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Original Article

Determinants of Adverse Drug Reaction Underreporting Among Healthcare Workers at a Tertiary Hospital in Eastern Democratic Republic of the Congo

Déterminants de la Sous-Notification des Effets Indésirables Médicamenteux par le Personnel de Santé dans un Hôpital Universitaire de l'Est de la République Démocratique du Congo

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ABSTRACT

Introduction. Underreporting of adverse drug reactions (ADRs) is a global patient safety concern, particularly acute in sub-Saharan Africa where pharmacovigilance systems are often weak. In the Democratic Republic of the Congo (DRC), the scale and causes of this underreporting within hospitals are poorly characterized, hindering improvement. This study aimed to determine the proportion of ADR reporting and identify associated determinants among healthcare workers at a tertiary hospital in Eastern DRC. **Methodology**. We conducted a prospective cross-sectional study at the HEAL Africa University Hospital from September 2024 to March 2025. We enrolled 76 healthcare workers, categorizing them as cases (n=18) if they had ever reported an ADR, or controls (n=58) if they had not. We collected data on sociodemographic and professional factors using electronic forms. We performed bivariate analysis using Pearson's chi-square test to identify factors associated with reporting. **Results**. Only 23.7% of participants had ever reported an ADR. Reporting was significantly more frequent among workers aged 41-50 years (p=0.032) and those with higher clinical qualifications (p=0.058). The most powerful associated factor was specific training on ADR reporting; 61.1% of trained workers reported events versus only 3.5% of untrained staff (p<0.001). The primary reasons cited for underreporting were lack of training (82.9% of participants were untrained), unawareness of the reporting procedure (69.0% of non-reporters), and the perception that the ADR was not severe enough to report (94.8% of non-reporters). Fear of reprisal or legal action was not a significant barrier. **Conclusion**. This study reveals critically low ADR reporting rates in a DRC teaching hospital, primarily driven by a lack of training and procedural awareness. Implementing mandatory, practical pharmacovigilance training and simplifying reporting mechanisms are urgent, actionable steps to enhance patient safety surveillance.

RÉSUMÉ

Introduction. La sous-notification des effets indésirables médicamenteux (EIM) est un enjeu mondial de sécurité des patients, particulièrement aigu en Afrique subsaharienne où les systèmes de pharmacovigilance sont souvent fragiles. En République Démocratique du Congo (RDC), l'ampleur et les causes de cette sous-notification en milieu hospitalier sont mal caractérisées, entravant toute amélioration. Cette étude visait à déterminer la proportion de notification des EIM et à identifier les déterminants associés parmi le personnel de santé d'un hôpital tertiaire de l'Est de la RDC. **Méthodologie**. Nous avons mené une étude transversale prospective à l'Hôpital Universitaire HEAL Africa de septembre 2024 à mars 2025. Nous avons inclus 76 soignants, classés comme cas (n=18) s'ils avaient déjà signalé un EIM, ou témoins (n=58) dans le cas contraire. Les données sociodémographiques et professionnelles ont été recueillies par formulaire électronique. Une analyse bivariée par test du chi-deux de Pearson a identifié les facteurs associés à la notification. **Résultats**. Seuls 23,7% des participants avaient déjà notifié un EIM. La notification était significativement plus fréquente chez les travailleurs âgés de 41 à 50 ans (p=0,032) et ceux ayant une qualification clinique supérieure (p=0,058). Le facteur associé le plus puissant était une formation spécifique à la notification ; 61,1% des formés notifiaient contre seulement 3,5% des non-formés (p<0,001). Les raisons principales de sous-notification étaient l'absence de formation (82,9% des participants), la méconnaissance de la procédure (69,0% des non-notifiants) et la perception que l'EIM n'était pas assez grave (94,8% des non-notifiants). La crainte de représailles ou d'actions légales n'était pas une barrière significative. **Conclusion**. Cette étude révèle un taux de notification des EIM très faible dans un hôpital universitaire de RDC, principalement dû à un manque de formation et de sensibilisation procédurale. La mise en œuvre d'une formation pratique obligatoire en pharmacovigilance et la simplification des mécanismes de signalement sont des mesures urgentes et réalisables pour améliorer la surveillance de la sécurité des patients.

