

Knowledge, attitudes and perspective on adverse drug reaction reporting in a public sector hospital in South Africa: baseline analysis

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Abstract

Background and aims: Adverse drug reactions (ADRs) can cause significant harm in patients; however, ADRs are under-reported in many countries, including South Africa, where evidence of a pharmacovigilance (PV) system to monitor and manage ADRs is a requirement for compliance with norms and standards for quality healthcare delivery. We conducted an analysis amongst health care professionals (HCPs) at Sebokeng Hospital to assess the situation there.

Methods: Data were collected using a structured self-administered questionnaire, targeting all medical practitioners, nurses, pharmacists and pharmacist assistants in the hospital. Current procedures for reporting of ADRs were documented. Records were reviewed to determine the number of ADR reports submitted for the 18-month period prior to the study. Data were analysed with SAS. Ethical clearance was obtained.

Results: The questionnaire was completed by 132 HCPs (nurses: 58.3%; medical practitioners: 23.5%; pharmacist assistants: 11.4%; pharmacists: 6.8%). The vast majority indicated ADR reporting is necessary (96.2%) and their professional obligation (89.4%). Only 18.9% were aware of an existing PV system in the hospital, 15.2% had an ADR form available and 18.9% knew to whom the form should be submitted. The vast majority had never reported an ADR, had never received training in PV, but wanted training on ADR reporting. Factors discouraging ADR reporting included not knowing how to report them (53.8%), lack of time (37.1%), additional work load (22.0%), uncertainty about the outcome of reporting (32.6%), and lack of confidence to discuss ADRs with colleagues (22.0%). Only 2.3% knew how many ADRs were reported, that ADRs are discussed by a committee (6.1%) and that internal feedback is received on reported ADRs (6.1%).

Conclusion: There is an extensive need in Sebokeng Hospital for training on ADR reporting and implementation of systems to facilitate relevant processes; a need which may also exist in other public hospitals in South Africa.

Key words: Pharmacovigilance, adverse drug reactions, health care professionals, hospitals, training, South Africa

1. Introduction

Adverse drug reactions (ADRs) have the potential to cause significant harm to patients (1) as they increase morbidity and mortality, adding to the suffering of patients (2-5). ADRs are among the leading causes of mortality in the USA and Europe (6-9). They have a major impact on public health with increased costs, exacerbated by an appreciable number of hospital admissions each year (10-15) as well as increasing in-patient ADRs (16).

There is a similar situation in South Africa, with 6.3% of hospital admissions as a direct result of an ADR, with a further 6.3% developing an ADR whilst in hospital (1,17). A recent cross-sectional survey conducted in the adult medical wards of four geographically diverse hospitals in South Africa, estimated that ADRs contributed to the death of 2.9% of adult medical ward admissions and 16% of deaths were ADR-related (5).

There are concerns at the considerable extent of under-reporting of ADRs in hospitals across all countries (4, 12, 18-20), with some authors putting this figure as high as 80-94% (21, 22). Correcting for under-reporting is difficult, however, because its extent is unknown and can be very variable. There are a number of reasons for under-reporting including ignorance of ADR reporting systems, unavailability of forms, lethargy, lack of interest, indifference and complacency (4, 20). This situation is not helped by a lack of training on the reporting of ADRs across countries (22, 23). The lack of reporting is a concern, especially among sub-Saharan African countries with their high prevalence of infectious diseases, which coupled with the introduction of newer more complex therapies, makes the detection and reporting of ADRs crucial to reduce subsequent morbidity, mortality and costs (12, 24).

Identifying ADRs and reporting them should be a vital part of healthcare professionals' (HCPs) daily practice. Spontaneous reporting systems are an efficient means of detecting and reporting drug safety signals (25) which are currently used in South Africa (26); however, they rely on vigilant HCPs not only to generate a suspicion of an ADR during their appraisal and treatment of a patient, but also to report it. They are though a crucial element in the worldwide practice of pharmacovigilance and form the core of the World Health Organization (WHO) Database (27), growing across countries including Africa (28).

Consequently, in all countries, there is a need to study the incidence of ADRs and create awareness among HCPs to encourage their reporting, reducing subsequent morbidity, mortality and costs. Early detection, evaluation, management and monitoring of ADRs are essential to reduce harm to patients and improve public health (29).

