A cross-sectional baseline assessment of the pharmacovigilance systems, processes and challenges faced by healthcare professionals in three south African districts prior to pharmacovigilance training and programme roll-out

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Abstract

This baseline assessment was conducted in order to document the knowledge, awareness and practice of pharmacovigilance systems among public health care professionals (HCPs) in the Eastern Cape (EC) Province of South Africa, as a key to understanding the strategies required for the roll-out of a pharmacovigilance programme. A semi-structured, researcher-administered questionnaire was used to interview seven key informants and 53 HCP. Informal conversations and observations were also conducted with various other HCPs to supplement the collected information. Findings from this baseline assessment revealed limited knowledge, awareness and practice around pharmacovigilance systems and processes among HCPs and key informants. They further highlighted gaps that can inform planning for training in the province. In conclusion, the baseline assessment found gaps that indicate the need for an appropriate training intervention of all relevant HCPs impacted by the roll-out of the decentralised pharmacovigilance programme in order to ensure the successful implementation of the programme in the EC Province of South Africa.

Key words: decentralised pharmacovigilance, ADRs, Eastern Cape, pharmacovigilance systems and processes.

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Introduction

In addition to their benefits, medicines may cause harm in the form of Adverse Drug Reactions (ADRs). An ADR is defined as a response to a drug which is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or the modification of physiological function (WHO, 2002). ADRs are major problems and are a leading cause of mortality and morbidity globally (Lazarou et al, 1998; Classen et al, 1997; Mouton et al, 2015; Mouton et al, 2016).

The implementation of pharmacovigilance defined as "the science and activities relating to the detection, evaluation, understanding, and prevention of adverse reactions to medicines or any other medicine-related problems" is crucial in minimising the harm that may result from medicines (WHO, 2002). This is particularly important in South Africa, which has the largest antiretroviral therapy (ART) programme globally, one of the highest TB burdens, a multi-ethnic population as well as a high rate of use of herbal and complementary medicines.

The National Pharmacovigilance Centre for Public Health Programmes (NPC) was established by the South African National Department of Health in 2004. Through its work, it identified the lack of correct knowledge, right attitudes and perception of HCPs toward pharmacovigilance as a whole and a potential bottle-neck to the establishment of a robust pharmacovigilance programme. In order to document this, the NPC conducted a baseline study whose main objective was to gauge the understanding of the existing pharmacovigilance systems, processes and activities in the Eastern Cape Province. This was done to customize an acceptable and feasible approach for the training/roll-out of a pharmacovigilance programme in the province. The Eastern Cape Province, in particular, its districts of Amathole, Chris Hani, and Alfred Nzo, were chosen because the national pharmacovigilance programme had not been rolled out in these areas.

Methods and materials

This was a cross-sectional study based on a researcher-administered questionnaire. Participants included key informants from provincial and district levels of administration as well as HCPs from healthcare facilities. Purposive sampling was used to identify the key informants while convenience sampling was used to enrol HCPs into the study. The HCPs were chosen from three randomly selected healthcare facilities within each district so that participants came from a hospital, a community health centre (CHC) and a primary health care (PHC). The survey was conducted over four days from the 20th July to the 23rd July 2015 in the three districts, Amathole, Chris Hani and Alfred Nzo. The sample included medical doctors, pharmacists, pharmacy assistants and professional nurses. In total, seven key informants and 53 HCPs were enrolled in the study.

Data were collected using a researcher-administered, semi-structured, tablet-based questionnaire. Two field workers, an adult male and an adult female administered the questionnaires to respondents who consented to participate after being briefed about the study's objectives. A boardroom or an empty office was used to conduct the interview privately. A tablet pre-loaded with the questions was used; respondents were first shown how to use it; then they were requested to punch in their answers to questions as they popped up. All interviews took place during working hours. The data captured from the tablet were synchronised directly with an online electronic database; hence, the dataset so constituted was exported to Microsoft Excel where analysis for descriptive statistics was conducted.

Ethics approval for the study was obtained from the Human Sciences Research Council Ethics Committee and permission to use data was obtained from the National Department of Health.

Results

Findings from health care professional interviews

Of the 53 HCPs, 18 (34.0%) were from Alfred Nzo, 11 (20.8%) from Amathole, and 24 (45.3%) from Chris Hani as shown in Table 1.

