted in Finland revealed that almost half of the participants in the study had not received training on ADR (Sandberg et al., 2022). Lack of training on ADR and AEFI among HCPs makes it difficult for them to confirm them, resulting in the ADR and AEFI not being reported. In addition, if HCPs are not trained on ADR and AEFI, they might not be aware of ADR and AEFI reporting procedures. This study also revealed that other challenges faced when reporting ADR and AEFI include the unavailability of ADR and AEFI reporting forms and the forms not being user-friendly. A study conducted in India also revealed that a lack of ADR reporting was associated with the unavailability of ADR reporting forms at the hospital (Kiran et al., 2014). Where ADR and AEFI reporting forms are not easily available, HCPs may not try to look for the forms since they are usually busy. In addition, HCPs might have forgotten about the ADR and AEFI by the time the reporting forms become available.

This scoping review revealed that challenges associated with the activities of national pharmacovigilance organizations contribute to challenges in ADR reporting. Some of the challenges include the shortage of personnel, an inadequate budget, a lack of a pharmacovigilance centre, and difficulties in communicating with the pharmacovigilance centre. A comparative assessment of the national pharmacovigilance systems in East Africa revealed that pharmacovigilance units were understaffed in all countries included in the study, and Ethiopia and Rwanda did not have a designated budget for pharmacovigilance activities (Barry et al., 2020). A baseline analysis of pharmacovigilance activities in four countries in SSA revealed that Ethiopia, Eswatini, and Nigeria's pharmacovigilance activities were not directly funded by the governments, while Eswatini did not have a medicine regulatory authority or general pharmacovigilance guidelines (Tiemersma et al., 2021). Without a pharmacovigilance centre, enough personnel, and an adequate budget, it is difficult to have guidelines and organize training of HCPs on ADR and AEFI. This study also revealed that the lack of feedback from the pharmacovigilance centre posed a challenge to ADR and AEFI reporting. This was also reported in a study conducted in Africa to evaluate pharmacovigilance systems (Sabblah et al., 2022). It is therefore important that HCPs who report ADR and AEFI receive feedback so that they are motivated to continue reporting the events.

4.2. Strategies to address the challenges of ADR and AEFI reporting

This review revealed that HCPs require training and mentoring to improve ADR and AEFI reporting. This recommendation was also suggested in a review conducted for Africa. The review suggested that HCPs should be trained in pharmacovigilance, ADR and AEFI during their training as regular in-service training (Kiguba et al., 2023). Training on ADR and AEFI should focus on awareness, knowledge, and reporting. Once HCPs are aware of ADR and AEFI and have knowledge of ADR and AEFI, they are more likely to report them. Regulatory staff training should also be strengthened since they are the ones who monitor ADR and AEFI reporting. Reporting of ADR and AEFI should also be made mandatory to increase the rates of reporting.

This review revealed that ADR and AEFI reporting may be improved by the use of electronic reporting tools, adopting user-friendly ADR and AEFI reporting forms, and improving access to ADR and AEFI reporting forms. A study conducted in East Africa also recommended the use of electronic reporting systems and mobile phone reporting applications as this may increase the number of reports. The study also recommended that national pharmacovigilance systems should establish a mechanism to capture medicine utilization, weigh the drug risk at the population level, and prioritize safety signals (Barry et al., 2020). Where electronic reporting forms are not being used, paper forms should be easily available at all healthcare facilities so that any HCP who needs to report an ADR and AEFI can easily access them.

This scoping review revealed that ADR and AEFI reporting can be improved by the establishment of a national pharmacovigilance centre, national pharmacovigilance guidelines and regulations, adequately funding the pharmacovigilance activities, improving feedback and collaboration, and decentralizing the activities. For regulatory authorities to execute their mandate, they require the necessary infrastructure and resources, including laws, systems, structures, human resources, and financial resources. Human resources should be adequate in terms of numbers, knowledge, and skills. The development of strong and sustainable pharmacovigilance systems that ensure improved reporting of ADR and AEFI requires strong political will and financial support from governments and partners. It is also essential that comprehensive guidelines on ADR and AEFI reporting are developed and implemented (Abiri & Johnson, 2019). Decentralization of pharmacovigilance activities will require healthcare facilities to have policies for universal and inclusive reporting (Adenuga et al., 2020a, 2020b).

This review revealed that community-level strategies that can be used to improve ADR and AEFI reporting include creating awareness and promoting self-reporting, using posters at healthcare facilities, and establishing toll-free telephone lines for ADR and AEFI reporting. Involving patients in ADR and AEFI reporting is important as patients are the first to notice any problems associated with the medications they are taking. However, for them to be able to recognize ADR and AEFI, they should be provided with information about ADR and AEFI when taking different types of medications. Apart from toll-free telephone lines, mobile applications for ADR and AEFI reporting should be developed to make it easier for patients to report adverse events.

4.3. Strengths and limitations of the study

One of the strengths of the study is that it followed PRISMA-P guidelines, which makes it easy for the results to be reproducible. The other strength is that two reviewers independently extracted and synthesized the data, then compared their results, which makes the results believable. The study, however, had several limitations. One of the limitations is that only articles published in English were included in this review, and this may have resulted in language bias. The other limitation is that only three databases were used for searching the articles, and this might have resulted in some articles being missed.

5. Conclusion

Patients living in low- and middle-income countries experience medication-related harm two or more times more frequently than those in high-income countries. SSA experiences more ADR and AEFI due to a lack of drug quality control facilities, extensive use of traditional medicines and herbal remedies whose contents are often not well known, and in some instances consisting of a cocktail of potentially harmful ingredients, and the use of data that are primarily derived from high-income countries with well-established pharmacovigilance systems, yet the safety profile of certain drugs may differ between settings due to environmental and genetic influences. Reporting of ADR and AEFI remains low in SSA due to several challenges. The challenges can be divided into HCP-related, work-related, material/tools-related, and national pharmacovigilance activities-related challenges. Several strategies can be used to address these challenges. These strategies are categorized into HCP, reporting material/tools and mechanisms, national or institutional pharmacovigilance, and community engagement strategies. Strategies identified to improve the reporting of ADR and AEFI should be prioritized so that unnecessary morbidity and mortality are avoided in the region.

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CRediT authorship contribution statement

Enos Moyo: Conceptualization, Formal analysis, Writing - original draft. **Perseverance Moyo:** Conceptualization, Formal analysis, Writing - original draft. **Derek Mangoya:** Writing – review & editing. **Mohd Imran:** Writing – review & editing. **Tafadzwa Dzinamarira:** Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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