Pharmacovigilance (PV) is a relatively new science and in Africa and before 2000, this was not a priority in view of a number of reasons including poor regulation for medicines, lack of access to them, concerns with supply chains, lack of knowledge regarding PV as well as lack of resources to promote PV (28). This is changing with 35 African countries part of the WHO Programme for International Drug Monitoring by the end of September 2015 (28). This includes South Africa, which joined in 1992 reporting 28,609 individual case report forms up to 2015 (28). This has been helped by the formation of a PV Group within the Medicines Council of South Africa (30), providing direction on ADR reporting in South Africa (31). This now includes regulations concerning post-marketing reporting of ADRs, with a directive that all serious or suspected ADRs, whether expected or unexpected, occurring in South Africa must be reported by the medicine licence holder or applicant to the Medicines Control Council within 15 days of receipt of such information (31). There are also now regional initiatives with South Africa promoting PV (32).

In addition, in order to provide safe quality services to the citizens of South Africa, compliance with specific norms and standards is a legislative requirement for different categories of health establishments (23,33,34). They are required to have systems in place to report adverse incidents to a structure within the health establishment or responsible authority that monitors these events. Pharmaceutical services in particular are required to ensure that reactions to drugs or severe side effects are reported, that the patient is properly cared for, and that a clear system is in place to manage ADRs (23,33). Specially designed forms are available to report ADRs to the National Adverse Drug Event Monitoring Centre (NADEMC) in Cape Town, although there is recognised under-reporting in South Africa (1, 35,36).

However, the extent of reporting of ADRs following these initiatives within public sector hospitals in South Africa is largely unknown, although this is changing with some local initiatives (32). Limited literature is available on actual current reporting of ADRs within general public sector hospitals in South Africa including potential barriers. Most studies highlighted lack of knowledge of ADR reporting with a need for targeted training (35,37,38). HCPs in clinical HIV practice in a district in Kwa-Zulu Natal, reported high awareness of ADR reporting (75.9% to 88.0%) with estimated adverse event reporting rates ranging from 1.6% to 8.7% (38). Focus group discussions from an antiretroviral

treatment programme in the Eastern Cape revealed lack of knowledge especially amongst junior staff (35). In a small study amongst HCPs from three districts in the Eastern Cape Province, less than 20% of HCPs indicated that they report ADRs externally (39). In a recent study amongst community and hospital pharmacists in North-West Province, 44% indicated that they have submitted an ADR report in the past (37).

Consequently, we undertook a study among HCPs in a public sector hospital in South Africa to assess their knowledge of, attitudes to and perceptions about ADR reporting. The findings would be used to guide similar research in other public sector hospitals, as well as to develop pertinent interventions to improve future reporting, if this is an identified concern. Previous studies have shown that suitable interventions can improve the rate of ADR reporting (19,40,41), with hospital pharmacists potentially playing a key role with improving reporting rates (42).

2. Methods

2.1 Study setting

This study was conducted in a secondary level care hospital in Sedibeng, Gauteng Province, South Africa. Sebokeng Hospital is an 800-bed referral hospital with a catchment population of over 1.1 million.

2.2 Study design

Knowledge of, attitudes to and perceptions about ADR reporting by HCPs of Sebokeng Hospital were evaluated in a descriptive study.

2.3 Study population and sample

The study population included all HCPs (doctors, nurses, pharmacists and pharmacist assistants) who were employed at Sebokeng Hospital at the time of the study. Hence convenience sampling was used.

2.4 Study instrument

The study instrument was a pre-designed structured questionnaire, adapted from previous studies (25,43), and further developed with the support of different HCPs to ensure its suitability for our hospital setting. The questionnaire was structured to obtain demographic information, knowledge of ADR reporting, attitudes to reporting, the types of ADRs and drug-induced reactions that must be reported, and factors perceived to influence ADR reporting. The final questionnaire contained 19 closed-ended questions with two or more response options, of which eight questions provided space for an explanation of the selected response. No prioritisation was requested with any of the questions. One open-ended question was included on where ADR reporting forms are kept and an invitation at the end of the questionnaire to state any needs or suggestions in terms of ADR reporting. The questionnaire was completed anonymously and took approximately 7-10 minutes to complete.

