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Semantic similarity-informed Bayesian borrowing for quantitative signal detection: a FAERS anaphylaxis case study

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Semantic similarity-informed Bayesian borrowing can trigger earlier signal alerts than traditional methods, making it a valuable complement to established QSD frameworks

Background

- Disproportionality analysis for quantitative signal detection (QSD) typically analyzes MedDRA PTs one at a time and independently,[1] which can obscure signals for a single medical concept.[2]
- While grouping methods like standardized MedDRA queries (SMQ) exist, they lack quantitative weighting based on semantic relationships among MedDRA PTs.[3]
- A recent pre-print article highlighted the potential of semantic similarity measures (SSM)-based weighting to enable better information sharing in QSD.[1]
- Anaphylaxis is a common adverse event that can be represented by a wide range of MedDRA PTs that fall under multiple system organ classes.

Aim

To compare the performance of IC SSM approach (based on semantic similarity-informed Bayesian borrowing) versus traditional QSD for anaphylaxis.

Conclusions

Using semantic similarity for weighted information sharing (IC SSM) may detect safety signals earlier than traditional PT-level QSD.

Limitations include a small drug-event sample size, and results require a more nuanced evaluation of the clinical meaningfulness of weighted terms.

These findings support further evaluation of semantic similarity approaches to complement existing QSD frameworks.

Methods

Weighted prior evidence: PTs contributed according to similarity with "anaphylactic reaction"

+

Data of anaphylactic reaction: Observed evidence for the PT of interest

→ **IC SSM**: Quantitative alerts based on posterior IC distribution

Data acquisition

Cumulative FDA Adverse Event Reporting System (FAERS) data from 2004 to 2013 were analyzed

Event selection

Focus on anaphylaxis
- Multiple PTs represent overlapping clinical manifestations
- Defined using broad and narrow SMQs

Drug class screening
- Identification: Published literature on anaphylaxis regulatory reports[4]
- Filtering: ≥25 reports, approved between 1999 and 2005
- Excluded: Vaccines

Drug selection

Included drugs:
4 products with "anaphylactic reaction" listed in their official US product labels before end of 2013 were considered

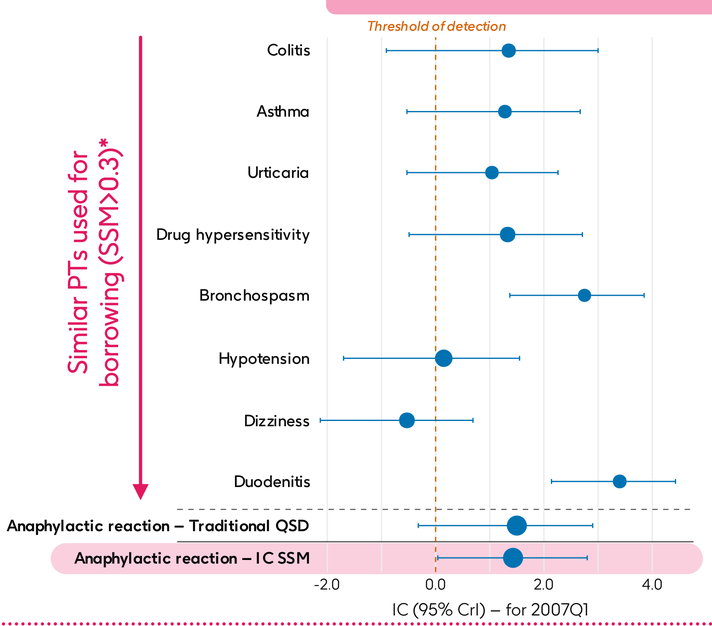
Analysis
- Comparation: IC SSM vs traditional QSD method
- Metric: Time to statistical alert (per drug-event pair)
- Threshold: First timepoint at which the lower bound of IC 95% CrI >0