Socio-demographic characteristics

Table 1: Gender characteristics of HCPs

Gender	***Total N=53***	***Alfred Nzo N=18***	***Amathole N=11***	***Chris Hani N=24***
	N (%)	*N (%)*	*N (%)*	*N (%)*
Male	14 (26.4)	3 (16.7)	4 (36.4)	7 (29.2)
Female	39 (73.6)	15 (83.3)	7 (63.6)	17 (70.8)

Overall, the majority of participants were in the 50-59 age category; but there were some differences in that in Chris Hani District, most of the participants were aged 30 to 59 years old; whilst in Amathole, young adults of 18-19 years old and those 50-59 years old were in equal numbers as shown in Table 2.

Table 2: Age distribution of respondents

Age categories (years)	***Total N=53***	***Alfred Nzo N=18***	***Amathole N=11***	***Chris Hani N=24***
	N (%)	*N (%)*	*N (%)*	*N (%)*
18 – 29	11 (20.8)	3 (16.7)	4 (36.4)	4 (16.7)
30 – 39	12 (22.6)	3 (16.7)	2 (18.2)	7 (29.2)
40 – 49	9 (17.0)	2 (11.1)	1 (9.1)	6 (25.0)
50 – 59	20 (37.7)	10 (55.6)	4 (36.4)	6 (25.0)
60+	1 (1.9)	0 (0.0)	0 (0.0)	1 (4.2)

Professional categories of respondents and types of facilities

The majority of respondents were nurses followed by medical doctors and pharmacists; though, in Chris Hani District, 25% of respondents were pharmacy assistants as reported in Table 3.

Table 3: Professional categories of respondents

Categories	***Total (N=53)*** *N (%)*	***Alfred Nzo (N=18)*** *N (%)*	***Amathole (N=11)*** *N (%)*	***Chris Hani (N=24)*** *N (%)*
Doctor	15 (28.3)	5 (27.8)	4 (36.4)	6 (25.0)
Nurse	24 (45.3)	9 (50.0)	5 (45.5)	10 (41.7)
Pharmacist	9 (17.0)	2 (11.1)	1 (9.1)	2 (8.3)
Pharmacy assistant	5 (9.4)	2 (11.1)	1 (9.1)	6 (25.0)

By type of health facility, the majority of respondents were based in hospitals, while others worked at primary health clinics and health centres (Table 4).

Table 4: Respondents by facility type

Facility type	***Total (N=53)*** *N (%)*	***Alfred Nzo (N=18)*** *N (%)*	***Amathole (N=11)*** *N (%)*	***Chris Hani (N=24)*** *N (%)*
Community Health Clinic	15 (28.3)	4 (22.2)	4 (22.2)	7 (29.2)
Primary Health Care	8 (15.1)	12 (66.7)	6 (54.6)	12 (50.0)
Hospital	30 (56.6)	2 (11.1)	1 (9.1)	5 (20.8)

Knowledge and understanding of ADRs

When asked to identify terms related to ADRs, overall 35 (66.0%) stated that it 'is a patient response to a drug'. Others referred to and ADR as 'unintended effect', or 'unexpected effect' or as a 'noxious or negative effect' as reported in the figure below.