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HIGHLIGHTS

What is known. Underreporting of adverse drug reactions (ADRs) compromises patient safety and system learning globally. This problem is exacerbated in low-resource settings with fragile health systems, but local data from hospitals in Eastern DRC are scarce.

The issue addressed. The magnitude and root causes of ADR underreporting among healthcare workers at a major referral hospital in Goma, DRC, were unknown, preventing targeted interventions.

What this study adds. This survey found that only 23.7% of staff had ever reported an ADR. Specific training was the strongest predictor: 61% of trained staff reported vs. 3.5% of untrained staff. The main barriers were lack of training, not knowing how to report, and perceiving events as "not severe enough."

Implications. Institutional change is required. Prioritizing hands-on ADR reporting training for all clinical staff and establishing a simple, blame-free reporting procedure are immediately feasible strategies to build a foundational culture of safety in this and similar settings.

INTRODUCTION

The administration of medicines in healthcare facilities is of paramount importance in saving human lives. However, this practice carries risks, particularly with regard to the adverse effects associated with medicines. These effects can vary in severity, ranging from mild to severe, even fatal, particularly when administered intravenously.

Adverse drug reactions, defined as a harmful or unpleasant reaction observed in a patient following the administration of a medicinal product, are a major concern for clinicians, particularly in resource-limited countries. These effects pose a risk to the patient's health, warranting prevention, specific treatment, dosage adjustment or withdrawal of the product [1].

Despite significant progress in healthcare, this cannot mask the negative consequences of adverse drug reactions on public health worldwide. These side effects are responsible for an increase in morbidity and mortality in various healthcare settings [2], resulting in prolonged hospital stays and increased healthcare costs [3], which are particularly pronounced among the elderly and children [4,5]. This situation represents a considerable additional burden on patient recovery and healthcare systems.

According to the World Health Organization (WHO), in 2017, in the United States of America alone, adverse drug reactions affected 1.3 million people, causing one death per day in hospitals and generating additional healthcare costs of $42 billion per year in that country [6]. On the African continent, although medication errors and their adverse effects are a universal problem that harms patients, the extent of this problem is very poorly documented on this continent [7]. Several factors could explain the occurrence of these adverse effects in patients in our healthcare facilities, namely the use of expired medicines due to inappropriate storage, failure to comply with the prescribed duration of administration, errors in drug dilution, especially when preparing drugs requiring a specific diluent, overestimation of the rate of intravenous drug administration, and overdose of administered drugs [8-11].

These unpredictable effects of medication may also be linked to the administration of known or unknown allergens to the patient because of poor communication, insufficient medical history, failure to observe drug interactions, and illegible instructions on both medication bottles and patient records. The latter accident often occurs when the prescribed drug is not available and is replaced by another similar drug [12].

In sub-Saharan Africa, the reporting of adverse drug reactions remains very low and poses a significant challenge in various healthcare settings, jeopardizing patient safety at every stage of medical care. This under-reporting is attributable to several factors, including the lack of an efficient national pharmacovigilance system to detect and report adverse drug reactions, a lack of awareness of reporting procedures among healthcare staff and patients, free and uncontrolled access to medicines without a prescription, and the presence of poor-quality medicines on the market that escape the surveillance of the local or national health system [13, 14].

For example, in Ivory Coast, Mendoza Y et al report in their study that a low proportion of serious adverse effects are reported within 72 hours, less than 20%, and only 0.4% of the reports analyzed were followed up with feedback to the incident reporters [15]. However, Mouton JP et al in Nigeria found a significantly lower proportion of around 0.29% among children who had their hospitalization prolonged due to a drug-related adverse reaction [16]. However, other authors in Burkina Faso, notably Millogo G et al., report a significant proportion of adverse drug reactions (60.1%) in specific groups of hypertensive patients. Calcium channel blockers were the most implicated (53.6%), followed by diuretics (48.6%). The specific molecules involved are amlodipine (28.1%) and hydrochlorothiazide (24.5%) [17]. The Democratic Republic of Congo (DRC) has established one of the most active pharmacovigilance systems in sub-Saharan Africa, thereby responding to the World Health Organization's call to ensure the safety of medical care provided to patients. The country has a national pharmacovigilance committee composed of 21 doctors and 9 pharmacists working at the central level. At the provincial level, the country has 4 regional centres and 115 subcommittees covering the country's 518 health zones. Reports of drug-related incidents are first compiled at the local level and then sent to the regional and national levels. To date, more than 15,000 incidents have been reported and recorded in the WHO global database from the DRC [18]. Despite the implementation of an effective pharmacovigilance system, some local studies show that adverse effects related to medicines and vaccines are underreported in this country for various reasons [19], including a lack of awareness of the procedure for reporting adverse effects among healthcare professionals and the general public, the absence of a functional incident reporting and management system, a lack of time or interest on the part of healthcare providers to report unexpected effects of

