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PHARMACOEPIDEMIOLOGY AND PRESCRIPTION

Knowledge, attitudes and practices of health care professionals towards adverse drug reaction reporting in public sector primary health care facilities in a South African district

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Abstract

Purpose Adverse drug reactions (ADRs) have an appreciable impact on patients' health. Little is known however about ADR reporting in ambulatory care environments especially in low- and middle-income countries. Consequently, our aim was to determine knowledge, attitudes and practices (KAP) among health care professionals (HCPs) towards ADR reporting in primary health care (PHC) facilities in South Africa. The findings will be used to direct future activities.

Methods Descriptive, cross-sectional design using quantitative methodology among 8 public sector community health care centres and 40 PHC clinics in the Tshwane Health District, Gauteng Province. A self-administered questionnaire was distributed to 218 HCPs, including all key groups.

Results A total of 200 responses were received (91.7%). Although an appropriate attitude towards ADR reporting existed, the actual frequency of ADR reporting was low (16.0%). Of the respondents, 60.5% did not know how to report, where to report or when to report an ADR and 51.5% said the level of their clinical knowledge made it difficult to decide whether or not an ADR had occurred. Over 97.5% stated they should be reporting ADRs with 89% feeling that ADR reporting is a professional obligation and over 70% that ADR reporting should be compulsory. When results were combined, the overall mean score in terms of positive or preferred practices for ADR reporting was 24.6% with pharmacists having the highest scores.

Conclusion Under-reporting of ADRs with gaps in KAP was evident. There is a serious and urgent need for education and training of HCPs on ADR reporting in South Africa.

Keywords Adverse drug reactions · Health care professionals · Pharmacovigilance · Ambulatory care · South Africa

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Introduction

Adverse drug reactions (ADRs) are a major public health problem that causes increased mortality, morbidity and costs, including increased hospital admissions and length of stay [1–9]. Physicians, pharmacists, dentists and nurses are in a position to play a key role in pharmacovigilance programmes; however, under-reporting of ADRs is common across countries especially in low- and middle-income countries (LMICs) [10–18].

Health care professionals (HCPs), especially in LMICs, should work together to remove barriers to ADR reporting across sectors and establish effective pharmacovigilance systems [15, 17, 19–24]. This includes physicians, pharmacists and nurses in ambulatory care in LMICs including South Africa [25–29]. Such activities should result in safety signals being detected at an earlier stage, leading to better and quicker decisions about medicine use. However, this cooperation means improved notification and recording of ADRs in ambulatory care where the majority of patients receive their medicines.

ADR spontaneous reporting is currently the basic method for collecting information about adverse post-marketing risks and events [17, 30]. Spontaneous reporting systems are inexpensive and simple to operate, and form the core of the global World Health Organization (WHO) database [31]. Their strength is connected to actual reporting rates of ADRs by HCPs, recognising through appreciable under-reporting in many countries [32–37].

Many factors are associated with ADR under-reporting among HCPs, referred to as 'the seven deadly sins' of pharmacovigilance [38]. These include a lack of knowledge about the necessary forms, ignorance of the rules and procedures and type of events that must be reported and lack of time and inertia, as well as lack of education among all key stakeholder groups [12, 16, 17, 19, 21, 23, 24, 37–40]. In addition, currently only a limited number of African countries have formal ADR reporting systems. Countries include Morocco, South Africa, Tanzania, Tunisia, Zimbabwe, Ghana, Egypt, Nigeria, Mozambique, Uganda and Togo, all of which are full members of the WHO Programme for International Drug Monitoring [41]. Progress has been hampered by lack of training and funding [42]. However, pharmacovigilance activities should increase with 35 African countries now part of the WHO Programme for International Drug Monitoring [41, 43]. The number of ADRs reported from African countries is also growing which is encouraging, with, for instance, South Africa reporting 28,609 individual cases by the end of 2015 [43]. However, more needs to be done. Implementation of successful spontaneous reporting systems requires resources of staff and systems. Concerns in LMICs include the remote location of a number of ambulatory care clinics and/or primary healthcare (PHC) clinics and poor telecommunication services, as well as low numbers of HCPs and inadequate training [44]. The knowledge of, attitudes towards and practices of spontaneous reporting may also differ at various levels of health care systems [15, 16, 19, 24].