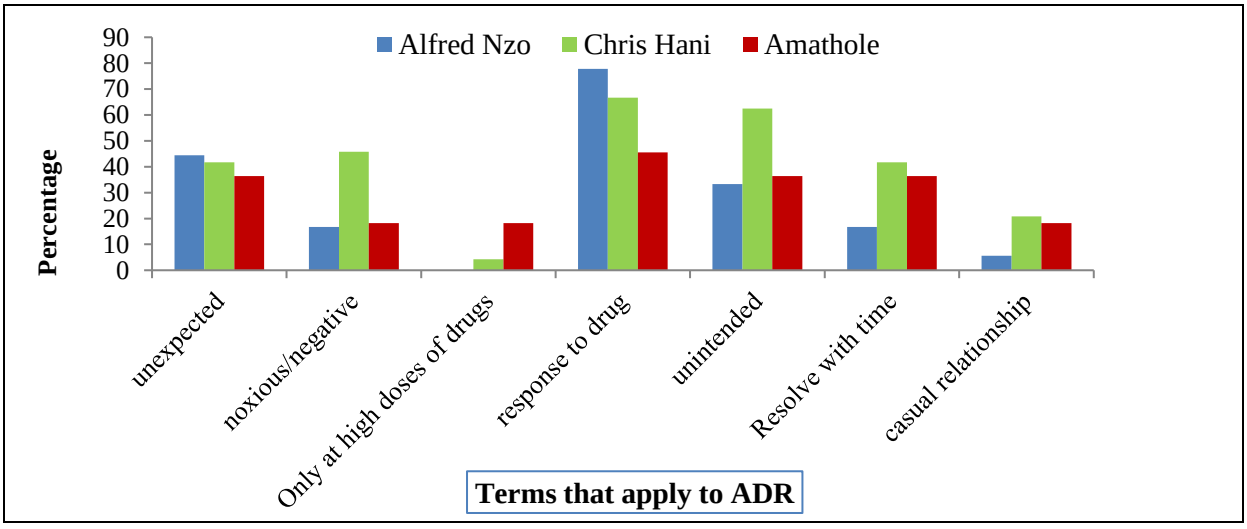

Figure 1: Summary of responses from districts on HCP understanding of the term ADR

Furthermore, approximately 45% of the respondents from each district were aware of the availability of an ADR protocol (Figure 2).

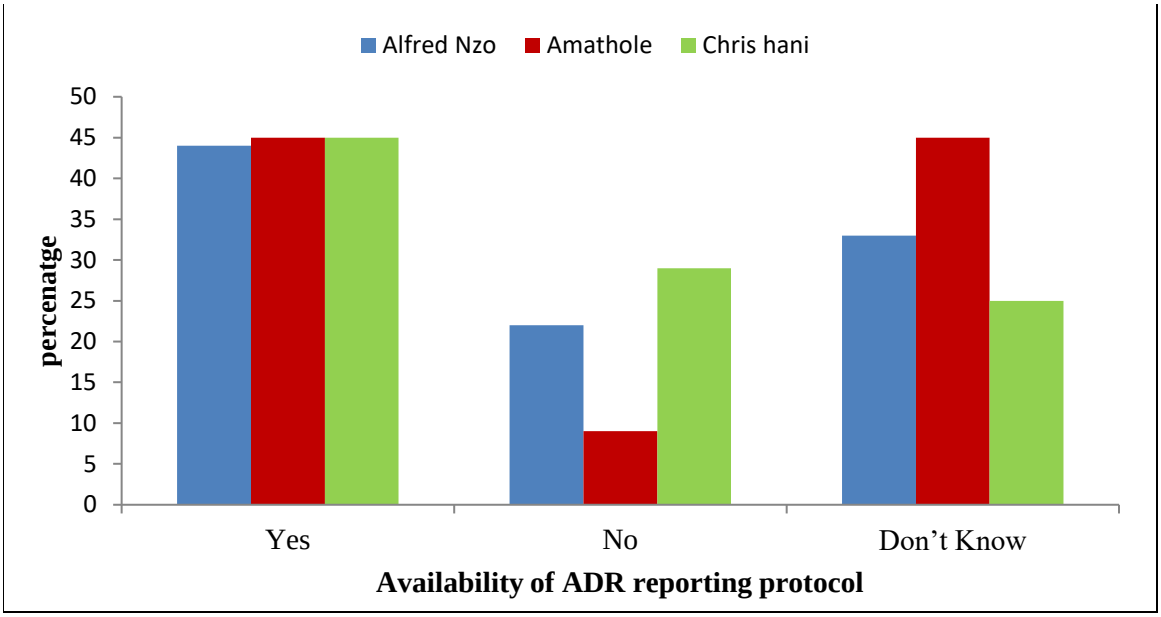

Figure 2: Awareness on the availability of a protocol for ADR reporting in the selected three districts of the Eastern Cape Province

