Competitive Intelligence in Pharmacovigilance - a case study on two covid-19 vaccines.

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Background

The comparison of safety profiles for products recently on the market is difficult. There is a lack of methodology for quantifying the potential differences between products that have the same indication.

Objective

Provide the tools to quantify the differences in spontaneous reporting between two products

Methods

Under the null assumption that two products have the same safety profile, the scatterplot of the Empirical Bayes Geometric Mean (EBGM) measured for the different MedDRA Preferred Terms (PTs) post Product A (axis x) and post Product B (axis y) should follow the diagonal line.

An Euclidian distance from the EBGM to the diagonal line measures the deviation from what would have been expected under the null assumption of similar safety profiles.

As the deviation does not capture the statistical uncertainty around the estimate, we propose as measure of the deviation the minimal distance of the four Euclidian distances calculated from each of the credibility intervals around the EBGM post Product A and Product B (see Figure 1).

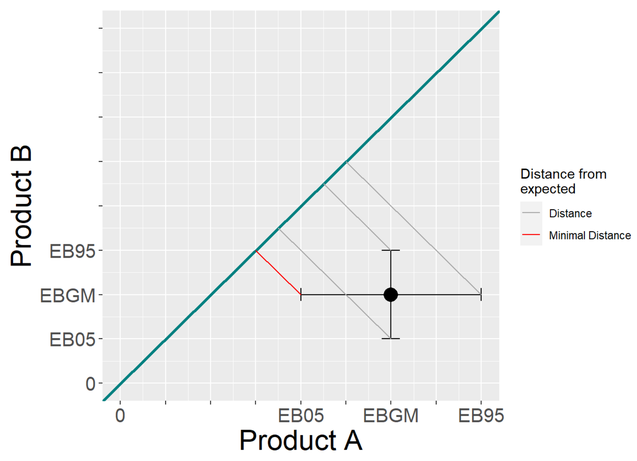

Figure 1: Quantification of the unexpectedness in differences in disproportionality for an event E post Product A and Product B

Results

We quantified the most significant differences in disproportionality measures between the Moderna and BioNtech/Pfizer Covid-19 vaccines using publicly available US data from the Vaccine Adverse Event Reporting System.

A visualization capturing the global trend of the most substantial differences in reporting rates was generated using publicly available exposure data per manufacturer (https://raw.githubusercontent.com/owid/covid-19-data/master/public/data/vaccinations/vaccinations-by-manufacturer.csv)

Conclusion

This method can provide quantification of the differences in reporting and could help prioritize one product over the other depending on what has been highlighted.