Adverse event reporting by consumers in the United States

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[Background]

Recent regulatory changes to streamline drug development and approval in the US have made the roles of post-marketing pharmacovigilance more important. The US Food and Drug Administration (FDA) encourages consumers to report adverse events (AEs) through the introduction of a new reporting form (FDA3500B) in 2013. However, it is still unknown how and to what extent consumers have recently contributed to AE reporting in the US. This study aimed to clarify the picture of current voluntary AE reports by consumers and examine how the reports by consumers are different from those by healthcare professionals in content and the ways they are reported.

[Methods]

We performed descriptive analysis on voluntary reports of AEs in the US FDA AE Reporting System database. We compared the reports by consumers with those by healthcare professionals including physicians and pharmacists.

[Results]

The numbers of voluntary reports by consumers and pharmacists have evidently increased since 2013. The proportion of reports on female patients and on disability as patient outcomes were higher in the reports by consumers than those by healthcare professionals. On average, the reports by consumers tended to have larger numbers of concomitant drugs and more subjective symptoms such as dizziness and pain than those by healthcare professionals. The proportion of reports regarding "known AEs" was not remarkably different across reporters' occupation. Safety labeling changes in warning and precaution sections seemed to have some impacts on the reporting behaviors of healthcare professionals but not on those of consumers.

[Conclusion]

Our analysis showed that consumers' reports, which have recently increased in the number of voluntary reports, seem to have information that reflects consumers' interest and concerns. To make use of the growing database and draw public health needs appropriately, we need to consider the heterogeneities in AE reports that may be caused by diversities in reporting routes, forms, and reporters' characteristics.