

Exploring patient reported information in signal detection within a global database

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Background

A recent systematic review summarised the current evidence on the value of patient reporting into pharmacovigilance systems. [1] However, descriptions of methodologies for using patient reports in signal detection are scarce, and published experiences of how patient reports are used in national pharmacovigilance centres are limited to a few countries. [2-3]

Objectives

To explore the contribution of patient reports to signal detection in the WHO global database of individual case safety reports (ICSRs), VigiBase.

Methods

Data was retrieved from VigiBase in September 2016. Suspected duplicate reports and reports from studies were excluded. Drug-ADR combinations were generated and restricted to report series with:

- At least 50% patient ICSRs
- at least one patient report received after 2014
- ≥ 2 countries
- ≤ 30 patient ICSRs

vigiRank⁴, an algorithm using multiple-strength-of-evidence aspects, was used to prioritize combinations for assessment. In the assessment of each combination, the product information for health care providers as well as patient information leaflets were reviewed for information on ADRs.

Results

A total of 212 drug – ADR combinations were assessed which resulted in 8 signals communicated within the WHO programme for international drug monitoring. Reviews of patient information leaflets were performed; examples of poor consistency with product information for physicians were found. Patient narratives were confirmed to provide details regarding the experience of the ADR and its impact on the quality of life of the patient; furthermore, there is evidence in narratives that patients make causality and benefit/harm assessments themselves.

Conclusions

Safety concerns described in patient reports can be identified in a global database including previously unknown ADRs as well as new aspects of known ADRs. Patient reports provide unique information valuable in signal assessment, and they should be included in signal detection as far as is possible.

WHO Pharmaceuticals Newsletter

The signals from UMC are available to the public through the WHO Pharmaceuticals Newsletter with the aim to disseminate information on the safety and efficacy of pharmaceutical products.

<https://goo.gl/64bgV4>



References

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Disclosure

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