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Research methodology used to evaluate the pharmacovigilance system in the Dr. Kenneth Kaunda district in the north west province, South Africa

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One of the main reasons for the failure of pharmacovigilance systems is under-reporting, and this has a direct effect on the universal pharmacovigilance system. Professional and personal barriers were identified as a cause for under-reporting of adverse effects. The question arises as to whether these barriers can be drawn to South Africa or if there are other factors that influence the standard of reporting of adverse drug reactions (ADR) in South Africa. The aim is to describe the methodology that will be followed to evaluate the public health pharmacovigilance system in the Dr. Kenneth Kaunda District (DKKD) in the North West Province in South Africa. Two steps will be followed: 1) Determination from the perception of health care professionals the possible factors that can contribute to the successful implementation of a pharmacovigilance system; and 2) Evaluation of the completeness of the content of the filled-in ADR forms available in the DKKD. A quantitative, non-experimental, cross-sectional research design will be followed to conduct the study in the DKKD in the North West Province in South Africa. The study population for step (1) will include all healthcare professionals (medical practitioners, pharmacists, professional nurses) in the Tlokwe Local Municipality, in the public health sector (hospitals and primary health care clinics) on a permanent or temporary contract. All the completed ADR forms independent of pharmacological category or drug use, from 2010 to 2014 available at the hospitals and primary health care clinics in DKKD will be used as study population for step (2). A self-completion questionnaire will be used to determine the perception of healthcare professionals in step (1). The focus of the questionnaire will be on the following aspects: (i) Demographic information, (ii) Adverse drug reaction system and structure, (iii) Healthcare professionals' perceptions regarding adverse drug reaction reporting; (iv) Adverse drug reaction reporting in practice; (v) Factors that may influence adverse drug reporting; (vi) Challenges of adverse drug reaction reporting. A checklist, based on the standard set by the South African Department of Health for an ADR report, will be used by the researcher to evaluate the completeness of the ADR reports in the DKKD. The study will help to identify current problems with the ADR documentation system on a district level in South Africa.

Biography

Martie S Lubbe is currently the leader of the research niche area, Medicine Usage in South Africa (MUSA) at the North-West University (NWU), Potchefstroom campus in South Africa. She obtained her Bachelor's degree, MPharm and PhD degrees in Pharmacy Practice at the Potchefstroom University for CHE. She has devoted 25 years of her career to pharmacy education and practice-related research and contributed significantly towards the development of Pharmacy Practice. From 2004 to 2009, she acted as Subject Head of Pharmacy Practice at the NWU.

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