2.5 Data collection

Data were collected over a period of one week in 2015. A total number (547) of medical practitioners, pharmacists and nurses were employed at Sebokeng Hospital at the time of the study. General communication to the wards was used to inform HCPs working in the hospital at the time of data collection of the study. Convenience sampling was used to invite the HCPs who were present in a particular ward at the time of data collection, to participate in the study and complete the needs analysis questionnaire. They were informed that participation was voluntary and were provided with written information about the study, explaining its aims and objectives. On their agreement to participate, written informed consent was obtained from them. The questionnaire was handed to respondents for immediate completion in a private area in the ward or pharmacy, such as an office or consultation room. Respondents were requested to place the questionnaire upon completion in a sealed container provided in the area.

A retrospective review of hospital records was also conducted to determine the number of ADR reports submitted at Sebokeng Hospital for the 18-month period prior to the study. Current procedures for reporting of ADRs for patients admitted to the hospital were also documented.

2.6 Data analysis

Data collected with the questionnaire were entered electronically on an MS Office Excel™ spreadsheet, proof-read for accuracy and completeness and cleaned prior to the analysis. All statistical procedures were performed on SAS, release 9.2, running under Microsoft Windows. Data were summarised descriptively and expressed as frequencies and percentages. Responses to questions where an explanation was requested, were read a number of times and categories were created based on the responses. Responses were then tabulated according to the categories, which allowed for counting of the responses in each category.

2.7 Ethical considerations Ethical clearance for the study was obtained from the Medunsa Research Ethics Committee of the University of Limpopo, now known as Sefako Makgatho Health Sciences University, prior to the commencement of the study (Clearance number: MREC/H/26/2014:PG). Ethical approval was also obtained from the Gauteng Provincial Ethics Committee. Permission to conduct the study was obtained from the Chief Executive Officer of the hospital. All respondents in the study remained anonymous and data were handled confidentially. Only the authors had access to the raw data, which were stored appropriately. The results of this study were subsequently made available to the Sebokeng Hospital Management and the Pharmacovigilance Unit of the Gauteng Department of Health to plan initiatives if needed to improve ADR reporting in the future.

3. Results

According to the review of records at the time of the study, only six ADRs were reported for the preceding 18 months, between January 2014 and May 2015.

Although the invitation to participate in the study was extended to all 547 HCPs employed at the hospital via normal communication channels, only 200 HCPs who were present in the wards on the day of data collection, agreed to participate in the study and received the questionnaire. Of the 200 questionnaires distributed, 132 were completed, giving a completion rate of 66% and a response rate of 24%. Respondents to the questionnaire consisted of 31 (24%) medical practitioners, 77 (58%) nurses, 15 (11%) pharmacist assistants and 9 (7%) pharmacists. Participants from all age groups completed the questionnaire: 21-30 years (30%), 31-40years (22%), 41-50 years (23%), 51-60years (20%) and more than 60 years (5%).

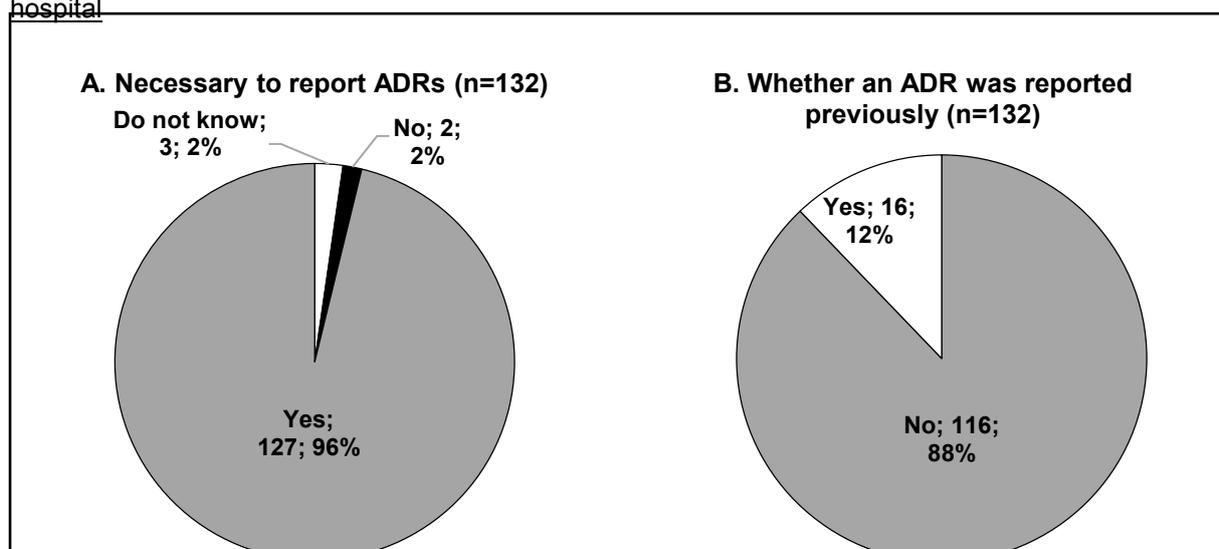
Table 1 shows the knowledge, attitudes and practices of HCPs on ADR reporting. Only 25 (18.9%) of the HCPs were aware of the existing ADR reporting system and 20 (15.2%) were aware that ADR reporting forms were available in the ward/hospital. Only seven (5.3%) HCPs indicated that they had received training on ADR reporting prior to this study, whilst almost 90% (118) of HCPs indicated that they would like to receive training on ADR reporting.

