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Titolo tesi: Nurses' Reporting of Spontaneous Adverse Drug Reactions (ADRs): Identifying The Factors that Hinder ADRs Reporting and Testing an Explanatory Model to Predict Nurses' Intention to Report ADRs.

ABSTRACT

Background. Adverse drug reactions (ADRs) are an important public health problem associated with mortality, morbidity and an increased financial burden on society and the healthcare system. Spontaneous ADR reporting by healthcare professionals represents a cornerstone of pharmacovigilance (PhV) as it enables an assessment of the risk/benefit ratio of all marketed drugs. Drug withdrawals are often based on data derived from spontaneous reporting systems. However, under-reporting is recognized as the main limitation of ADR reporting systems. In Italy, the current literature gives evidence for the potential capacity of nurses to improve the detection of ADRs, but the frequency of ADRs reported by nurses is still minimal. Although the involvement of nurses is a prior requirement for spontaneous reporting systems to function effectively, no previous literature review has examined the factors that contribute to ADR reporting among nurses, no previous study has described Italian nurses' knowledge, attitudes and practices towards spontaneous ADR reporting, and no previous study has evaluated the predictors of nurses' intentions to report ADR. The theory of Planned Behaviour is one of the frameworks most frequently used to study intentions and behaviours among healthcare professionals. Objectives. The objective of this doctoral program is: (1) to examine current literature related to the factors that affect ADR reporting among nurses; (2) to assess nurses' knowledge, attitudes and practices towards spontaneous ADR reporting; (3) to test an explanatory model of nurses' intentions to report ADRs, basing on the Theory of Planned Behaviour.

Methods. Three separate studies were carried out to test these doctoral objectives. First, an integrated review of the literature was conducted using MEDLINE, CINAHL, Embase, Scopus databases, and Google Scholar. Second, a mixed-method study was conducted following a quanti-qualitative sequential approach: a survey (using a KAP questionnaire), followed by a focus group. Third, based on the results derived from the first two studies and on the Theory of Planned Behaviour, a cross sectional study was performed using the Adverse Drug Reporting Nurses' Questionnaire (ADRNQ). The data analysis consisted of two steps. The first step aimed to investigate the ADRNQ dimensionality; the second step aimed to testing the hypothesized model based on the Theory of Planned Behaviour through a structural equation model.

Results. From the integrative review, two factors that condition ADR reporting among nurses emerged: (1) intrinsic factors related to nurses' knowledge and attitudes (i.e., ignorance, insecurity, fear, and lethargy); (2) extrinsic factors related to nurses' interaction with healthcare organisations and to the relationship between nurses and physicians. From the mixed-methods study, in the quantitative findings, many responders (570 Italian hospital nurses) declared that they were unaware of the PhV system (58.1%, n=331); did not know where to find the reporting form (63.5%, n=362); did not know how fill it in (71.6%, n=408); and did not know to whom or how to send it (65.8%, n=375). Only 11.1% (n=63) had reported ADRs. The qualitative phase supported the quantitative findings and provided new information about other factors that condition ADR reporting: misinterpretations of the meaning of "reporting", unawareness of nurses' autonomy in ADR reporting, and fear of consequences after ADR reporting. From the cross-sectional study, where the sample was composed of 500 Italian hospital nurses, the confirmatory factor analysis of the ADRNQ constructs confirmed the dimensionality of the scales, with high values for the RMSEA, CFI, TLI, and SRMR

indices. Although the chi-square statistic was associated with a significant probability value [$\chi 2$ (43) =114.875, p<.001], the structural equation model indicated that the model fitted the data well (RMSEA=.058, CFI=.944, TLI=.914, SRMR=.040). The intention of nurses to report was significantly and positively predicted by their attitude, subjective norm and perceived behavioural control in relation to ADR reporting. The amount of explained variance for subjective norm, attitude, and perceived behavioural control (R2=.51, .40, and .28, respectively) were higher than the variance of Intention to report ADR (R2=.16). More empowered organizations were associated with more positive beliefs towards ADR reporting. This was especially true for normative beliefs towards ADR reporting, which was associated with the highest portion of explained variance (R2=.27).

Conclusion. All the above findings have high levels of practical and operative value. The need to enhance nurses' knowledge of ADRs and of the procedures for reporting was evidence that emerged from all findings. Also, the role of the healthcare organization was identified as essential. If healthcare organizations give priority to safe drug use, it can generate an increased sense of responsibility towards the reporting of ADRs, and greater awareness of drug-related problems. The explanatory model employed has adequate psychometric properties and is suitable for use in clinical investigations. The subjective norm is a major predictor of nurses' intention to report, so nurse-physician-pharmacist collaborations have the potential to stimulate the detection of possible ADRs and prompt decision-making to report. When pursuing future research and future actions in clinical practice, organizational and educational interventions should be carried out simultaneously.

Key words: Pharmacovigilance, Adverse Drug Reaction Reporting, Nurses, Theory of Planned Behaviour.