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medicines, the complexity of the reporting procedure, and the fact that these effects are often considered benign or unnoticeable by healthcare staff. In North Kivu, a province in the east of the Democratic Republic of Congo, the health system is currently facing several major challenges related to three decades of chronic armed conflict, such as the deterioration of health infrastructure, a lack of qualified personnel, limited access to quality healthcare, the outbreak of epidemic diseases, and the collapse of the pharmacovigilance system, which jeopardizes patient safety in various health facilities in the province [20].

At the Heal Africa University Hospital in the city of Goma, we found no publications on adverse drug reactions and no local pharmacovigilance committee responsible for managing incidents. A better understanding of the factors associated with under-reporting of adverse drug reactions in this tertiary healthcare facility in eastern Democratic Republic of Congo will enable us to improve patient safety.

This study therefore aims to fill this gap by analyzing the significant factors associated with the under-reporting of adverse drug reactions at Heal Africa Hospital during the study period.

METHODOLOGY

Context, type and period of the study C

We conducted a prospective cross-sectional study from 1 September 2024 to 31 March 2025 at the Heal Africa University Hospital Centre (Health-Education-Community Action-Leadership), a Christian non-governmental organization based in the east of the Democratic Republic of Congo. Its mission is to provide holistic care to the most vulnerable populations in the country, particularly women and children, who are most affected by the ongoing conflict in the region. Its primary vision remains the promotion of a healthy and resilient community that reflects the love, compassion, and justice of Christ. In terms of geolocation, this hospital is in the center of Goma at 111 Lyna Lusi Street. Heal Africa is a parastatal tertiary healthcare facility of a humanitarian and religious nature, in accordance with the ministerial decree and legal statutes authorizing its operation. It is bordered to the north by Lyn Lusi Street, the Regional Association for the Supply of Essential Medicines (ASRAMES) office, to the south by the Diakonie Catastrophe office, Lake Kivu, to the east by Ronds-points des Banques and the Grand Lakes Development Bank (BDEGL) district towards the city of Gisenyi, and finally to the west by the Bakanja reception center, the Water Distribution Authority (REGIDESO) office and Mount Goma. Historically, for many decades, the people of eastern Democratic Republic of Congo have suffered the severe consequences of persistent and widespread conflict. Using their skills in medicine and administration, founders Dr Jo and his wife Lyn LUSI created Doctors on Call for Service (DOCS) in 2000, an organization whose goal is to train local health professionals to serve suffering communities in the Democratic Republic of Congo (DRC). In 2005, after integrating a holistic approach to medicine, the organization changed its name from DOCS to Heal Africa. The latter is a non-profit association (asbl) with civil status granted under the name Docs-Heal Africa by Ministerial Decree No. 935/CAB/MIN/J/2005 of 30 December 2005. Since 2017, Heal Africa Hospital has been designated as an integrated tertiary referral hospital by the governorate of North Kivu province and by the health inspectorate of the same province. As such, it is used as a university hospital by the university consortium comprising the University of Goma, the Official University of Bukavu and the Catholic University of Graben, which organizes postgraduate medical studies there.