Concerns with the under-reporting of ADRs in South Africa led to the establishment of a Pharmacovigilance Committee within the previous Medicines Control Council (MCC) of South Africa [45], providing direction on ADR reporting [46]. The MCC has now been replaced by the South African Health Products Regulatory Authority (SAHPRA) [47, 48]. Post-marketing reporting of ADRs is a legal requirement. All serious or suspected ADRs must be reported to the regulatory authority by the medicine licence holder or applicant within 15 days of receipt of such information [46]. There are also initiatives among the provinces (regions) to promote pharmacovigilance activities to increase the number of ADR reports [49].

Between 2012 and 2017, pilot projects were rolled-out in 10 health districts in South Africa to evaluate various health system strengthening interventions focused at the PHC level [50], in preparation for the implementation of the National Health Insurance (NHI) scheme for universal healthcare including improved quality of care and services. One of these districts was the Tshwane Health District in Pretoria, delivering PHC services through community health centres (CHCs) incorporating PHC clinics as the first point of entry to healthcare services. Health status reports, including ADRs, are discussed at the Tshwane Health District Pharmaceutical and Therapeutics Committee (PTC) meetings on a quarterly basis. PTCs are now a formal requirement across sectors in South Africa [51]. Over the 18-month period prior to this study, very few ADRs were considered, which is a concern. Actual numbers were not available due to poor record-keeping.

To date, few published studies have determined which factors relate to under-reporting of ADRs among PHC facilities especially in LMICs [15, 19]. This compares to multiple studies among hospitals including South Africa where there are concerns with the lack of reporting of ADRs although this is now being addressed [1, 3–5, 14, 16, 17, 52–57].

This is a critical concern given the high prevalence of both infectious and non-communicable diseases across Africa [58–64]. In addition, there are appreciable differences in patients with HIV in sub-Saharan Africa compared with western countries, with a higher percentage being women, leading to appreciable genetic differences between the populations [63, 65]. There are also a considerable number of patients with concomitant infectious diseases, including HIV, alongside NCDs in sub-Saharan Africa, impacting on potential ADRs with patients likely to be on multiple medications [66, 67].

An overview of concerns regarding the lack of reporting of ADRs at a secondary level hospital in South Africa has recently been published alongside potential ways to address this [16,

52]. To the best of our knowledge, information about these variables among PHC facilities in South Africa has not been published. This omission is a concern given the number of patients treated at public PHC facilities in the country, coupled with ongoing initiatives to improve the care of patients with chronic diseases [68]. This study was undertaken to determine the current ADR reporting situation among PHC facilities in Tshwane Health District. The findings could be used to design and implement programmes to improve ADR reporting at PHC facilities in the province and other sites and could also be of interest to other African countries striving to improve healthcare delivery.

Methods

Study design and setting

A descriptive, cross-sectional design used quantitative methodology and a self-administered questionnaire. The study was conducted among all 48 PHC facilities in the Tshwane Health District (8 CHCs and 40 PHC clinics), situated in the Gauteng Province of South Africa. This district was chosen as it was a pilot area for the introduction of NHI.

In the public sector, approximately 80% of consultations at the PHC level are with a professional nurse. PHC clinics are smaller facilities, mainly staffed by nurses and sometimes a visiting physician. A pharmacist will visit clinics once a month and, at the time of the study, post-basic pharmacist assistants (PBPAs) were being introduced into clinics' staff complement, working under the direct supervision of a pharmacist. CHCs are larger facilities than clinics, staffed by a multidisciplinary PHC team consisting of professional nurses, physicians, a pharmacist and PBPAs. Some CHCs operate 24 h per day with staff rotating.