Table 1: Knowledge, attitudes and practices of healthcare professionals on adverse drug reaction reporting at Sebokeng Hospital

Adverse drug reaction (ADR) reporting	Number (%) of healthcare professionals				
	Medical Practitioner (n=31)	Pharmacist (n=9)	Pharmacist Assistant (n=15)	Nurse (n=77)	Total (n=132)
Aware of an ADR reporting system in Sebokeng Hospital	2 (6.5%)	8 (88.9%)	5 (33.3%)	10 (12.9%)	25 (18.9%)
Know of an ADR reporting form available in the ward/ hospital	4 (12.9%)	2 (22.2%)	8 (53.3%)	6 (7.8%)	20 (15.2%)
Know to whom the completed ADR form must be submitted	4 (12.9%)	6 (66.7%)	3 (20.0%)	12 (15.6%)	25 (18.9%)
ADR reporting is a professional obligation	31 (100%)	9 (100%)	11 (73.7%)	67 (87.0%)	118 (89.4%)
ADR reporting should be voluntary	5 (16.1%)	0 (0%)	2 (13.3%)	5 (6.5%)	12 (9.1%)
ADR reporting should be remunerated	1 (3.22%)	0 (0%)	2 (13.3%)	8 (10.4%)	11 (8.3%)
ADR reporting should be compulsory	25 (80.7%)	9 (100%)	11 (73.3%)	64 (83.1%)	109 (82.6%)
Received training on ADR reporting	0	2 (22.2%)	4 (26.7%)	1 (1.3%)	7 (5.3%)
Would like to receive training on ADR reporting	30 (96.8%)	9 (100%)	14 (93.3%)	65 (84.4%)	118 (89.4%)

The vast majority (96.2%) of HCPs indicated that it was necessary to report an ADR (Figure 1A), however only 16 (12.1%) had ever reported one (Figure 1B). The 16 HCPs who indicated that they had reported an ADR in the past included four medical practitioners, five pharmacists and seven nurses.