Population, sample and sampling

As the sampling for this study was non-probabilistic and convenience-based, the study population consisted of 266 members of staff at Heal Africa Hospital, spread across different wards or departments, as shown in the table below:

Table I: Distribution of Heal Africa staff by department (N= 266)

Service /Dpartment	N	%
Obstetrics and gynecology		
Gynecologist	04	1,5
Medical doctor	03	1,1
Nurse	15	5,6
Internal medicine		
Internist	06	2,3
Medical doctor	04	1,5
Nurse	30	11,3
General surgery		
Surgeon	03	1,1
Medical doctor	05	1,9
Nurse inpatient	10	3,8
Nurse in operating theatre.	15	5,6
Orthopedic		
Orthopedist	02	0,8
Medical doctor	05	1,9
Nurse	13	4,9
Pediatric		
Pediatrician	02	0,8
Medical doctor	04	1,5
Infirmiers	15	5,6
Emergency		
Specialist	01	0,4
Medical doctor	07	2,6
Nurses	10	3,8
Anesthesiologist-resuscitation		
Specialist	01	0,4
Anesthesia technicians	09	3,4
Other staff		
Administration and statistics	14	5,3
Pharmacy	05	1,9
Medical imaging - biomedica	09	3,4
Laboratoire	16	6,0
Specialties (Phyio ophta, Dent, nutrition)	07	2,6
Hygiene and sanitation	42	15,8
Other [1]	09	3,4

Other[1]: nursing directorate, community health sterilization agent. The table clearly shows that 154 out of 266 employees (57.9%) are medical (47 employees) and paramedical (107 employees) healthcare professionals.

Samples

Heal Africa Hospital employs 266 people, 154 of whom are medical (47) and paramedical (107) personnel. Twenty out of 47 medical staff members and 56 out of 107 paramedical staff members participated in the study. Our

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sample consists of 76 medical and paramedical staff members.

The criteria for sample selection and exclusion

To participate in the study, participants had to meet the following criteria, be medical or paramedical staff at the Heal Africa University Teaching Hospital (specialist, general practitioner or nurse) during the study period, and freely consent to participate in the study.

All medical and paramedical staff at Heal Africa Hospital who freely expressed their refusal to participate in this study, as well as all staff belonging to a professional category other than doctors or nurses, were systematically excluded from the study.

Data collection Tools and techniques

The data collection for our study on 'factors associated with the under-reporting of adverse drug reactions in a university teaching hospital in eastern Democratic Republic of Congo' was carried out using a pre-established survey questionnaire covering the independent variables to be analyzed.

Data entry, recording, processing and analysis system

The collected data were entered, recorded and processed using Excel 2016 software, then analyzed using Statistics Product and Service Solution (SPSS) version 27.0 software. Pearson's chi-square statistical test (X^2) was applied in this study to investigate a possible association between the explanatory variables and the explained variable, namely the under-reporting of adverse drug reactions in our context. At a 95% confidence interval, the significance threshold was set at $P < 0.05$. In this case, the null hypothesis (H0) was rejected if the calculated chi-square was greater than 3.84 or if $P > 0.05$ (significant dependence existing). Conversely, the null hypothesis (H0) was accepted when the calculated chi-square was less than 3.84 or $P < 0.05$ (significant independence).

Methods for research used

Given that this research is based primarily on the assessment of participants' opinions, we use quantitative and qualitative methods to collect our data. The quantitative approach allowed us to validate our measurements while ensuring the representativeness of the sample of healthcare workers, which represents 49.4% of all Heal Africa healthcare workers. The qualitative approach allowed us to discuss with participants the reasons for reporting or not reporting adverse drug reactions within their respective departments, as well as their knowledge of the consequences or impact of not reporting these adverse reactions.

The questionnaire used in our study included open-ended, closed-ended and semi-open-ended questions. The open-ended questions focused on collecting sociodemographic data: age, gender, level of education, marital status, on-the-job training, and experience with reporting or not reporting cases of adverse drug reactions at the Heal Africa hospital department. The closed questions measured variables related to the reasons for under-reporting of adverse drug reactions within the department, as well as the possible consequences of this under-reporting during the period of our study.

As for the semi-open questions, they concerned participants' intentions that were not included in the questionnaire. Thus, for each intention not mentioned in the questionnaire, a space was reserved for participants to explain it freely.

