Who’s at risk? Identifying risk groups for adverse drug reactions using VigiBase

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Background
In recent years, Uppsala Monitoring Centre has initiated a shift toward signal characterisation and risk group identification in support of our vision for wise therapeutic decisions. As a first attempt at broader open-ended risk group detection, we conducted a signal screening focused on identifying risk groups for adverse drug reactions (ADRs).

Objective
To explore the possibility of identifying signals of ADRs in risk groups using VigiBase, the WHO global database of individual case safety reports.

Methods
Dataset: 15.4 million reports retrieved on 28 August 2017 from VigiBase

Disproportionality analyses performed for drug-adverse event (AE) pairs (1) in the entire database and (2) across a range of data subsets. Drug-AE pairs disproportionally overreported in such subsets but not in the whole data were identified.

Prioritization
Identified drug-AE-subset associations ordered by (1) vigiRank [2] for strength of evidence, and (2) weighted random sampling for subset balancing.

Initial review
Out of 386 manually reviewed drug-AE-subset associations, 18 (4.6%) were classified as potential signals. The highest yield was identified in females (5), underweight adults (3), and the elderly (3).

In-depth review
As of August 2018, in-depth clinical reviews have been completed for 14 out of 18 potential signals, resulting in seven signals describing potential risk groups for ADRs [3].

Conclusions
Signals of ADRs in risk groups can be identified from a global database using subset disproportionality analysis. Continued development of statistical screening methodologies to highlight potential signals within subgroups could usher in a new era of “precision pharmacovigilance”.

References

Disclosure
The authors are indebted to the national centres that contribute data to the WHO Programme for International Drug Monitoring. However, the opinions and conclusions in this study are not necessarily those of the various centres, nor of WHO.