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Full Length Article

Knowledge, perceptions and practices of pharmacovigilance amongst community and hospital pharmacists in a selected district of North West Province, South Africa

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ABSTRACT

Background: Pharmacovigilance (**PV**) as a means of ensuring drug safety is an essential component of the process ensuring that the risk of drug use does not outweigh the benefit. Pharmacists are valuable in collecting PV information, but not many studies explored the knowledge, perceptions and practices of both community and hospital pharmacists towards the practice of PV.

Objectives: The aim of the study was to explore the knowledge, perceptions and practise of PV amongst the pharmacists in a selected district of North West Province, South Africa.

Method: A cross sectional study was conducted amongst pharmacists in a selected district of the North West province, using a pre-tested questionnaire. Descriptive statistics were used to analyse the results including ANOVA testing.

Results: One hundred and two pharmacists (68.9%) completed the questionnaire. Although familiar with the concept of PV, pharmacists knowledge scores were low. Pharmacists agreed that PV is a useful tool, but perceived the PV authorities to be distant and remote. Although more than 90% indicated that all adverse drug reactions should be reported, only 44.1% indicated that they have reported adverse drug reactions (ADRs). Only 6.7% of pharmacists were satisfied with feedback received from authorities after reporting an ADR. Barriers were cited that prevented them from reporting ADRs. Over 80% indicated they would participate in further PV training.

Conclusion: The majority of pharmacists are familiar with the concept of PV, but less than half reported any ADR. They are willing to participate in PV processes but are unsure what their exact role playing should be. More than half indicated that they would like to see improvements to the current PV system in South Africa. The majority are prepared to undergo further education to improve their PV knowledge.

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1. Introduction

Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality worldwide (WHO, 2002). It is an important and sometimes avoidable cause for hospital admissions, adding to the social and financial burden of healthcare (Patel, Bell, & Molokhia, 2007). In Europe ADRs are responsible for 5% of all hospital admissions causing on average 1.91 extra hospital days (Montanari-Vergallo, 2013). In the USA, ADRs are among the top 10 leading causes of death (Montanari-Vergallo, 2013). Over a 10 year period (1999–2009) the number of hospital admissions associated with ADRs in England increased by 76.8% (Wu et al., 2010).

In a South African study, hospital admissions because of ADRs were found to be 6.3% and 41% of these developed while the patients were in hospital. Many of the ADRs (46.2%) were considered preventable. The median hospital stay of patients because of ADRs was 5 days, placing a substantial additional burden on the healthcare system (Mehta et al., 2008).

Managing ADRs are done by applying the science and principles of the discipline of pharmacovigilance (PV). The World Health Organisation (WHO) initially defined PV as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problem (WHO, 2004). The definition has since been extended to include all aspects of medicine development, manufacturing, registration, warehousing, logistics, prescribing, dispensing, use and the destruction of expired medicine stock – spanning the complete product life cycle. Many countries, notably in Europe and the USA, formalised PV risk-benefit legislation to be enforced by their medicine regulatory authorities (Montanari-Vergallo, 2013).

All effects and interactions of medicine, including ADRs, cannot be detected during pre-marketing clinical trials because of the minimal number of patient exposure, lack of long term use, existence of co-morbid conditions, diversity of patient populations and concomitant use of a wide variety of other medications, herbs and foods (Smith, Wertheimer, & Fincham, 2013). Post-marketing surveillance and continuous PV processes are therefore essential to monitor effects of medicine, ensuring the safe use of medicine.

2. Key concepts

2.1. *Spontaneous reporting*

This is reporting an ADR by any healthcare professional, including patients, relatives and others,"spontaneously" as it was observed. A spontaneous report is an unsolicited communication by healthcare professionals or consumers that describes one or more ADR in a patient who was given one or more medicinal product. Spontaneous reporting, also called individual case safety reports (ICSR), is the most common method of medicine surveillance worldwide. ICSRs play a major role in the identification of signals of risk once a medication is used. It may also be possible to recognise a new risk factor for a product or as a sub-group of patients at particular risk (WHO, 2009).

The main limitation of spontaneous reporting is underreporting of ADRs. As in most countries, spontaneous reporting is voluntary and unpaid without specific target goals. However, the main purpose is not the quantification of the frequency of adverse reactions, but the identification of signals (WHO, 2009). Studies indicated that various barriers exist that hinder persons to report ADRs (Zollezzi & Parsotam, 2005).

2.2. *Cohort event monitoring (CEM)*

This is a prospective, observational, cohort study of adverse events associated with one or more medicines. It is normally recommended that a cohort of 10,000 patients be enrolled giving a 95% chance of identifying a specific event that has an incidence of CI:3000. For a meaningful assessment, at least three events need to be identified, hence the higher objective to include 10,000 patients (WHO, 2009). Where available, CEM is often combined with Prescription Event Monitoring (PEM), for example the Intensive Medicines Monitoring Programme in New Zealand and the Prescription Event Monitoring in the UK and Japan. PEM is a system where the pharmacists, after dispensing the medication of interest, reports the patient details to a PV centre who then contacts the patient or physician regarding the patient-experience with the medicine (Pal, Duncombe, Falzon, & Olsson, 2013).

2.3. *Targeted spontaneous reporting (TSR)*

This is where all the patients are monitored when and where the medicine of interest is dispensed. For instance, where patients receive treatment changes for drug-resistant TB or switching from first-line to second-line antiretroviral therapy, the pharmacists is sensitised to be cognitive for the occurrences of ADRs. The advantage of TSR is that an ADR can be identified sooner and the patient is referred for treatment immediately (Pal et al., 2013).

Reporting by consumers have also been allowed by many countries.

3. Purpose, aims and objectives

3.1. *Importance of pharmacists*

Pharmacists have a central role in drug safety by contributing to the prevention, identification, documentation, and reporting of ADRs (Zollezzi & Parsotam, 2005).

Pharmacists do not have the same clinical experience as physicians but are capable of reporting ADRs on their own. Indeed, over a 10 year period, pharmacists reported 31% of all ADRs in a Portuguese study (Marques, Ribeiro-Vaz, Costa Pereira, & Polónia, 2013). In many other countries, especially the Netherlands, pharmacists report a substantial number of ADRs (Van Grootheest, 2003).

Communicating effective risk information back to healthcare workers is the result of a successful PV process. A major step in the prevention of ADRs is to ensure that all healthcare workers are informed about the change in the risk-benefit profile of the medicine (Van Grootheest, 2003).