The variables measured in this study

Several independent variables related to socio-demographic factors were considered in this study: age, gender, level of education, marital status, and on-the-job training. The independent variables related to reasons for non-reporting are as follows: lack of training, lack of knowledge of the reporting procedure, unavailability of a reporting tool/form, severity of adverse effects, fear of administrative sanctions or legal proceedings, lack of knowledge of adverse effects. The independent variables correlated with lack of awareness of the consequences of under-reporting for the patient are as follows: patient progress, clinical management of effects, analysis of the root causes of unknown effects, and prevention of future incidents. Finally, under-reporting of adverse drug reactions was the only dependent variable considered by this team.

Ethical considerations

This study, which examined the 'factors associated with underreporting of adverse drug reactions in a university hospital in eastern Democratic Republic of Congo,' was approved by the relevant authorities. The confidentiality of participants' identities and responses was strictly respected. Furthermore, although written in French, participants' informed consent was obtained in the language of their choice. This consent was typically given orally.

RESULTS

Table II: Sociodemographic distribution of participants (N=76)

Variables	N	%
Occupation		
Specialist	06	07,9
Medical doctor	14	18,4
Nurse A0	19	25,0
Nurse A1	35	46,1
Nurse A2	02	02,6
Age(years)		
18-30	06	7,9
31-40	35	46,1
41-50	26	34,2
51 and more	09	11,8
Gender		
Male	42	55,3
Female	34	44,7
Marital statut		
Single	07	09,2
Married	65	85,5
Widower	04	05,3
Seniority (years)		
< 5	21	27,6
5-10	32	42,1
≥ 10	23	30,3
Trained on the topic		
Yes	13	17,1
No	63	82,9
Notification of effects		
Yes	18	23,7
No	58	76,3

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It is observed that the predominant professional category among the participants is that of paramedics, constituting 56 out of 76 individuals (73.7%). Most participants are between the ages of 31 and 50 (80.3%). The male population constitutes a majority of 55.3%, exhibiting a sex ratio of 1.23 that favors males. The data presented in this table indicates that most of the participants are married (85.5%). Regarding seniority, 42.11% of the participants have five to 10 years of experience, while 30.3% have more than 10 years of seniority. A mere 17.1% of the participants have received training on reporting adverse effects and incidents related to medical care. A minority of participants (23.7%) have reported at least one adverse drug reaction to the department, while 76.3% have never made a report, highlighting an under-reporting of adverse effects.

Table III: Socio-demographic determinants associated with reporting adverse drug reactions to the department

	Notification					
Factors	**Yes=18 (100%)**	**No =58 (100%)**	**N=76 (100%)**	**Chi-square**	**Dff**	**p**
Age (years)						
18-30	01 (5,6%)	05 (8,6%)	06 (7,9%)	**8,775**	**3**	**0,0324**
31-40	06 (33,3%)	29 (50,0%)	35 (46,1%)			
41-50	11 (61,1%)	15 (25,9%)	26 (34,2%)			
51 and more	00 (0,00%)	09 (15,5%)	09 (11,8%)			
Gender						
Male	13 (72,2%)	29 (50,0%)	42 (55,3%)	2,743	1	0,0976
Female	05 (27,8%)	29 (50,0%)	34 (44,7%)			
Education level						
Specialist	04 (22,2%)	02 (3,5%)	06 (7,9%)	**9,657**	**4**	**0,0513**
Medical doctor	05 (27,8%)	09 (15,5%)	14 (18,4%)			
Nurse A2	00 (0,0%)	02 (3,5%)	02 (2,6%)			
Nurse A1	05 (27,8%)	30 (51,7%)	35 (46,1%)			
Nurse A0	04 (16,7%)	15 (24,1%)	17 (22,4%)			
Marital statut						
Single	01 (5,6%)	06 (10,3%)	07 (9,2%)	1,802	2	0,4060
Married	17 (94,4%)	48 (82,8%)	65 (85,5%)			
Widowed	00 (0,0%)	04 (6,9%)	04 (5,3%)			
Seniority (years)						
< 5	02 (11,1%)	19 (32,8%)	21 (27,6%)	**4,401**	**2**	**0,1107**
5-10	11 (61,1%)	21 (36,2%)	32 (42,1%)			
> 10	05 (27,8%)	18 (31,0%)	23 (30,3%)			
Staff Trained						
Yes	11 (61,1%)	02 (3,5%)	13 (17,1%)	**32,212**	**1**	**<0,001**
No	07 (38,9%)	56 (96,6%)	63 (82,9%)			

A thorough examination of the data presented in Table 1 indicates that the strongest associations with reports of adverse drug reactions are found in participants of advanced age (p = 0.0324), those with a higher level of education (p = 0.0578), those with long-standing service (p = 0.1107), and those with training in adverse drug reactions (p < 0.001).