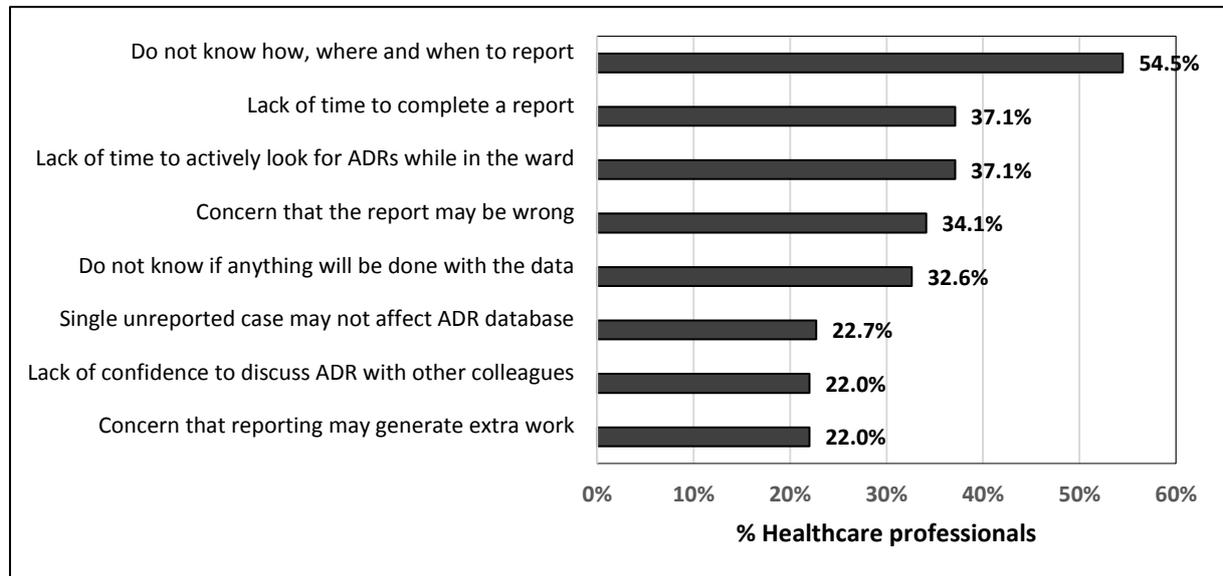
Figure 1A and B: Reporting of adverse drug reactions by health care professionals at Sebokeng hospital.



One of the questions was aimed at determining whether the HCPs knew to whom they should submit completed ADR forms. Only 25 (18.9%) HCPs (4 medical practitioners, 12 nurses; 3 pharmacist

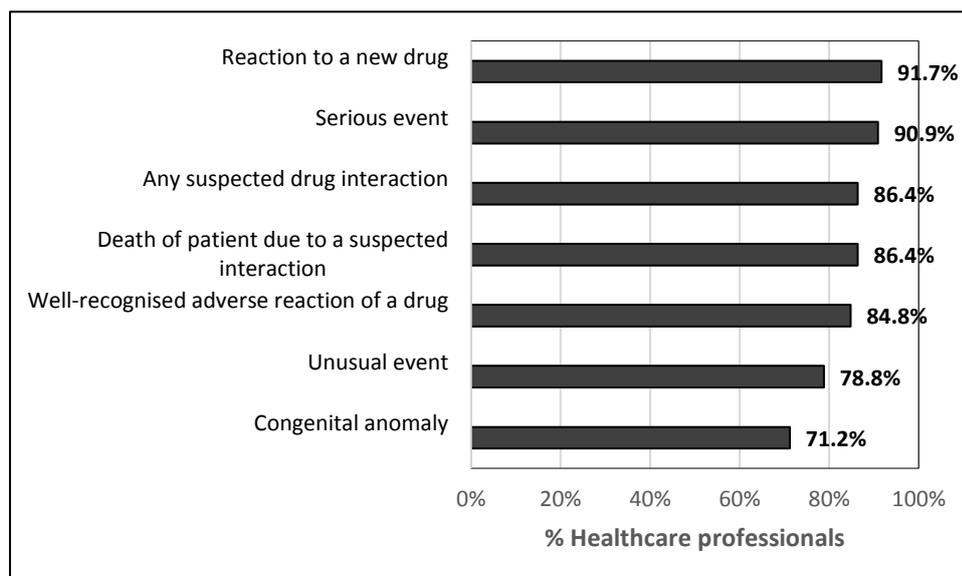
assistants; 6 pharmacists) knew that ADR reports should be sent to the pharmacy within the hospital. Other factors associated with under-reporting of ADRs are shown in Figure 2. They included a lack of time to look for ADRs in the ward (37.1%) as well as a lack of time to complete a report (37.1%), the 'report may be wrong' (34.1%) and 'do not know if anything will be done with the data' (32.6%). More than half (54.5%) of the HCPs indicated that they did not know how, where or when to report an ADR.

Figure 2: Determinants of under-reporting of adverse drug reactions by healthcare professionals at Sebokeng Hospital (n=132)



Other questions probed HCPs' perceptions about ADRs and spontaneous ADR reporting. Types of ADRs that might elicit reporting by HCPs are presented in Figure 3. Adverse reactions to a new medicine (91.7%) and a serious adverse event to a particular medicine (90.9%) were the ADRs that most needed to be reported.