Commonly observed ADR conditions in the province

Table 5: Commonly reported ADRs

Symptoms	***Total (N=53)***	***Alfred Nzo (n=18)***	***Amathole (N=11)***	***Chris Hani (N=24)***
	N (%)	*N (%)*	*N (%)*	*N (%)*
Stevens Johnson Syndrome	29 (54.7)	7 (38.9)	10 (90.1)	12 (50.0)
Back pain	18 (34.0)	5 (27.8)	4 (36.4)	9 (37.5)
Fat redistribution	18 (34.0)	6 (33.3)	5 (45.5)	7 (29.2)
Dizziness	17 (32.1)	7 (38.9)	1 (9.1)	9 (37.5)
Pain/tingling/numbness	17 (32.1)	3 (16.7)	5 (45.5)	9 (37.5)
Unusual bleeding	14 (26.4)	3 (16.7)	2 (18.2)	9 (37.5)
Anaemia	12 (22.6)	3 (16.7)	2 (18.2)	7 (29.2)
Headache	11 (20.8)	3 (16.7)	3 (27.3)	5 (20.8)
Insomnia	11 (20.8)	3 (16.7)	3 (27.3)	5 (20.8)
Enlarged breasts	10 (18.9)	4 (22.2)	1 (9.1)	5 (20.8)
Fatigue	10 (18.9)	2 (11.1)	4 (36.4)	4 (16.7)
Fever	10 (18.9)	3 (16.7)	3 (27.3)	5 (20.8)
Heartburn	10 (18.9)	4 (22.2)	0 (0.0)	6 (25.0)
Nausea	10 (18.9)	1 (5.6)	4 (36.4)	5 (20.8)
Appetite loss	10 (18.8)	3 (16.7)	4 (36.4)	3 (12.5)
Abdominal pain	9 (17.0)	3 (16.7)	2 (18.2)	4 (16.7)
Diarrhoea	9 (17.0)	3 (16.7)	0 (0.0)	6 (25.0)

Renal failure	9 (17.0)	4 (22.2)	2 (18.2)	3 (12.5)
Jaundice	8 (15.1)	2 (11.1)	3 (27.3)	3 (12.5)
Vomiting	8 (15.1)	3 (16.7)	3 (27.3)	2 (8.3)
Difficulty breathing	7 (13.2)	3 (16.7)	0 (0.0)	4 (16.7)
Constipation	4 (7.6)	2 (11.1)	1 (9.1)	1 (4.2)
Rash	4 (7.6)	2 (11.1)	1 (9.1)	1 (4.2)
Persistent muscle pain	4 (7.5)	2 (11.1)	1 (9.1)	1 (4.2)
Chills	3 (5.7)	0 (0.0)	2 (18.2)	0 (0.0)
Depression	3 (5.7)	1 (5.6)	0 (0.0)	6 (25.0)
Cough	1 (1.9)	0 (0.0)	1 (9.1)	0 (0.0)
Loss of libido	1 (1.9)	0 (0.0)	1 (9.1)	0 (0.0)

The most common ADRs cited were Stevens-Johnson syndrome, back pain, fat redistribution, dizziness, peripheral neuropathy and some others. In total, 28 ADRs were cited (Table 5).

Post-ADR protocol for patient Care

A larger percentage of the respondents from Amathole district, as compared with the other two, were not aware of the availability and existence of a post-ADR patient care protocol (Figure 3).

