

製薬医師の視点でとらえた本邦の医薬品安全性調査の現状

—日本製薬医学会アンケート調査結果—

日本製薬医学会*

A Drug Safety Questionnaire Survey for Medical Doctors Working
in Pharmaceutical Industry in Japan

Japanese Association of Pharmaceutical Medicine*

Summary

Objectives: The objective of this review is to overview the current situation of pharmacovigilance and pharmacoepidemiology in Japan from medical doctors' point of view. For this purpose, The Japanese Association of Pharmaceutical Medicine (JAPhMed) searched the clinicians' perception on post-marketing surveillance (PMS), causality assessment of adverse reactions, and interest for pharmacoepidemiology.

Methods: The 243 medical doctors belonged to JAPhMed and worked for a pharmaceutical company were requested to participate in the questionnaire survey by e-mail on March 29th, 2010, using a web-based system. Three additional reminders were sent before the response due date (April 6th, 2010).

Results: A total of 81 physicians (33.3%) responded to the questionnaire. The year of graduation from medical school varies from 1976 to 2005. 71.6% of the responders had experience in drug development, 54.3% in drug safety, and 44.4% in medical affairs. The survey results revealed that the PMS was not recognized widely and accurately among the physicians, even for those who had participated in PMS. For causality association between drug/vaccine and adverse events, 95 % felt it is challenging for physicians to evaluate causality based on one or a few cases' experiences, except some rare situations. Almost all the responders considered that most of the physicians would not know that the "causality unknown" case is eventually interpreted as "positive causal association" based on the judgment that causality cannot be completely denied for the case. Importantly, the responders considered that the causality evaluation by physician could be altered with this knowledge either to as "without causal association" (54.3%) or to as "with causal association" (17.3%). 59.3% of the responders needed drug safety studies designed based on pharmacoepidemiology methods.

Conclusions: The JAPhMed members are not necessarily representing entire physicians' population in Japan since all of them work for pharmaceutical industry. Also, the responder rate was low and the results might not be a consensus of JAPhMed either. Nevertheless, the JAPhMed hopes better mutual understanding and effective collaboration between pharmaceutical industry and clinicians to promote good pharmacovigilance and pharmacoepidemiology practice in Japan..

Key words

Drug safety, Medical Doctor, Database, Questionnaire, Causality, Post-Marketing Survey