Figure 3: Types of adverse drug reactions that elicited reports from healthcare professionals at Sebokeng Hospital (n=132)



The majority of HCPs (89.4%) felt that ADR reporting is a professional obligation. In terms of whose professional responsibility it is to report an ADR, 85.6% felt it was the responsibility of a medical practitioner and a nurse to report ADRs, while 72.0% felt it was the responsibility of a pharmacist (see Figure 4).

Figure 4: Perceived professional responsibility to report an adverse drug reaction by healthcare professionals at Sebokeng Hospital (n=132)

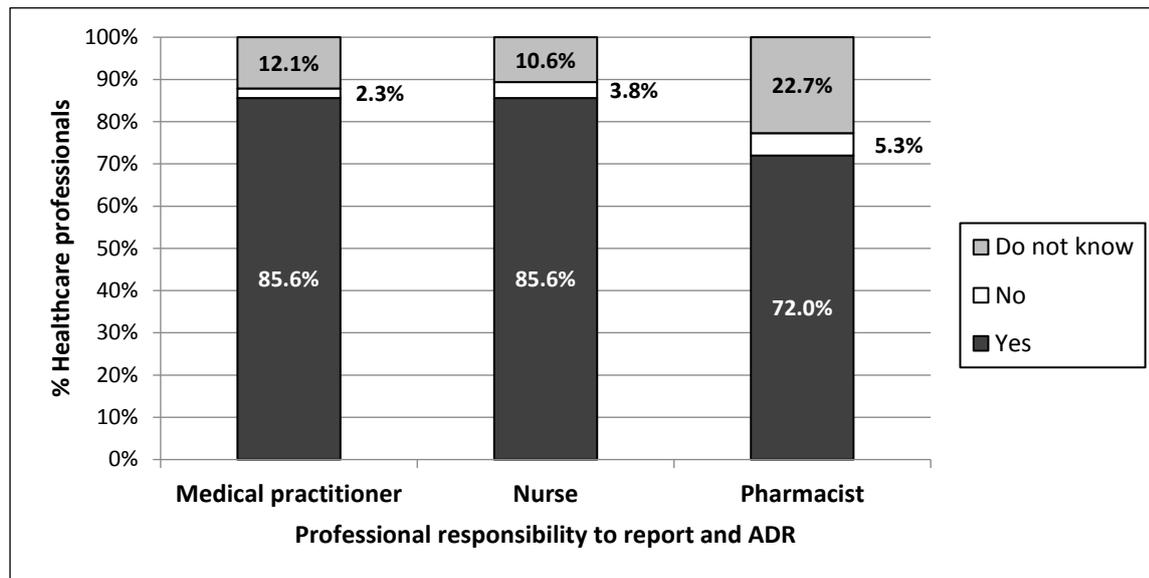
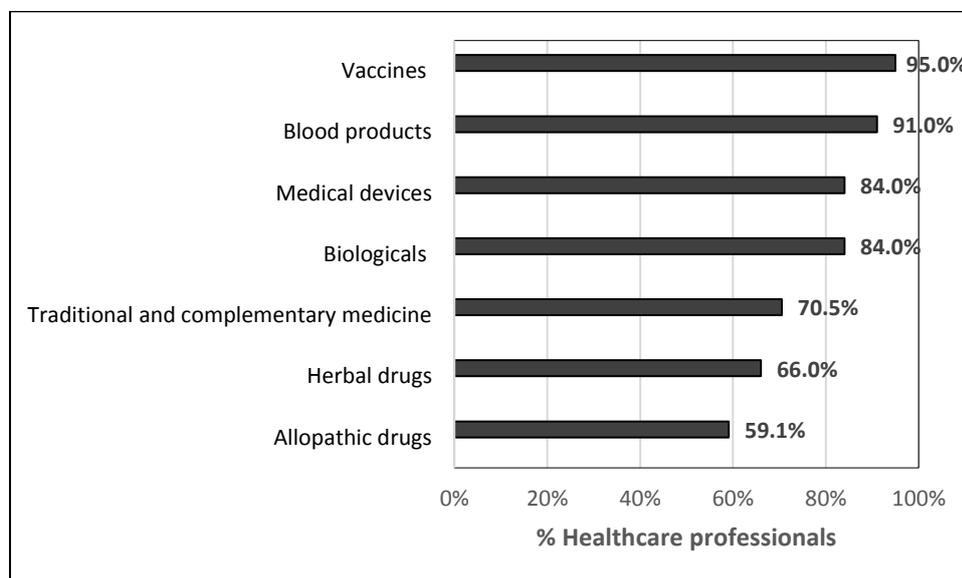