Study population and participants

The study population consisted of 475 HCPs (38 physicians, 317 professional nurses, 10 pharmacists and 110 PBPAs) employed at the 48 PHC facilities in the Tshwane Health District at the time of the study.

A combined sample size estimation of all HCP categories was performed on nQuery Advisor, Release 7.0, considering staff rotations, visiting staff and that all facilities are not equally staffed. It was estimated that with a combined sample size of 212 respondents, a two-sided 95% confidence interval for the percentage HCPs with satisfactory knowledge, attitude and practices would be within ± 5% of the percentage that would be calculated from the sample, assuming that 80% of the respondents had satisfactory knowledge, attitudes and practices.

Convenience sampling was employed. HCPs who were available on the day of data collection and who complied with the following inclusion criteria were approached:

- HCPs permanently employed by the Gauteng Department of Health
- Registered pharmacists, professional nurses, physicians and PBPAs
- Willingness to participate in the study
- Provision of written informed consent.

Data collection instrument and process

A self-administered, structured questionnaire was developed based on previous practice experience among the co-authors, discussions with experts and consideration of the literature [69]. Two experts in the field of pharmacovigilance reviewed the questionnaire for content validity; after which, it was tested among 6 HCPs for feasibility. The questionnaire was subsequently revised to improve its robustness to achieve appropriate outcomes (Appendix 1 in the Supplementary Material).

Potential participants at the clinics were approached by one of the six community service pharmacists. The aim and objectives of the study were explained to them and written consent to participate was obtained (Appendices 2 and 3 in the Supplementary Material). A total of 218 questionnaires were distributed. The questionnaires were handed to participants for anonymous completion in a private room. On completion, respondents placed questionnaires in a sealed box to ensure confidentiality of responses.

Data entry and analysis

Data were captured using Microsoft Excel™, checked for accuracy and cleaned before analysis with SAS, release 9.2, running under Microsoft Windows.

Responses were categorised according to knowledge, attitudes and practices based on the questions included in the questionnaire. Correct or preferred responses were subject to frequency counts and percentages for each item as well as for the respective HCP category.

An individual overall mean score (%) was calculated for each participant according to their knowledge, attitudes and practices, followed by an overall mean and median (%) score for each HCP category. Mean (%) scores for the different HCP categories were compared by analysis of variance (ANOVA), followed by pairwise comparisons using the *t* test. Statistical significance was set at $p < 0.05$. An overall mean score (%) with a 95% confidence interval (CI) for all participants was also calculated for knowledge, attitudes and practices.

Ethical considerations

Ethical clearance for the study was obtained from the Medunsa Research Ethics Committee of the University of Limpopo, now Sefako Makgatho Health Sciences University, prior to the commencement of the study (MREC/H270/2013). Permission to conduct the study at the PHC facilities was obtained from the Tshwane Research Committee and the Chief Director of the Tshwane Health District. All participants provided written informed consent.

Results

Demographic characteristics

Two hundred of the 218 distributed questionnaires were completed, giving a response rate of 91.7%. No questionnaires were excluded from the analysis. One hundred and sixty-six (83%) respondents were female with 73.0% employed at PHC clinics and 27% at CHCs. Table 1 gives further details of respondents' professions.

Health care professionals' knowledge of what should be reported as ADRs

More than three-quarters of respondents understood the term 'adverse drug reaction' (75.6%) with 92.5% aware that ADRs must be reported (Table 1). Over 90% were also aware of the objectives of pharmacovigilance in the public sector. However, only 57.5% were aware of an ADR reporting and monitoring system in the district, only 33% where to find the forms and only 9.0% where to submit them (Table 1). Table 1 also contains data related to the need for reports for important treatment options as well as the breakdowns by specific HCP groups.

The overall mean knowledge scores for all participants, based on individual mean scores, are also presented in Table 1. Medical practitioners (82.8%; $p = 0.0174$), pharmacists (91.4%; $p = 0.0025$) and professional nurses (84.0%; $p < 0.0001$) scored significantly higher than PBPAs (72.2%).