Results – Anaphylactic Reaction

Semantic similarity measure: 0.25 · 0.50 · 0.75 · 1.00

Earlier signal alert

Meloxicam

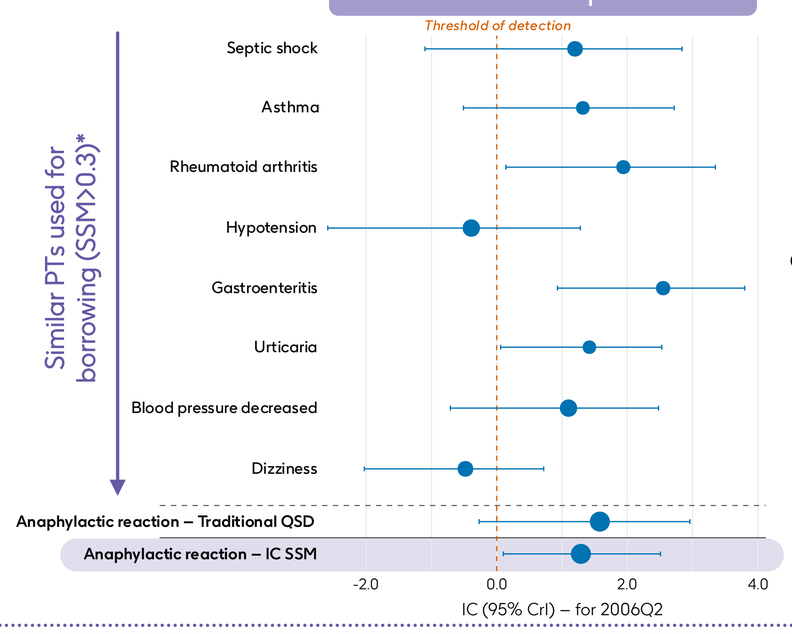


Impact on time to signal alert

IC SSM: generated a quantitative alert two quarters sooner (2007Q1) than the corresponding label update

Traditional QSD: no alert

Abatacept



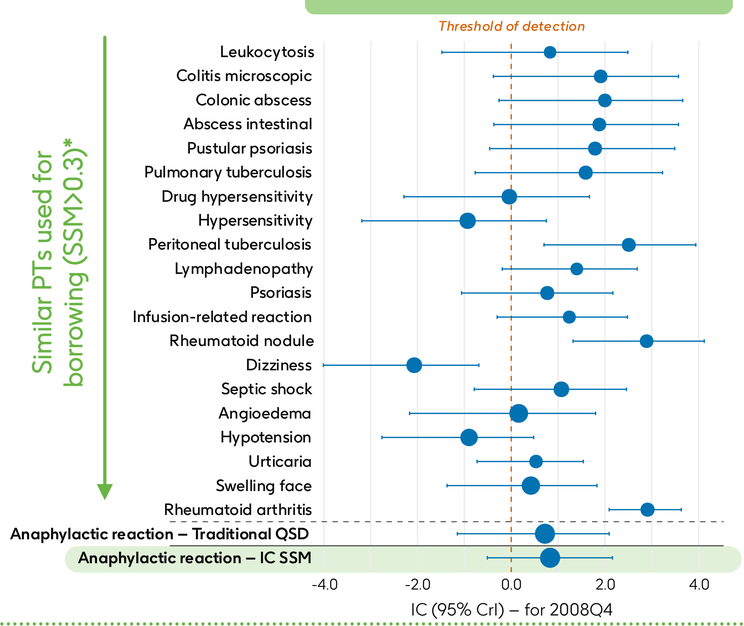
Impact on time to signal alert

IC SSM: generated a quantitative alert two quarters sooner (2006Q2) than traditional QSD

Traditional QSD: 2006Q4

No improvement in time to signal alert

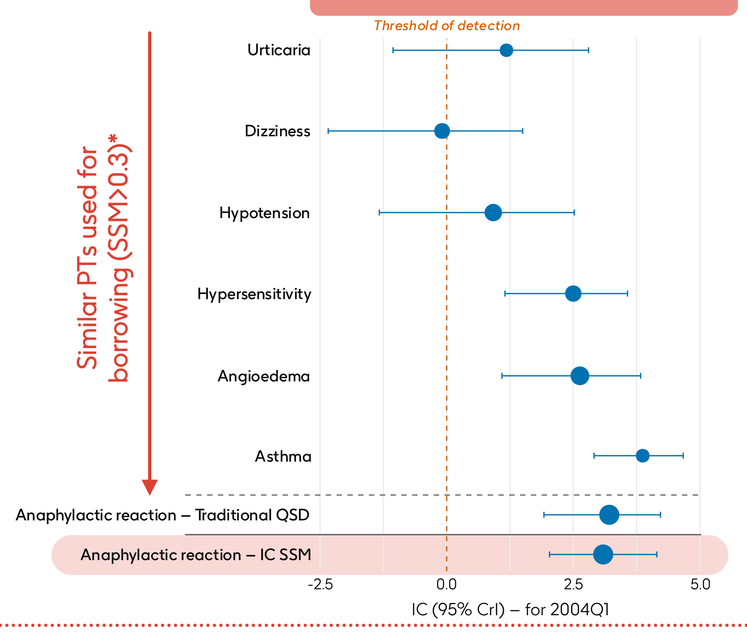
Adalimumab



Impact on time to signal alert

No quantitative alert for either method

Omalizumab



Impact on time to signal alert

Both methods generated quantitative alerts for all quarters in the analysis period

*by increasing borrowing weight

Abbreviations

CrI, credible interval; **FDA**, Food and Drug Administration; **IC**, information coefficient; **MedDRA**, Medical Dictionary for Regulatory Activities; **PT**, preferred term; **Q**, quarter; **US**, United States.

References

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Data sharing statement

The data that support the findings of this study are available from the presenting author, upon reasonable request.

Authors' contributions

All authors contributed to the study concept or design, as well as data acquisition, analysis, and interpretation.

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