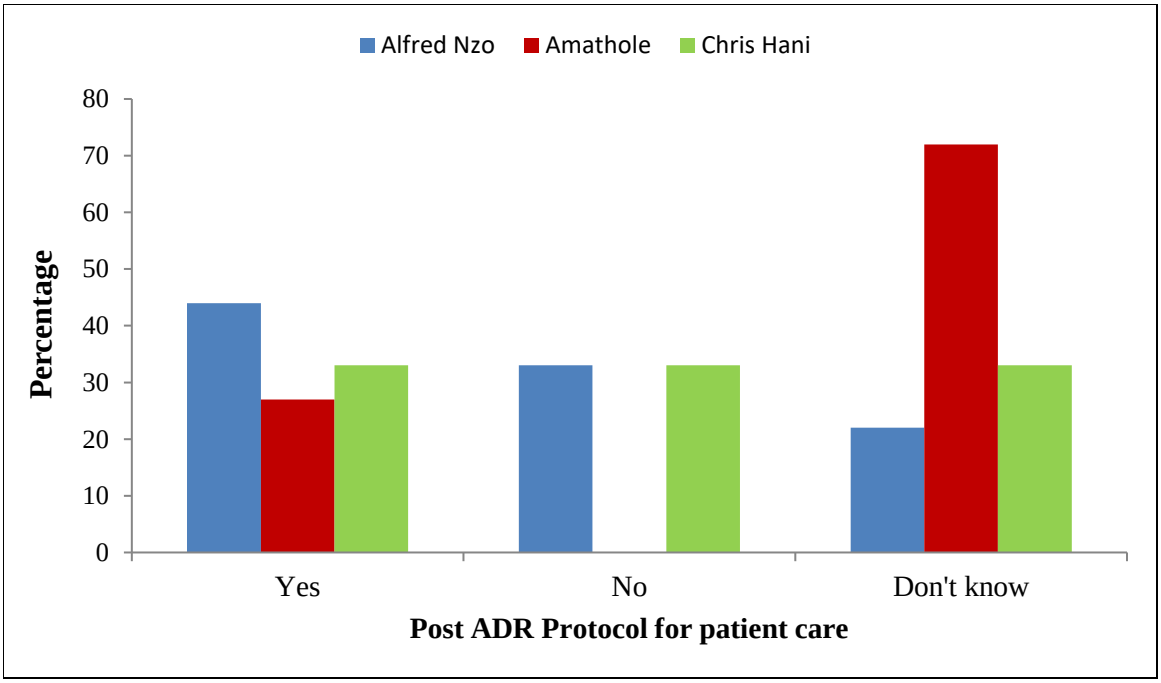

Figure 3: Awareness, by district, of the availability of a protocol for patient care following the report of a suspected or confirmed ADR.

Pharmacovigilance programme

Between 27% and 34% of participants reported a formal pharmacovigilance programme at their facility (Figure 4).

The remaining participants either reported no existing of a formal programme (average 37.7%) or that they had no knowledge of any formal programme (average 30.2%).

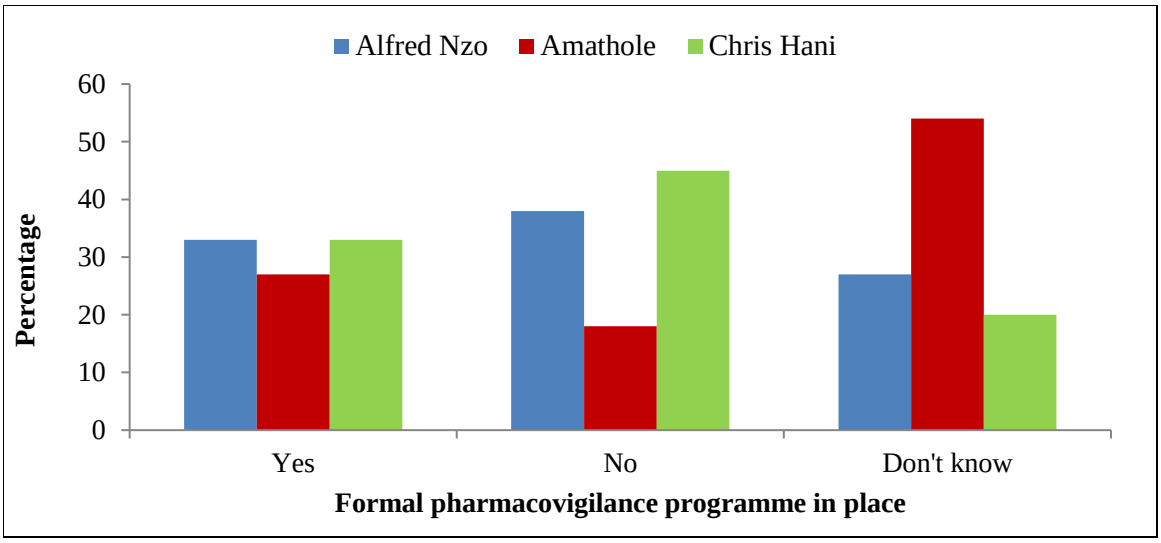

Figure 4: Responses on the availability of formal pharmacovigilance programme

Pharmacovigilance training needs

When asked about specific training needs in pharmacovigilance, it is noteworthy that no respondent mentioned the need to be trained in the detection and reporting of ADRs (Table 6).

