Lawyer reporting creates false data mining signals in FDA’s Adverse Event Reporting System (AERS)

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**Background**

AERS is an FDA-administered post-marketing drug safety database that collects reports of adverse events (AEs) submitted by manufacturers and the public. Lawyers may submit AE reports either through pharmaceutical companies (expedited or periodic reports), or directly to AERS. Lawyers may be a source of over-reporting when they submit many reports for the same drug-reaction pair that otherwise would have gone unreported. All data mining techniques that are based on disproportional reporting may be vulnerable to biases introduced by lawyer over-reporting.

**Objectives**

- Describe the most common drugs in lawyer-originated reports, and the reactions usually associated with these drugs.
- Estimate the degree to which an excess of lawyer-originated reports have inflated signal for drug-reactions.
- Explain how to estimate signal inflation factor.
- Identify the most vulnerable drugs.
- Illustrate how signal mining in AERS data may be prone to signal inflation from lawyer-originated reports.

**Methods**

Data collection: AERS reports were accessed electronically using QScan-FDA (Druglogic, Las Vegas, NV).

Search criteria: All AERS reports and all lawyer-originated reports from Feb. 2002 to Sep. 2009. The ten most common brand name primary suspect drugs among lawyer-originated reports were tabulated. For each drug, information about the most common reaction, by higher level term (HLT), among lawyer-originated reports was collected.

Statistical methods: The primary measure of association was the Proportional Reporting Ratio (PRR).

**Results**

- **Characteristics of lawyer-originated and other AERS reports, Feb 2002-Sep 2009.**
  - PRR: Proportional Reporting Ratio
  - Signal inflation factor

**Conclusions**

- Lawyer-originated reports represent a small but persistent proportion of all AERS reports.
  - The vast majority of lawyer reports are submitted via pharmaceutical companies (expedited or periodic reports).
- A large proportion of lawyer reports are for a small number of drugs.
  - The resulting bias can amplify or create signals for drug-reaction pairs.
  - However, a large amount of lawyer over-reporting does not necessarily cause substantial signal inflation.

**References**


**Disclosure**

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the conclusion of the presentation: Nicholas Schluterman nothing to disclose, Sheila Weiss Smith nothing to disclose.