The respondents showed reasonably good knowledge of the type of adverse events that should be reported, ranging from 65.5% for congenital anomaly to 89.5% for reaction to a new medicine and a serious event (Fig. 1).

Attitudes towards adverse drug reaction reporting

Table 2 contains data related to the attitudes and importance of ADR reporting. A high percentage (89.0%) agreed that reporting ADRs is a professional obligation and that there was a need for training. ADR reporting is also considered very important in everyday work (63.0%).

Individual overall attitude scores (%) were calculated for each HCP participant, based on positive or preferred responses, and then combined in group scores. The overall mean positive or applicable attitude score was 63.3% (95% CI 60.7–65.8%). The mean attitude scores of medical practitioners (66.7%; $p = 0.0055$), pharmacists (73.9%; $p = 0.0011$) and professional nurses (68.3%; $p < 0.0001$) were significantly greater than those of PBPAs (55.2%).

The major factors which were perceived to discourage ADR reporting are listed in Table 3. Nearly two-thirds of participants (60.5%) did not know how to report, where to report or when to report an ADR. Over half of the HCPs (51.5%) said that the level of their clinical knowledge made it difficult to decide whether or not an ADR had occurred.

Respondents' perceptions of possible roles of HCPs in responding to ADRs are contained in Fig. 2. Over 97% stated that they should be reporting ADRs with over 92% stating that they should try to prevent ADRs when selecting medicines to treat their patients.

HCP current practice of ADR reporting

Table 4 shows that only 16.0% of HCPs surveyed had ever reported a suspected ADR, although 65.0% said that ADR forms were available in their facilities and only 12.0% knew where the forms were kept.

In contrast to the 16.0% of respondents who stated that they had reported an ADR, more than a third (36.5%) of respondents said that they kept copies of the forms they submitted, but only three could attach a copy of the completed form. This anomaly casts doubts on their understanding of these two questions. Only 17.0% of respondents indicated they had ever received training on ADR reporting, more among pharmacists than other HCPs (Table 4).

When all practice questions and statements for all HCPs were combined, the overall mean score in terms of positive or preferred practices for ADR reporting was 24.6% (95% CI 21.7–27.4%). The mean practice score for PBPAs (20.9%) was significantly lower than the mean for pharmacists (33.3%; $p = 0.050$), whilst not significantly different from the mean practice scores of medical practitioners (21.7%) and professional nurses (27.5%).

Based on the overall mean scores, pharmacists achieved the highest ranking in terms of knowledge, attitudes and practice. Although the differences were not statistically significant, these findings would not have been out of place due to pharmacists' training focussing on medicines.

Discussion

Whilst a positive attitude to ADR reporting existed among HCPs working at PHC facilities in our study, the actual

Table 1 Knowledge of health care professionals on adverse drug reactions (ADRs) ($n = 200$)

