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Decision Support for Signal Assessment of Large Case Series in Pharmacovigilance

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Abstract. In pharmacovigilance, signal assessment of a medicinal product and adverse event can involve reviewing prohibitively large numbers of case reports. A prototype of a decision support tool guided by a needs assessment was developed to help manual review of many reports. In a preliminary qualitative evaluation, users said the tool was easy to use, improved efficiency and provided new insights.

Keywords. Decision support, pharmacovigilance, signal assessment

1. Introduction

Post marketing safety surveillance involves monitoring medicinal products already in routine clinical use for safety concerns not detected during the pre-marketing clinical trials. At Uppsala Monitoring Centre (UMC), this involves screening VigiBase, the WHO global database of individual case safety reports, which contains over 33 million reports. A signal is a hypothesis of "a new potentially causal association, or a new aspect of a known association, between an intervention and an event" [1].

Signal assessors (SA) investigate case series which can contain hundreds or even thousands of reports about a medicinal product and adverse event. As the size of case series increases, so does the complexity of signal assessment. Currently, all reports are manually reviewed, a task that can be prohibitively time consuming. We hypothesized that one way of addressing this problem is by providing a set of decision support functionalities that allow SAs to identify subsets of reports for analysis from specific points of view. Other groups have proposed similar hypotheses [2]. To this end, we carried out a needs assessment, built a tool prototype, and evaluated its usefulness and usability.

2. Methods

Six SAs at UMC were interviewed to capture their needs regarding assessment of large case series. From the interviews we derived a common workflow for the signal assessment process, and its associated challenges. One of the needs identified was in identifying reports relating to specific risk factors or confounders, as finding such patterns is highly time consuming.

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A decision support tool was built using Python and the Streamlit framework to facilitate the users' needs, including the definition of risk factors through coded (MedDRA) medical and free text search terms within the relevant fields in reports. Predefined risk factor definitions were provided to identify cases involving patients with COVID-19 disease, and tools were implemented allowing users to define their own risk factors. Defined risk factors can be stored in a knowledge repository, for later reuse in the analysis of other case series. This allows users to explore salient subsets of reports.

A preliminary assessment was conducted on the effectiveness of the predefined risk factors. A small-scale qualitative evaluation was conducted to assess usability and usefulness. Four SAs used the tool for a week and received a questionnaire which was followed by a focus group discussion to capture additional feedback.

3. Results

In a preliminary experiment on a single vaccine adverse event combination with 123 reports, the predefined risk factor had a recall of 0.81 and a precision of 0.59 in finding the 52 true relevant reports. The outcome of the questionnaire and focus group discussion suggest that the tool is easy to use and effective in reducing the time required to perform an analysis. SAs said they would use the current version as part of their signal assessment process. The tool allowed users to find information in reports faster, confirm previous manual findings and detect new relevant reports. Possibilities to explore ideas more easily gave new insights into the case series. Features for collaboration between assessors and further editability were wished for.

4. Discussion

A caveat in this qualitative evaluation was that users only used the tool in the late stages of signal assessment. In the future, a more in-depth evaluation is planned when users have used the tool for longer, including in the early phases of signal assessment.

5. Conclusions

This preliminary study indicates that a decision support tool that enables the identification of subsets of case reports to reduce the complexity of pharmacovigilance signal assessment is considered useful by SAs and has the potential to improve their time efficiency.

References

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