Table IV: The rationales or motivations underpinning the under-reporting of adverse effects to the service

	Notification					
Reasons	**Yes=18 (100%)**	**No=58 (100%)**	**N=76 (100%)**	**Chi-square**	**Dff**	**p**
Training						
Yes	7 (38,9%)	56 (96,6%)	63 (82,9%)	**32,212**	**1**	**< 0,001**
No	11 (61,1%)	02 (3,5%)	13 (17,1%)			
Known procedure						
Yes	03 (16,7%)	14 (24,1%)	17 (22,4%)	**39,721**	**2**	**< 0,001**
No	14 (77,8%)	04 (6,9%)	18 (23,7%)			
Unknown	01 (5,6%)	40 (69%)	41 (53,9%)			
Severity of effects						
No notifie	00 (0,0%)	55 (94,8%)	55 (72,4%)	**63,928**	**2**	**< 0,001**
So minimal	08 (44,4%)	03 (5,2%)	11 (14,5%)			
So important	10 (55,6%)	00 (0,0%)	10 (13,1%)			
Fear of retribution						
Yes	02 (11,1%)	07 (12,1%)	09 (11,8%)	0,0121	1	0,912
No	16 (88,9%)	51 (87,9%)	67 (88,2%)			
Fear of legal action						
Yes	05 (27,8%)	15 (25,9%)	20 (26,3%)	0,0260	1	0,871
No	13 (72,2%)	43 (74,1%)	56 (73,7%)			
Ignore the effects						
Yes	10 (55,6%)	34 (58,6%)	44 (57,9%)	0,0529	1	0,818
No	08 (44,4%)	24 (41,4%)	32 (42,1%)			

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We observe in this table that the main reasons significantly associated with under-reporting of adverse drug reactions are the lack of training of healthcare personnel on unexpected drug reactions ($p < 0.001$), lack of knowledge of the procedure for reporting adverse effects ($p < 0.001$) and, finally, the severity of the effects considered significant ($p < 0.001$).

Table V: Knowledge of the impact of underreporting of adverse drug reactions in the department

	Notification					
Consequences	**Yes=18 (100%)**	**No =58 (100%)**	**N=76 (100%)**	**Chi-square**	**Dff**	**p**
Patient progress						
Risk of death	03 (16,7%)	25 (43,1%)	28 (36,8%)	4,677	2	0,0964
Unfavorable	15 (83,3%)	32 (55,2%)	47 (61,8%)			
Don't know	00 (0,0%)	01 (1,7%)	01 (1,3%)			
Management						
Delayed	18 (100%)	53 (91,4%)	71 (93,4%)	1,661	1	0,1975
None impact	00 (0,0%)	00 (0,0%)	00 (0,0%)			
Doesn't know	00 (0,0%)	05 (8,6%)	05 (6,7%)			
Analysis of causes						
Not done	17 (94,4%)	50 (86,2%)	67 (88,2%)	0,969	2	0,6158
Treatment Delayed	01 (5,6%)	07 (12,1%)	08 (10,5%)			
Don't know	00 (0,0%)	01 (1,7%)	01 (1,3%)			
Future prevention						
None in place	16 (88,9%)	41 (70,7%)	57 (75,0%)	2,426	1	0,1193
Reproduction risk	02 (11,1%)	17 (29,3%)	19 (25,0%)			
Don’t know	00 (0,0%)	00 (0,0%)	00 (0,0%)			

We note in this table that participants, regardless of whether they reported adverse effects, are aware of the consequences of not reporting unexpected adverse effects related to medicines.

About patient outcomes, the association is not statistically significant ($p = 0.0964$). Among those who believe there is a risk of death, few people report adverse effects (16.7% compared to 43.1% in the control group). On the other hand, among those who believe that under-reporting of adverse effects can lead to an unfavorable patient outcome, the case group reports more (15 out of 32, or 83.3%) than the control group (16 out of 25, or 64%).