Item		Pharmacist ($n = 10$)	Medical practitioner ($n = 23$)	Professional nurse ($n = 89$)	Post-basic pharmacist assistant ($n = 78$)	Total ($n = 200$)
Number (%) of correct responses per health care professional category						
Understanding the term 'adverse drug reaction'		10 (100%)	19 (82.6%)	66 (74.2%)	56 (71.8%)	151 (75.6%)
Know that ADRs must be reported		10 (100%)	18 (78.3%)	87 (97.8%)	70 (89.7%)	185 (92.5%)
Know of existence of an ADR reporting and monitoring system in district		7 (70.0%)	12 (52.1%)	58 (65.2%)	38 (48.7%)	115 (57.5%)
Know where to find the form to complete for reporting ADRs		6 (60.0%)	4 (17.4%)	33 (37%)	23 (29.5%)	66 (33.0%)
Know where the ADR reporting form must be submitted		3 (30.0%)	2 (8.7%)	7 (7.9%)	6 (7.7%)	18 (9.0%)
An event related to these items must be reported	Allopathic drugs	9 (90.0%)	15 (65.2%)	55 (61.8%)	40 (51.3%)	119 (59.5%)
	Herbal drugs	9 (90.0%)	15 (65.2%)	56 (62.9%)	41 (52.6%)	121 (60.5%)
	Traditional and complementary medicine	8 (80.0%)	15 (65.2%)	65 (73.0%)	45 (57.7%)	133 (66.5%)
	Blood products	8 (80.0%)	22 (95.7%)	76 (85.4%)	52 (66.7%)	158 (79.0%)
	Biologicals	9 (90.0%)	18 (78.3%)	64 (73.0%)	47 (60.3%)	138 (69.0%)
	Medical devices	10 (100%)	21 (91.3%)	79 (88.8%)	54 (69.2%)	164 (82.0%)
	Vaccines	8 (80.0%)	22 (95.7%)	81 (91.0%)	61 (78.2%)	172 (86.0%)
Main objectives of pharmacovigilance in the public sector	Improve patient care and safety	10 (100%)	23 (100%)	86 (96.6%)	69 (88.5%)	188 (94.0%)
	Improve public health and safety	10 (100%)	23 (100%)	84 (94.4%)	68 (87.2%)	185 (92.5%)
	Contribute to assessment of risk/benefit of medicines	10 (100%)	22 (95.7%)	87 (97.8%)	66 (84.6%)	185 (92.5%)
	Promote understanding, education and clinical training in field	9 (90.0%)	23 (100%)	84 (94.4%)	67 (85.9%)	183 (91.5%)
	Ensure effective communication of ADR reporting to public	10 (100%)	20 (87.0%)	83 (93.3%)	68 (87.2%)	181 (90.5%)
Mean and median (%) knowledge score on ADRs per health care professional category						
Mean % (standard deviation)		91.4 (12.3)	82.8 (14.7)	84.0 (17.0)	72.2 (22.0)	79.6* (19.6)
Median % (quartile 1–quartile 3)		95.2 (85.7–100)	85.7 (71.4–95.2)	90.0 (76.2–95.2)	76.2 (61.9–90.5)	85.7 (71.4–95.2)

*95% CI 76.9–82.3

practice of ADR reporting was poor, similar to studies in other LMICs including India [57, 69–73], Pakistan [54] and Romania [74].

Our results reflected a lack of awareness (57.5%) of HCPs about the existence of an ADR reporting system (Table 1), reflected by very few HCPs ever reporting an adverse event

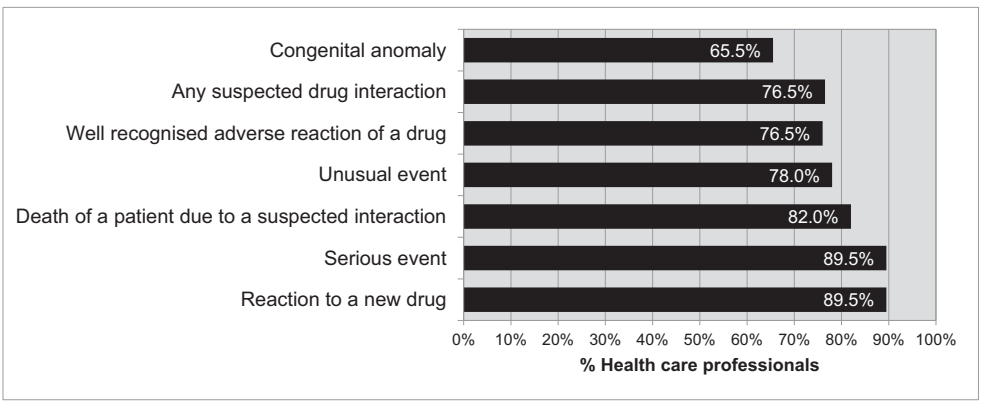

Fig. 1 Percentage of health care professionals with knowledge of the type of events that should be reported ($n = 200$)