Figure 5 shows HCPs' perceptions about whether adverse events related to specific categories of medicines and devices must be reported. The majority believed that it was mandatory to report adverse events due to vaccines (95.0%) and blood products (91.0%).

Figure 5: Perceived importance to report adverse events related to various categories of medicines (n=132)



4. Discussion

There appeared to be serious under-reporting of ADRs within Sebokeng hospital with only six ADRs reported between January 2014 and May 2015. According to an ADR database kept for the 34 public sector hospitals in the Gauteng Province, only 41 ADRs were reported by the hospital between 2012 and March 2017 (32). Only 44% of the 34 hospitals in the province reported any ADRs with the number of ADR reports submitted, ranging from one to 123 for the 5-year period. Only two hospitals reported more ADRs than Sebokeng hospital (secondary level of care) with 123 and 59 ADR reports respectively submitted for the 5-year period by a tertiary and central academic hospital. These figures

suggested that the number of reports submitted is not associated with the size of the hospital, nor the level of care provided; for example, 11, 22 and 59 reports were submitted by the three largest central academic hospitals, while most ADRs were reported by a tertiary level hospital (32). Similar to other studies, these figures are showing serious under-reporting (12, 19, 21, 22).

Comparable to other studies (4, 20, 44, 45), low reporting rates may be due to the fact that the majority of HCPs in the hospital (81.1%) were not aware of the existing ADR reporting and monitoring systems as well as the process for reporting. In addition, most of them (94.7%) had not been trained in ADR reporting (Table 1). The fact that a higher percentage of pharmacists than other HCPs were aware of the system may be related to pharmacists' education about drug safety and the fact that ADR report forms were required to be channelled to and through the pharmacy. In addition, more pharmacists than other HCPs had been trained in ADR reporting (Table 1). This lack of training and awareness of reporting ADRs may have been behind the fact that very few HCPs had ever reported an ADR (12.1%) as found in our study, despite the high number (96.2%) knowing it was necessary to report these when they occur (Figure 1). This figure is lower than the 22.8% of respondents in a hospital of Madhya Pradesh, in India (46), and may reflect the high number of HCPs in our study (89.4%) requesting training in ADR reporting (Table 1).

This lack of knowledge is reflected by the high percentage of HCPs stating they did not know how, when and where to report ADRs as well as lacked confidence in their reporting (Figure 2). This was despite, as mentioned, the overwhelming number of the HCPs feeling that ADR reporting was necessary and that it is a professional obligation (89.4%). This is seen as particularly important for ADRs to new medicines and a serious adverse event to particular medicines (Figure 3), with the responsibility of reporting ADRs up to all HCPs, particularly medical practitioners and nurses (Figure 4).

In addition to not knowing how, where and when to report ADRs, the lack of time to complete an ADR report as well as actively look for ADRs while on the ward, coupled with concerns that the report may be wrong, were principal reasons for not completing one (Figure 2). These results differ from an Australian study where the most frequently stated barrier to reporting ADRs among medical practitioners and nurses was the lack of feedback (47). Encouragingly, only a limited number of HCPs (22.0%) were concerned that reporting may generate extra work. Although there are a number of studies that assess causes of under-reporting ADRs (4, 20, 40, 41, 44, 48-50), only a few have fully evaluated barriers in hospitals. We believe this is important, given the potential impact of ADRs in hospitals on morbidity, mortality and costs. Through baseline assessments and training undertaken in our hospital, a number of factors were identified as contributing to the poor culture of ADR reporting among HCPs. These included: unavailability of ADR forms in consulting; lack of awareness of the importance of ADR reporting; poor feedback of what happens after HCWs complete ADR forms; and lack of awareness of what to report.