With respect to the correlation between the failure to report unexpected effects related to the medicine and patient management, it is observed that these two variables are independent ($p = 0.1975$). Many participants in both groups perceive that under-reporting leads to delays in the treatment of potential complications. The proportion of subjects in the group that reports cases is 100%, while the proportion in the control group is 91.4%.

Regarding the impact on the analysis of the root causes of adverse effects or possible medical errors, no statistical association was found ($p = 0.6158$). Most study participants clearly understand that under-reporting prevents the identification of the root causes of adverse events: 94.4% in the case-reporting group and 86.2% in the control group.

Finally, the impact of underreporting on the future prevention of these effects was not significantly associated in the present study ($p = 0.1193$). However, most participants believe that underreporting leads to a lack of future prevention plans for these incidents. The case group demonstrated an 88.9% response rate, while the control group exhibited a 70.7% response rate.

DISCUSSION

The reporting of suspected adverse effects in patients is a fundamental process inherent to pharmacovigilance and the safety of patients receiving any medical care in a healthcare facility, regardless of its level. The preponderance of data concerning the harm suffered by patients during their medical care is derived from developed countries, with scant contributions from African nations, including the Democratic Republic of Congo [21].

In the present study, 18 out of 76 subjects, constituting 23.7% of the total sample, reported at least one adverse drug reaction in the ward. This proportion exceeds the 16.6% documented by Katusiime B et al. in Uganda [22]. Conversely, in Quebec, Maurin C et al documented 23,284 drug-related accidents over a four-year period, averaging 15.9 accidents per day. This outcome indicates the efficacy of the pharmacovigilance system in place within this developed country [23]. This variability may be attributable to the population included in the study, the sampling technique employed, the setting, and the duration of the study. In the present series, a case-control study was conducted, with healthcare providers from a tertiary hospital participating. The present study spanned a comparatively brief period of six months, in contrast to the four-year study that was conducted in Quebec [23].

Most respondents were paramedical staff, 56 out of 76, or 73.7%. Most participants were between the ages of 31 and 50 (80.3%). The male population outnumbered the female population (55.3%), exhibiting a sex ratio of 1.23 that favored males. Most of the participants were married (85.5%). A significant proportion of the participants, more than 40%, had accumulated between five and 10 years of seniority, while more than 30% had accumulated more than 10 years. A mere 17.1% of the participants had received training on reporting adverse effects and

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incidents related to medical care. Most participants (76.3%) reported no adverse effects. This finding suggests that the documented effects may be underreported. This profile, as delineated in the present study, corresponds to individuals traditionally responsible for reporting adverse drug reactions. These individuals include, but are not limited to, doctors, nurses, midwives, and pharmacists, who play a pivotal role in the prescription, administration, or management of medications.A comparable socio-demographic profile of respondents is described in Uganda by Katusiime et al. [22], who note a median age of 32.6 years for all respondents, with ages ranging from 23 to 65 years. Among the participants, 41.1% had a higher education level and were familiar with the procedure for reporting adverse drug reactions. Notably, most respondents were women (62.3%), which contradicts our initial observation. The identification of factors contributing to the under-reporting of adverse effects in a healthcare facility offers several advantages, including the optimization of the pharmacovigilance system within the facility, the minimization of the risk of repeating the same errors related to the administration of medicines and their side effects, the adjustment of the content of training programs to make them more relevant and useful for healthcare staff, and finally, the maximization of the safety of patients receiving medical care within the healthcare facility [24-26].

In the present survey series, the following factors were identified as the most significant determinants associated with the reporting of adverse drug reactions: advanced age of participants ($p = 0.0324$), level of education ($p = 0.0578$), long service ($p = 0.1107$), and training on adverse drug reactions ($p < 0.001$). In contrast to the findings of this study, other researchers have identified notable discrepancies in the identified risk factors. These include a lack of awareness regarding adverse effects (86.2%), procrastination, disinterest, and other rationalizations (84.6%), complacency (46.2%), the reluctance to report mere suspicions of adverse effects due to the perceived risk of appearing absurd (44.6%), uncertainty surrounding side effects (33.8%), the absence of feedback to the healthcare provider who initially reported the incident (9.2%), and the absence of a perceived obligation to report adverse effects [27].

