

ABSTRACT

Prevalence and Determinants of Serious Spontaneously Reported Adverse Drug Events Among Three Outpatient Care Settings in Ghana: Findings and Implication

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Objective

Most evidence of adverse drug events (ADEs) come from hospitals as the risks associated with hospital care are higher. However, under-reporting of ADEs is a critical problem in all health care settings. This is important in Sub-Saharan African countries like Ghana with limited resources and high prevalence of both infectious and non-infectious diseases. Consequently, this study sought to determine the annual prevalence of spontaneously reported ADEs using six years reports and factors associated with the occurrence of serious ADE among outpatient care settings in Ghana to provide future guidance.

Method

A cross-sectional study was conducted using duplicates of Ghana Food and Drugs Authority adverse event forms retrieved from 3 outpatient care setting who had submitted their reports to the National Pharmacovigilance Centre in Ghana between 2013 and 2018. The raw data were entered into Microsoft excel and analyzed using stata version 14. Bivariate analyses were performed using Pearson chi square and all variables that were statistically significant were used for a multivariate analysis.

Results

Overall, 93 spontaneously reported cases of ADEs were identified during the study period. The mean age of the patients with a reported ADE was 42 ± 17 years, the annual prevalence rate was 192 reports per 1,000,000 population among our study population and the rate of serious ADE was 35.48% (95% CI: 25.83%-46.09%). Serious ADEs were associated with the type of indication for which the drug was prescribed ($p=0.048$), the duration of ADEs ($p=0.047$) and the decision to administer treatment at the reporting facility ($p=0.017$) and was independently predicted by duration of ADEs (aOR =7.63, 1.37-42.65) and decision to administer treatment for ADEs (aOR=20.28, 2.38-172.57).

Conclusion

Early reporting of ADEs at outpatient settings is essential. Patient education and awareness of potential ADE must be intensified for early identification and we will be following this up.

Keywords: Adverse drug event, serious adverse drug event, spontaneous reporting, outpatient care setting, Ghana