In this study, there was a general perception that ADR reporting is mostly for blood products and vaccines (Figure 5). The finding that only 59.1% of respondents identified allopathic drugs, i.e. the mainstream Western medicines, as requiring reporting is a concern (Figure 5). It implies that reporting of ADRs to common therapeutic medicines is currently not seen as important, except in the case of new medicines. Only one study was found where reporting all ADRs was regarded as more important than reporting only serious and unexpected reactions (51). Consequently, there appears to be a lack of awareness that well-recognised ADRs, when an ADR is suspected, even those not known to the drug or even suspected drug interactions, and related morbidity and mortality, require equal vigilance and prompt reporting to meet international, national and regional requirements, for marketed medicines (27, 28, 31, 52). This matter needs to be addressed.

Encouragingly, while some HCPs felt that ADR reporting should be voluntary (9.1%) and remunerated (8.3%), the majority (82.6%) felt that it should be made compulsory (Table 1), which is a standards requirement for quality service delivery in South Africa (23,33).

To improve spontaneous reporting rates, 89.4% of our respondents indicated that they would like to receive appropriate training (Table 2). HCPs also need to be familiarised with the PV system in hospitals and trained in using it. This objective could be achieved through in-house meetings and training sessions. Appropriate training has been shown to improve HCPs reporting of ADRs in other

countries (19, 40, 41, 53, 54), with hospital pharmacists potentially playing a key role in improving reporting rates (42).

We are now planning continuing education of HCPs about PV in our hospital through oral presentations, verbal reminders, increasing the accessibility of ADR report forms, and increased attendance of pharmacists in the wards, similar to methods described in other studies (47). The impact of these interventions will be measured to guide future activities in this and other public hospitals in South Africa.

We are aware that the major limitation of this study is that it was carried out in only one public sector hospital in South Africa. We believe though other public sector hospitals in South Africa will show similar findings and are undertaking similar research in other hospitals, as well as undertaking educational activities in this hospital, to try to address the appreciable under-reporting of ADRs in South Africa and the consequences among public sector hospitals in South Africa.

5. Conclusion

This study provides insight into various reasons for extensive under-reporting of ADRs among public sector hospitals in South Africa building on previous research, highlighting the lack of knowledge and awareness among HCPs about PV and ADR reporting systems. Principal reasons for under-reporting included HCPs did not know how to report, where to report and when to report ADRs. The fact that most HCPs admitted that they had not previously received training on ADR reporting indicates that providing training would be useful to address current concerns. There are ongoing activities in our hospital to address critical under-reporting of ADRs and to use the findings to guide future activities in this and other public sector hospitals in South Africa.

We hope our findings and activities will also be of interest to other public hospitals in Africa and other countries with similar situations to South Africa to help improve ADR reporting in general, and with it reduce associated morbidity, mortality and costs.

Key points and what this study adds

- ADRs are important causes of mortality and morbidity in both hospitalised and ambulatory patients adding to costs; however, they continue to be under-reported across all countries including South Africa. This is important as an appreciable number of ADRs can be prevented
- Under-reporting of ADRs frustrates efforts to identify, evaluate and prevent unusual, serious, hazardous and novel ADRs, and thus under-estimates their burden in populations
- The lack of knowledge about ADR reporting amongst HCPs in South Africa and across countries remains a problem, adding to the extent of under-reporting including South Africa where reports remain low
- Training on PV should be continuous among HCPs across sectors to identify potential ADRs and deal with them to improve future care
- The importance of PV has not been emphasized enough in the training of HCPs across countries, which needs to be addressed. This includes raising the importance of reporting ADRs which is sub-optimal even in countries where such reporting is mandatory
- Barriers to ADR reporting should be identified and reduced through activities such as education, monitoring and feedback
- Staff shortage remain a barrier because if there are not enough staff, there will not be enough time to complete the forms. This needs to be addressed since recognising and reporting ADRs will reduce mortality and costs in the long term saving, with beds available to treat other patients

Authors' contributions

AT, JCM and RSS developed the concept and designed the study. AT and BBG conducted the literature review. AT collected and analysed the data, which was supervised by JCM and RSS. All authors interpreted the data and AT drafted the manuscript. All authors participated in the critical review of subsequent versions of the manuscript and contributed significantly to its contents and to the management of the manuscript.

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Declaration of Interests

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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