Table 2 Attitudes of health care professionals towards the reporting of adverse drug reactions (ADRs) ($n = 200$)

Item		Pharmacist ($n = 10$)	Medical practitioner ($n = 23$)	Professional nurse ($n = 89$)	Post-basic pharmacist assistant ($n = 78$)	Total positive responses ($n = 200$)
Number (%) of positive responses per health care professional category						
ADR reporting is necessary		10 (100%)	21 (91.0%)	84 (94.4%)	67 (85.9%)	182 (91.0%)
ADR reporting is a professional obligation		10 (100%)	18 (78.3%)	87 (97.8%)	63 (80.8%)	178 (89.0%)
Need for training on ADR reporting		7 (70.0%)	20 (87.0%)	78 (87.6%)	73 (93.6%)	178 (89.0%)
ADR reporting should be	Voluntary	4 (40.0%)	3 (13.0%)	5 (5.6%)	8 (10.3%)	20 (10.0%)
	Compulsory	6 (60.0%)	13 (56.5%)	76 (85.4%)	54 (69.2%)	149 (74.5%)
	Remunerated	0	2 (8.7%)	2 (2.2%)	1 (1.3%)	5 (2.5%)
Health care worker's role	Preventing ADRs	9 (90.0%)	22 (95.7%)	83 (93.3%)	71 (91.0%)	185 (92.5%)
	Detecting ADRs	10 (100%)	23 (100%)	85 (95.5%)	64 (82.1%)	182 (91.0%)
	Managing ADRs	10 (100%)	23 (100%)	85 (95.5%)	63 (80.8%)	181 (90.5%)
	Reporting ADRs	10 (100%)	22 (95.7%)	88 (98.9%)	75 (96.2%)	195 (97.5%)
The importance of pharmacovigilance in everyday work	Very important	5 (50.0%)	13 (56.5%)	57 (64.0%)	51 (65.4%)	126 (63.0%)
	Important	5 (50.0%)	7 (30.4%)	21 (23.6%)	20 (25.6%)	53 (26.5%)
	Slightly important	0	0	0	0	0
	Not important at all	0	0	0	0	0
Mean and median (%) attitude score on ADRs per health care professional category						
Mean % (standard deviation)		73.9 (18.5)	66.7 (15.5)	68.3 (17.8)	55.2 (16.9)	63.3* (18.3)
Median % (quartile 1–quartile 3)		77.8 (66.7–83.3)	66.7 (61.1–83.3)	72.2 (55.6–83.3)	50.0 (44.4–66.7)	63.9 (50.0–77.8)

*95% CI 60.7–65.83

(16.0%) or contributed to the ADR monitoring system in the district (7.0%) (Table 4), again similar to other LMICs including secondary care facilities in South Africa [16, 17, 72, 75]. However, reporting rates in this study are appreciably lower than seen in India where 47% of respondent physicians had reported an ADR [71] and Malaysia where 51.9% of physicians and pharmacists in PHC facilities had reported an ADR in the past year [19].

Whilst the majority of HCPs surveyed (89.0%) felt that ADR reporting is a professional obligation (Table 2) similar to other countries [17, 19, 56, 71, 74, 76], they would be encouraged to report ADRs if the reaction is serious (89.5%), for a new product (89.5%) or unusual (78.0%) (Fig. 1), similar to other studies [75–77]. However, 22 (11.0%) of HCPs were unaware of the professional obligation to report ADRs (Table 2). Personal discussions and awareness programmes should help to remove misconceptions and modify attitudes so that ADR reporting becomes an integral part of clinical practice [19, 76, 78, 79]. The attitude of HCPs that a single unreported case may not affect the ADR database (19.0%) also needs to be challenged and changed. Addressing this through education may well lead to enhanced spontaneous reporting.