Table 6: Training needs to improve ADR reporting

Training area	***n***	***%***
ADR reporting regulations in South Africa	39	73,6
Effective communication and risk management in pharmacovigilance	35	66,0
ADR Alerting Conditions	31	58,5
Understanding common serious ADRs to ART	28	52,8
Counseling patients to address side effects of ART	27	50,9
Causality Assessment in pharmacovigilance	19	35,8
Adherence to ART	19	35,8
Decentralised pharmacovigilance for Public Health	18	34,0
ADR Detection and Reporting by healthcare professionals	0	0,0

It is notable that more than half of respondents stated that they needed to be trained on topics such as regulations about ADR reporting, risk communication and management, ADRs alerting conditions (premonitions), understanding of serious ADRs and how to counsel patients about ADRs experienced.

ADR reporting

The majority of respondents (N=49, 92.5%) stated that ADRs are reported; among them, 39 (73.6%) indicated that observed ADRs were only reported internally within their facilities; nine (17.0%) stated that ADRs are reported both internally and to external agencies; and one (1.9%) stated that reporting was done to external agencies only. In this group, the frequency of reporting as described as follows: 20 (41.7%) always, 6 (12.5%) usually, 13 (27.1%) sometimes, and 9 (18.8%) rarely. It is noted that while four (7.6%) persons did not report any identified ADRs at all.

Factors influencing ADR reporting

When asked about factors that facilitated reporting, the most cited reason for reporting an ADR was the level of seriousness (17, 32%) followed by the HCP's obligation to report (16, 30.2%) as reported below (Table 7).

Table 7: Factors influencing ADR reporting

Factors mentioned	*Total (N=53)*		*Alfred Nzo (N=18)*		*Amathole (N=11)*		*Chris Hani (N=24)*	
	N	*%*	*N*	*%*	*N*	*%*	*N*	*%*
The intensity and severity of patient symptoms	17	32,1	3	16,7	4	36,4	10	41,7
My responsibility/obligation to do so as a health worker professional	16	30,2	6	33,3	2	18,2	8	33,3
My confidence in the suspected diagnosis	12	22,6	5	27,8	3	27,3	4	16,7
My position in my organization	11	20,8	1	5,6	2	18,2	8	33,3
Availability of ADR forms	10	18,9	4	22,2	2	18,2	4	16,7
Familiarity with the process for reporting suspected ADRs internally.	10	18,9	3	16,7	1	9,1	6	25,0
The availability of time to make a report	6	11,3	1	5,6	1	9,1	4	16,7
Unstated	2	3,8	0	0,0	1	9,1	1	4,2

Findings from key informants

Due to the unpredicted unavailability of some personnel, out of the 15 planned key informant interviews, only seven took place as follows: 2 in Alfred Nzo, 3 in Amathole and 2 in Chris Hani. These key informants were provincial and district mid- to senior-level managers who were asked questions on issues such as the existence of ADR reporting protocols, data flow systems and usefulness of ADR data, the perceived reporting culture among HCPs, the burden of care on the health system due to ADRs, likely pharmacovigilance training needs for HCPs and finally, possible approaches for managing ADR patient outcomes.

It is interesting to note that they confirmed the existence of protocols for ADR reporting in their districts or the province, but acknowledged underreporting by HCPs. They also acknowledged the disadvantage to the health system of not knowing the true burden of morbidity due to ADRs in the absence of valid data. When probed further about underreporting of ADRs,

they cited negative attitudes and unavailability of time as completing forms was time-consuming. They also cited lack of feedback on reports submitted. Other reasons cited were as follows: Limited HCP knowledge about ADRs; reluctance to report for fear of negative consequences on reporter; infrequency of the observed ADRs; transport challenges making it difficult to deliver and collect completed forms from primary health care facilities; unavailability of reporting forms at clinics; competing health care priorities; being overwhelmed due to high patient numbers; lack of awareness of ADR reporting by clinicians; lack of culture of reporting; and the lack of legal requirement compelling for HCPs to report ADRs.

Discussion

A baseline assessment is a key tool in the preparatory stages preceding the implementation of a new programme. It enables gathering information for planning and strategizing a proposed intervention(s). The results of this assessment have revealed several challenges to the successful introduction of the decentralised pharmacovigilance programme in the Eastern Cape Province and highlighted key issues to be addressed.

