Detection of medication error signals through identification of uncoded high dose case reports in VigiBase

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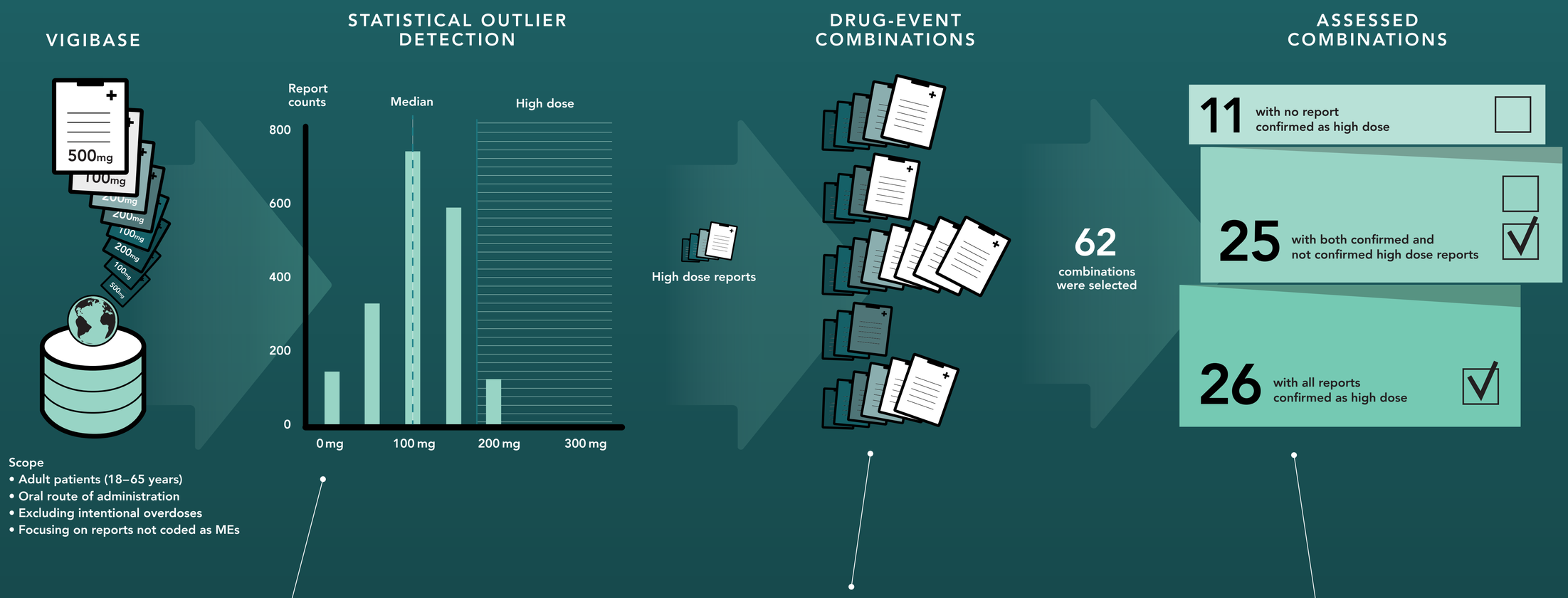
Background

Medication errors (MEs) occur everywhere independently of the degree of development of healthcare systems. Organisations such as the World Health Organization (WHO) and the European Medicines Agency have issued guidelines and expanded legislation to improve reporting of MEs into spontaneous databases.[1–4]

Objectives

To explore the feasibility of quantitative signal detection in VigiBase, the WHO global database of individual case safety reports, on suspected reports associated with high doses that have not been coded as MEs.



Methods

Reports with high daily dose as compared to the median dose reported in VigiBase were identified using statistical outlier detection. The threshold for outliers was established based on a subset of 12 drugs and their maximum daily dose according to United Kingdom Summary of Product Characteristics.[5]

Scope
- Adult patients (18–65 years)
- Oral route of administration
- Excluding intentional overdoses
- Focusing on reports not coded as MEs

A drug-event combinations list containing suspected high dose reports was generated using the following criteria:

1. At least three suggested high dose reports
2. Reports shared from at least two countries
3. One recent report from the last three years
4. At least 50% serious cases

To order the list, we computed the odds ratio comparing reports with identified high doses to those with normal doses for the drug-event pair.

A subset of the combinations was selected for manual review to verify that the outlier doses were higher than the authorised daily dose and to assess possible preventability.

Results

Clinically evaluated 62 drug-event combinations.

Threshold for identifying high dose reports was not optimal and may not have generalised across different drugs.

In 44% of the assessed reports narratives were missing.

Most reporters were not reflecting on the rationale behind the reported dose in the narratives available in 56% of reports.

Conclusions

The pharmacovigilance community has the power to prevent unnecessary patient harm by identifying, reporting, analysing and communicating MEs as part of their mission.

- Statistical outlier detection could support the identification of potential high dose reports.
- Validating this approach to detecting MEs signals was challenging due to limited information about the reasoning around administered doses.
- Despite existing regulation, MEs detection and reporting is still not established in global pharmacovigilance practice.

References/further sources of information

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