ADRs of herbal and traditional medicines are well known [80–83]. However, only 60.5% of HCPs considered it necessary to report events related to herbal drugs which is a concern

Table 3 Major factors which discouraged reporting of adverse drug reactions (ADRs) ($n = 200$)

Factors discouraging ADR reporting	Number (%) of HCPs ($n = 200$)
A single unreported case may not affect the ADR data base	38 (19.0%)
Non-remuneration for reporting	47 (23.5%)
Lack of confidence to discuss the ADRs with other colleagues	56 (28.0%)
Concern that reporting may generate extra work	67 (33.5%)
Lack of time to actively look for ADRs whilst at work	79 (39.5%)
Lack of time to complete a report	88 (44.0%)
Concern that the report may be incorrect	93 (46.5%)
Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred	103 (51.5%)
Do not know how to report, where to report and when to report	121 (60.5%)

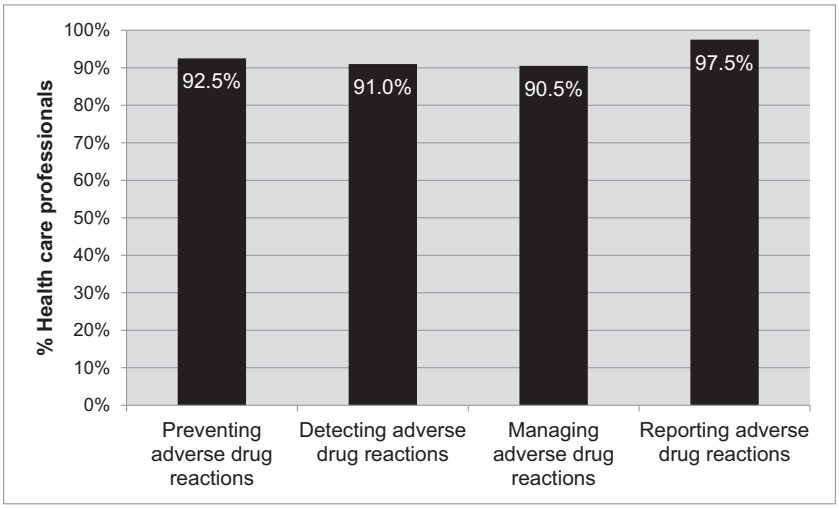

Fig. 2 Health care professionals' perceived roles in ADR reporting ($n = 200$)

(Table 1). This is important in South Africa and across Africa since many such remedies are currently being used [84–86] and there is appropriate legislation to address this [87]. However, this attitude may reflect a general reluctance among the population to admit to seeking traditional remedies although such practices may be common especially among rural black households in South Africa [88].

A number of factors impacted negatively on the willingness to report ADRs of which 'Do not know how to report, where to report and when to report' (60.5%) was the most prominent (Table 3). These findings suggest that under-reporting of ADRs is associated with gaps in knowledge, attitudes and practices, similar to other studies including hospital-based studies [17–19, 23, 72, 74, 76]. Concerns with lack of knowledge may reflect a spontaneous reporting rate of only 16.0% (Table 4), similar to other reported studies [72, 75]. Another concern was that only 12.0% of HCPs knew where the ADR forms were kept (Table 4). These joint findings again suggest a serious and urgent need for appropriate education and training, from identification to reporting, which should improve spontaneous reporting [19, 72, 76, 89–91]. We have seen the successful implementation of a pharmacist-directed improvement plan to enhance ADR reporting in secondary care in South Africa [52]. Whether a similar approach would be successful over a number of widespread PHC facilities remains to be seen. However, such approaches are being tried in other countries [19, 72, 78], and

Table 4 Practice of health care professionals in adverse drug reaction (ADR) reporting ($n = 200$)

