

## ABSTRACT

**Introduction:** It is recognized worldwide that adverse drug reactions (ADR) are an important cause of morbidity and mortality. A voluntary reporting system of ADR is fundamental to drug safety surveillance. However, under-reporting among healthcare professionals is its major limitation. It is estimated that just about 10% of all serious ADRs are reported to the competent authorities. In this matter, nurses can bring fundamental information, even if, the reasons for the high under-reporting among them are not well-known.

**Objectives:** The main aim of this study was to identify the knowledge and attitude-related factors associated with ADR under-reporting by nurses.

**Methods:** We conducted a case-control study, by clusters, among nurses working in the Northern Portugal. The 265 cases, comprised nurses who had reported at least one ADR to the drug surveillance unit from the year 2000 to the year 2010. The 1060 controls, were randomly selected from among the remaining nurses. All interviews were conducted using a self-administered questionnaire.

**Results:** A total of 263 questionnaires were received from 1286 eligible nurses (response rate 20,5%). Reporting probability proved higher among nurses working in primary versus hospital care ( $OR_{ajust}=14,10$ ;  $95\%IC: 7,27 - 27,36$ ;  $p<0,001$ ). Concerning to the attitudes to ADR associated with reporting probability, hence, an interquartile decrease in any of the following attitudes increased the probability of reporting: near two times for (i) indifference (*"The one case an individual nurse might see could not contribute to medical knowledge"*) ( $1/IqOR_{ajust}=1,84$ ;  $95\%IC: 1,12 - 3,02$ ;  $p=0,016$ ); three times for (ii) *"I would be more likely to report ADRs if there were an easier method"* ( $1/IqOR_{ajust}=3,36$ ;  $95\%IC: 1,76 - 6,38$ ;  $p<0,001$ ), and two times for (iii) *"I do not know how the information reported in the yellow card is used"* ( $1/IqOR_{ajust}=2,26$ ;  $95\%IC: 1,30 - 3,92$ ;  $p=0,004$ ).

**Conclusion:** This study shows that there are certain attitudes among nurses associated with under-reporting. Design an educational intervention target to change these attitudes identified, can possibly minimize under-reporting among nurses and contribute for the safety of medicines and improving Public Health.