Knowledge and understanding of ADRs

Although the majority of HCPs had some knowledge of terms applicable to the description of an ADR, this knowledge varied from district to district with the gap in positive knowledge about ADRs being greatest between the Chris Hani respondents and the Amathole respondents. This finding concurs with what was reported in a study from KwaZulu-Natal (Nlooto and Sartorious, 2015). However, since respondents from all districts failed to consistently choose the best descriptive terms for ADRs, the results clearly show that upgrading and standardising knowledge and understanding of ADRs by HCPs in this province must be prioritised.

Since a similar study investigating HCP knowledge, experience and challenges of reporting ADRs also revealed that scanty reporting was a result of poor knowledge and limited experiences of HCPs (Parrella et al., 2013), this approach is therefore expected to engender a positive attitude change in ADR reporting by HCPs and optimise the introduction of the decentralised pharmacovigilance programme.

Commonly reported ADRs

The most commonly encountered ADRs were Stevens Johnsons Syndrome, peripheral neuropathy, fat redistribution and back pain, all consistent with the drugs commonly used in the national ART programme. Despite the opinion of some key informants that the lack of reporting is a consequence of the HCPs' lack of knowledge about ADRs, this finding highlights the existence of a good level of knowledge about common ADRs to ART (Nlooto and Sartorius, 2015). It also suggests that one approach to improving reporting would be to build upon their existing knowledge and increase HCPs confidence in reporting with supplementary knowledge about assessing, understanding and managing a wider range of ADRs.

Training of health professionals

Findings in this study are consistent with previous reports about the importance of continued training of HCPs in South Africa (Letlape et al, 2014). It suggests that in-service training is crucial for HCPs before programme implementation. This is particularly important for the decentralised pharmacovigilance programme as evidenced by the findings of this survey. Other studies have likewise accentuated the importance of strengthening HCP knowledge and understanding of the processes of identification and reporting of ADRs at facility levels (Anderson et al, 2011; Parrella et al, 2013).

Pharmacovigilance programmes and ADR reporting systems

A greater proportion of HCPs across the districts were not aware of either the availability of an ADR protocol for patient care following reporting of an ADR or a pharmacovigilance programme at their facility. This lack of awareness and lack of shared pharmacovigilance information potentially compromises the quality of patient care. In order to cultivate a robust pharmacovigilance programme, it is imperative that information on pharmacovigilance systems, processes and guidelines in districts and provinces are clearly communicated to HCPs (WHO, 2004; Malangu, 2014).

Further, the value of the system must be continuously reiterated through feedback to HCPs on ADR trends and updates in ADR management strategies (Mehta et al, 2014). The findings from key informant interviews highlighted the commonality of the negative HCP attitude to identifying and reporting ADRs across the districts despite the presence of some system for reporting. The findings provide a context for understanding the responses of the HCPs and structuring the proposed intervention to complement provincial and district-level strategies and objectives (Van Grootheest and De Jong-van den Berg, 2005).

Monitoring the number of ADR reports in any treatment programme is a key outcome useful in evaluating the implementation success of a pharmacovigilance programme. The many reported challenges to ADR reporting by HCPs draw attention to specific activities and interventions that can be resolved through targeted training, a redeployment of para-medical staff where possible and the creation of clear and logical reporting protocols and paradigms (Jacob et al, 2013; Zhang et al, 2014). To date, the latter have previously been unclear in South Africa. However, this baseline study has exposed specific areas for intervention that should facilitate a smooth introduction of the new pharmacovigilance programme with the HCPs of the Eastern Cape.

This baseline survey had some limitations. The sample size was small and thus not representative of all HCPs in the province. Additionally, the limited timeframe for the exercise to be completed meant that there was no alternative day to re-visit the field for additional interviews (Yin, 2013). However, the findings have provided insights of what ought to be considered in planning and implementing a decentralised pharmacovigilance system in the province.

Conclusion

This baseline assessment study has provided an opportunity to clearly identify and understand the current pharmacovigilance systems, processes, and activities existing in the Eastern Cape Province. It has offered a snap-shot of the knowledge, awareness and practice of pharmacovigilance in the target districts. Given the pharmacovigilance activities currently occurring in these districts, it is most pertinent to consider these findings for integrating/aligning the pharmacovigilance training prior to implementing the national decentralised pharmacovigilance programme in these districts. This study contributes meaningfully to the ability of the National Department of Health to develop an appropriate training intervention for the decentralised pharmacovigilance programme provincially.

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