Item		Pharmacist ($n = 10$)	Medical practitioner ($n = 23$)	Professional nurse ($n = 89$)	Post-basic pharmacist assistant ($n = 78$)	Total correct responses ($n = 200$)
Number (%) correct responses per health care professional category						
Have you ever reported any suspected ADR?	Yes	4 (40.0%)	6 (26.1%)	12 (13.5%)	10 (12.8%)	32 (16.0%)
Have you reported any suspected ADR to the ADR reporting and monitoring system in your district?	Yes	1 (10.0%)	3 (13.0%)	4 (4.5%)	6 (7.7%)	14 (7.0%)
Do you have the adverse reporting form available in your facility?	Yes	7 (70.0%)	10 (43.5%)	70 (78.7%)	43 (55.0%)	130 (65.0%)
Where are the ADR forms kept in your facility?	Pharmacy/managers office	3 (30.0%)	3 (13.0%)	13 (14.6%)	5 (2.5%)	19 (12.0%)
Copies of the submitted ADR forms are kept	Yes	2 (20.0%)	6 (26.1%)	37 (41.6%)	28 (35.9%)	73 (36.5%)
Copy of form attached to questionnaire	Yes	0	0	2 (2.2%)	1 (1.3%)	3 (1.5%)
Training received on ADR reporting	Yes	4 (40.0%)	4 (17.4%)	18 (20.2%)	8 (10.3%)	34 (17.0%)
Mean and median (%) practice score on ADRs per health care professional category						
Mean % (standard deviation)		33.3 (31.4)	21.7 (24.3)	27.5 (18.0)	20.9 (20.4)	24.6* (20.7)
Median % (quartile 1–quartile 3)		25.0 (0.0–66.7)	16.7 (0.0–33.3)	33.3 (16.7–33.3)	16.7 (0.0–33.0)	16.7 (8.3–33.3)

*95% CI 21.7–27.4

we will be following the findings with interest. In the meantime, all HCPs in South Africa should be encouraged to report suspected ADRs irrespective of the level of association with the possible cause [36]. Reporting whether known, unknown, common, uncommon, serious or mild ADR, even with established medicines, should be encouraged. Training in pharmacovigilance should also be included in the core curriculum of all HCPs following government initiatives [47], helped by the introduction of a new reporting form [48, 68]. Provision is also being made for a mobile electronic version (App), which would include an acknowledgement of a receipt sent to the reporter to address concerns. These initiatives will be investigated in future studies for their impact.

In addition, SAHPRA is in the process of strengthening its vigilance and post-marketing surveillance programme, including the development of a communication strategy to support improved external stakeholder interactions and relations. Providing relevant and user-friendly feedback to stakeholders, particularly health professionals and the public, should start to address previous concerns [47].

We are aware of a number of limitations with this study such as including only one district and an unequal distribution of participants from the different HCP categories. For instance, there was low participation (28%) from nurses. We are not sure why but possible reasons could include being reluctant to participate, being too busy or being on night duty at the 24-h CHCs. However, all pharmacists as well as a high percentage of PBPAs (71%) and physicians (60%) took part. In addition, qualitative research methodologies would have provided a more in-depth understanding. Future research is planned to address these concerns. Despite these limitations, we believe our findings are robust and provide direction for the future as the authorities strive to improve the use of medicines in ambulatory care.

Conclusion

Our findings strongly suggest that under-reporting of ADRs is associated with gaps in knowledge, attitudes and practices among ambulatory care HCPs in South Africa. Consequently, there is a great need to create awareness about ADRs and to promote the reporting of ADRs among HCPs. This is especially important given the rising burden of non-communicable diseases in South Africa along with infectious diseases. Training sessions should help, augmented by structured surveillance and electronic methods of data handling, analysis and the generation of ADR reports. In addition, ADR reporting must be seen as an integral part of undergraduate training and the clinical activities of all ambulatory care HCPs. We will be monitoring this process in the future.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval In addition as mentioned, ethical clearance for the study was obtained from the Medunsa Research Ethics Committee of the University of Limpopo, now Sefako Makgatho Health Sciences University, prior to the commencement of the study. Permission to conduct the study at the PHC facilities was also obtained from the Tshwane Research Committee and the Chief Director of the Tshwane Health District, and all participants provided written informed consent to be part of the study.

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