



# Awareness and attitudes regarding adverse drug events and reporting in South Africa

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## INTRODUCTION

In recent years, there has been an increase in direct consumer reporting of ADEs to national pharmacovigilance centres [1]. Consumer reporting offers additional perspectives on people's experiences with ADEs that are unavailable from the HCP reports. With the rise of the internet and social media, consumers can play a significant role in pharmacovigilance because their experiences could alter the benefit-harm analysis of drugs [2]. To allow for consumer involvement in pharmacovigilance, they must be aware of what needs to be reported and who to report to, and they must have easy access to the reporting tools [3].

## AIM

The aim of this study was to explore adults' awareness of ADEs, attitudes towards reporting and perceptions of their role in reporting ADEs in South Africa.

## METHODOLOGY

**Study design:** An analytical, cross-sectional study.

**Data collection tool:** A self-administered, online, structured questionnaire was created using questionnaires from published studies with comparable objectives. The questionnaire contained 32 questions organised into: Section A: Socio-demographic information; Section B: Awareness of adverse drug events; Section C: Attitudes regarding adverse drug events and adverse drug events reporting; Section D: Practices and experience with reporting adverse drug events; Section E: Barriers to reporting adverse drug events. The questionnaire's section A, B and C are presented in this paper. A statistician evaluated the questionnaire's face validity, and experts from the Medicine Usage in South Africa Scientific Committee evaluated its relationship to the study's objectives.

**Participant recruitment:** A news article was published on the English News24 and Afrikaans Netwerk24 online platforms that contained a link to a SurveyMonkey questionnaire. The survey was available for data collection from 18 April 2023 to 18 June 2023. To participate in this study, participants had to be at least 18 years old, live in South Africa, and give their informed consent.

**Data analysis:** The statistical analysis for both descriptive (numbers and/or percentages) and inferential statistics was carried out using R statistical software version 4.3.1.

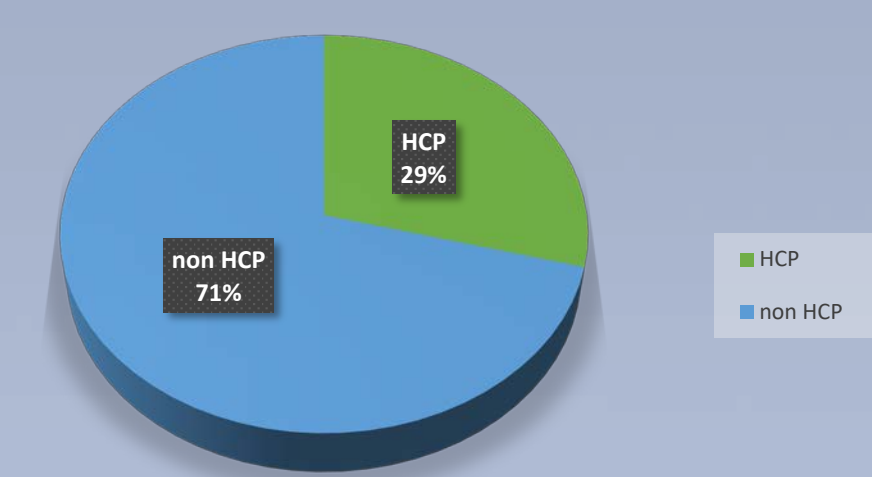
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## RESULTS

Participants in the study included both healthcare professionals (HCP) and non-HCP, as Figure 1 illustrates.

Figure 1: Proportion of HCP versus non-HCP



Although most participants showed a good level of awareness about ADEs, there was a poor level of awareness about the Med Safety App, which is a reporting tool. The data on awareness criteria that were evaluated for this study is displayed in Table 1.

Table 1: Awareness of ADEs

Characteristic	N	Non-HCP <sup>1</sup>	HCP <sup>1</sup>	p-value
Has heard about the Med Safety app	336	N = 237 20 (8.4%)	N = 99 38 (38.4%)	<0.001
Has heard about SAHPRA	336	N = 237 168 (70.9%)	N = 99 92 (92.9%)	<0.001
Has heard about the term adverse drug events	350	N = 248 202 (81.5%)	N = 102 100 (98.0%)	<0.001
Know that adverse drug events should be reported	302	N = 202 167 (82.6%)	N = 100 97 (97.0%)	<0.001
Know that all age groups can experience adverse drug events	291	N = 194 182 (93.8%)	N = 97 94 (96.9%)	0.4
Aware that any person can report ADEs	291	N = 194 157 (80.9%)	N = 97 90 (92.8%)	0.008

With questions about interactions with HCPs, reading medication leaflets, and the significance of ADE reporting, the study investigated the participants' attitudes toward ADEs and ADE reporting. Table 2 shows results on medicine user attitudes.

Table 2: Attitudes on ADE and ADE reporting

Characteristic	N	Non-HCP <sup>1</sup>	HCP <sup>1</sup>	p-value
History of medication use	336	N = 237 231 (97.5%)	N = 99 98 (99.0%)	0.7
Asked the health professional about ADEs	323	N = 225 118 (52.4%)	N = 98 45 (45.9%)	0.3
Read the medication leaflet	322	N = 225 200 (88.9%)	N = 97 90 (92.8%)	0.3
Healthcare professionals provided information on ADEs	323	N = 225 115 (51.1%)	N = 98 65 (66.3%)	0.011
Medicine not obtained from health professional	323	N = 225 42 (18.7%)	N = 98 10.2 (10%)	0.057
Believe it is important or necessary to report ADEs	319	N = 224 208 (92.9%)	N = 95 93 (97.9%)	0.075

The three key reasons why the participants felt (agree and strongly agree) it was important to report ADEs were indicated as:

- making the HCP aware of what the medicine has caused (95.9%  $n=306$ ;  $N=319$ );
- avoiding the repeat of the reaction in other people, (94.6%,  $n=302$ ;  $N=319$ ); and
- ensuring that the report reaches the medicine's manufacturer (92.2%,  $n=294$ ;  $N=319$ ).

Overall, 45.6% ( $n=99$ ;  $N=217$ ) of non-HCPs did not feel well informed about the adverse effects that their medication may cause, compared with 25.5% ( $n=24$ ;  $N=94$ ) of the HCPs. A larger percentage (71.4%,  $n=155$ ;  $N=217$ ) of non-HCPs expressed a wish to learn more about the side effects of their medicine compared with 61.7% ( $n=58$ ;  $N=94$ ) of the HCP

## CONCLUSION

Most participants were aware of the need to report any ADEs they experience. Awareness of ADEs was noticeably higher among HCP compared to non-HCP. A small proportion of participants knew about the Med Safety App, which was launched in 2021 in South Africa to improve ADE reporting. Participants agreed on the importance of ADE reporting in raising awareness and protecting others from experiencing ADEs. The optimistic outlook seen in this study should be leveraged to support initiatives that encourage reporting of ADEs in South Africa. Both HCPs and non-HCPs must be the target of these activities.

## DISCLOSURES

This research was not funded and the authors declare that they have no conflicts of interest.