In our context, we posit that these three factors are interrelated. Staff members with higher levels of education, experience, and training are better able to understand the importance of reporting any adverse drug reactions and the value of promptly managing such incidents, compared to young and inexperienced staff.

The under-reporting phenomenon at the Heal Africa University Hospital Centre can be attributed to several factors. Primarily, most healthcare professionals lack training on unexpected drug-related effects ($p < 0.001$). Additionally, there is a lack of awareness regarding the reporting procedures for adverse effects ($p < 0.001$). Finally, the severity of the effects that are considered significant ($p < 0.001$) plays a significant role in under-reporting. This observation is widely shared by several authors [28], except in Tanzania, where, despite training and a thorough knowledge of both physical and digital platforms for reporting adverse drug reactions, healthcare professionals did not comply with this strategy. The subjects reported that they found the process of reporting adverse drug reactions to be tedious and burdensome. Furthermore, it was determined that the reporting of all adverse reactions was not deemed obligatory [29].

Regardless of whether they report adverse effects, most participants in this study are aware of the consequences of not reporting unexpected adverse effects related to medicines. About awareness of the various possible outcomes for patients associated with under-reporting of adverse effects, the association is not statistically significant ($p = 0.0964$) in our context. Among those who believe there is a risk of death, few people report adverse effects: 16.7% compared to 43.1% in the control group. On the other hand, those who consider that under-reporting of adverse effects can lead to an unfavorable outcome for the patient, the case group reports more: 15 out of 32 (83.3%) compared to 16 out of 25 (64%) in the control group. With regard to the link between the lack of reporting of unexpected drug-related effects and the medical management of patients, we note that these two variables are independent ($p = 0.1975$). Most participants in both groups perceived that under-reporting led to delays in the treatment of potential complications: 100% in the group that reported cases and 91.4% in the control group. Even in cases where such events are rare or detected after a significant delay, it is imperative to maintain continuous monitoring of the medicine once it has been placed on the market. This is a fundamental step in pharmacovigilance. It is therefore imperative that healthcare professionals and patients promptly report any adverse effects that they deem to be significant, as this enables the assessment of severity, the provision of early medical management, and the prevention of recurrence [30].

About the impact on the analysis of the root causes of adverse effects or possible medical errors, no statistical association was found ($p = 0.6158$). Most study participants demonstrated an understanding of the concept that under-reporting hinders the identification of the root causes of adverse events (94.4% for the reporting group and 86.2% for the control group).

Finally, the impact of under-reporting on the future prevention of these effects was not significantly associated in the present study ($p = 0.1193$). However, most participants believe that under-reporting leads to a lack of future prevention plans for these incidents. The case group demonstrated an 88.9% response rate, while the control group exhibited a 70.7% response rate. Similar observations have been described by other authors, who report that adverse drug reactions prolong hospital stays by 61.7% in nearly a quarter of cases, immediately threaten the patient's life in 9.2% of cases, physical disability such as facial paresis, and limb amputation in 3% of cases [31].

CONCLUSION

The proportion of healthcare providers who have reported adverse drug reactions in our context remains low. The reporting of adverse reactions is associated with several predictable and reducible factors, including length of

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service, experience, and training. The effective and functional implementation of pharmacovigilance at the Heal Africa University Hospital Centre would facilitate improved management of medical care-related incidents and patient safety during the various phases of medical care administration.

RECOMMENDATIONS

The authors of this study therefore recommend the establishment of a guide for recognizing adverse effects, the implementation of tools and a system for spontaneous reporting of adverse effects by healthcare staff, staff training, the creation of a database, conducting a periodic review of reports of adverse drug reactions, and organizing regular feedback to providers in order to improve the quality of medical care provided to patients.
The implementation of pharmacovigilance as a local, regional, and national strategy for monitoring adverse effects related to medical care should facilitate the identification of any adverse effects, including those associated with the most recent medications, as rare adverse effects do not always manifest during the clinical trial phase.

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Author contributions

Mashako Many drafted the first version of the manuscript, after which all authors contributed substantially to revising the final draft of this study.

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Conflict of interest

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