Patient Reporting of Adverse Drug Reactions (ADRs): Survey of Public Awareness and Predictors of Confidence to Report

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Abstract
Background: Many countries incorporate direct patient reporting of adverse drug reactions (ADRs) into their pharmacovigilance systems as patients provide a different insight into drug safety compared to health care professionals. This study aimed to examine public awareness about ADR reporting in Malaysia and patients’ confidence in reporting ADRs.

Methods: Using a cross-sectional design and convenient sampling, data were collected in public areas within Kuala Lumpur, Malaysia, via face-to-face interview with a structured questionnaire. Multivariate logistic regression analysis was used to identify the significant predictors of patients’ confidence in ADR reporting.

Results: Out of 860 consented respondents achieving a response rate of 73.5%, only 69 (8%) were aware of the Malaysian ADR monitoring system. The majority (60%) of the respondents indicated they had the confidence to report ADRs. Multivariate logistic regression analysis revealed that ease in completing the ADR reporting form was the strongest variable predictive of confidence to report ADRs (odds ratio [OR], 18.45; 95% confidence interval [CI], 10.55-32.25). Increased confidence in ADR reporting was also associated with education level. Respondents with a higher education level were more likely to be confident to report ADRs compared to those with primary or no formal education (OR, 2.49; 95% CI, 0.77-8.1).

Conclusions: Lack of awareness of the ADR monitoring system is still prevalent among Malaysian patients. The ease of completing the ADR form and education level are predictive of patient confidence to report ADRs. These factors should be considered in designing public promotional activities to encourage patient contributions to pharmacovigilance.