STATISTICAL ANALYSIS AND DATA MINING

Review

A pattern discovery framework for adverse event evaluation and inference in spontaneous reporting systems

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Abstract

Safety of medical products is a major public health concern. We present a critical discussion of the currently used analytical tools for mining spontaneous reporting systems (SRS) to identify safety signals after use of medical products. We introduce a pattern discovery framework for the analysis of SRS. The terminology 'pattern discovery' is borrowed from the engineering and artificial intelligence literature and signifies that the basis of the proposed framework is the medical case, formalizing the cognitive paradigm known to clinicians who evaluate individual patients and individual case safety reports submitted to SRS. The fundamental contribution of this approach is a strong probabilistic component that may account for selection and other biases and facilitates rigorous modeling and inference. We discuss somewhat in depth the concept of signal in pharmacovigilance and connect it with the concept of a pattern; we illustrate this conceptual framework using the example of anaphylaxis. Finally, we propose a research agenda in statistics, informatics, and pharmacovigilance practices needed to advance the pattern discovery framework in both the short and long terms.