Detecting Duplicates in Adverse Event Reports for *Cannabis sativa* and *Mitragyna speciosa* (Kratom) Products

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INTRODUCTION

BACKGROUND

Spontaneous safety reports submitted to the FDA Adverse Event Reporting System (FAERS)[1] can be used for post-marketing safety surveillance of cannabis and kratom products.

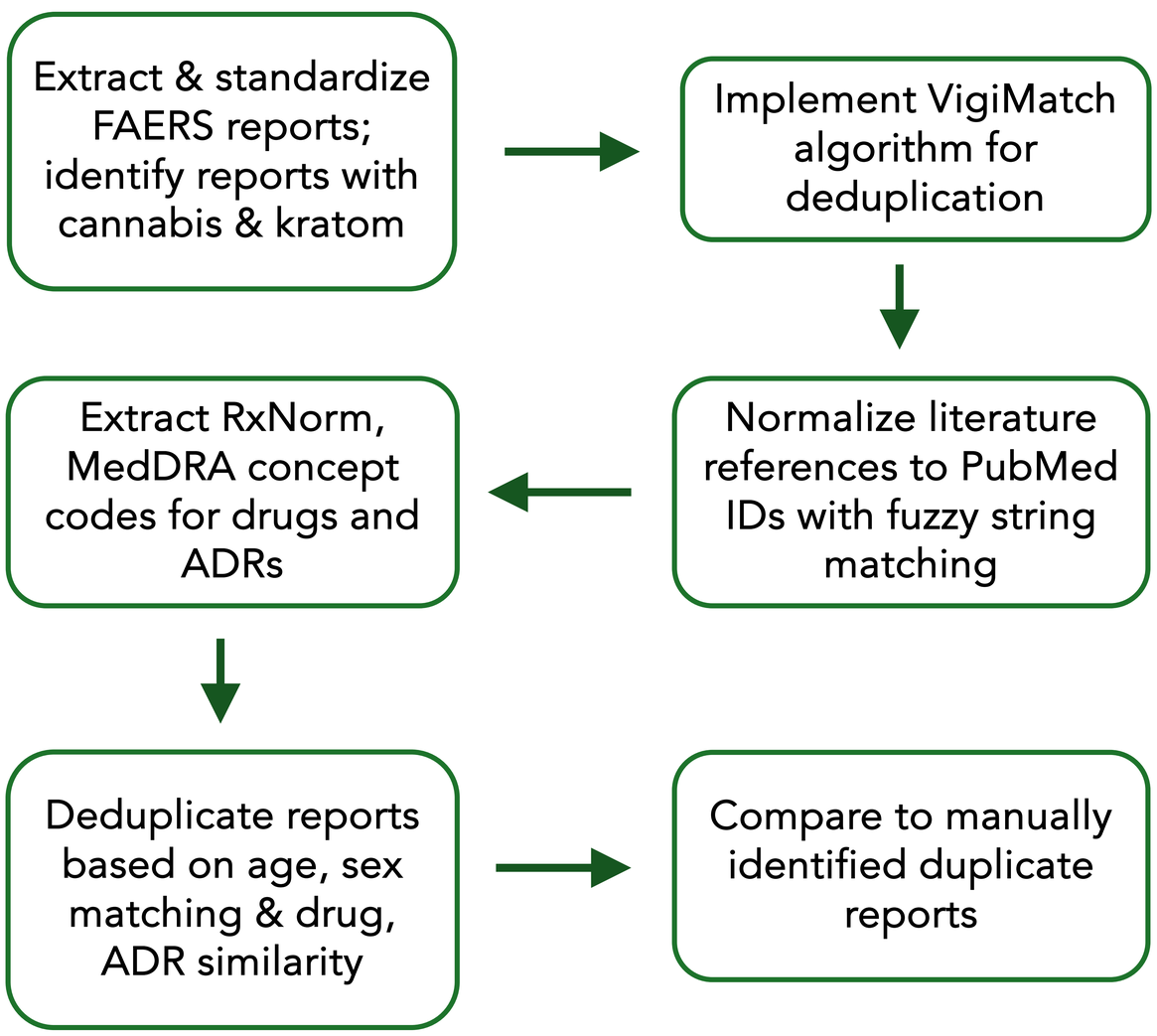
MOTIVATION

Duplicate adverse event reports are a common issue with very few methods for deduplication. Primary report identifiers are not reliable as the reporting of same events is common.

OBJECTIVE

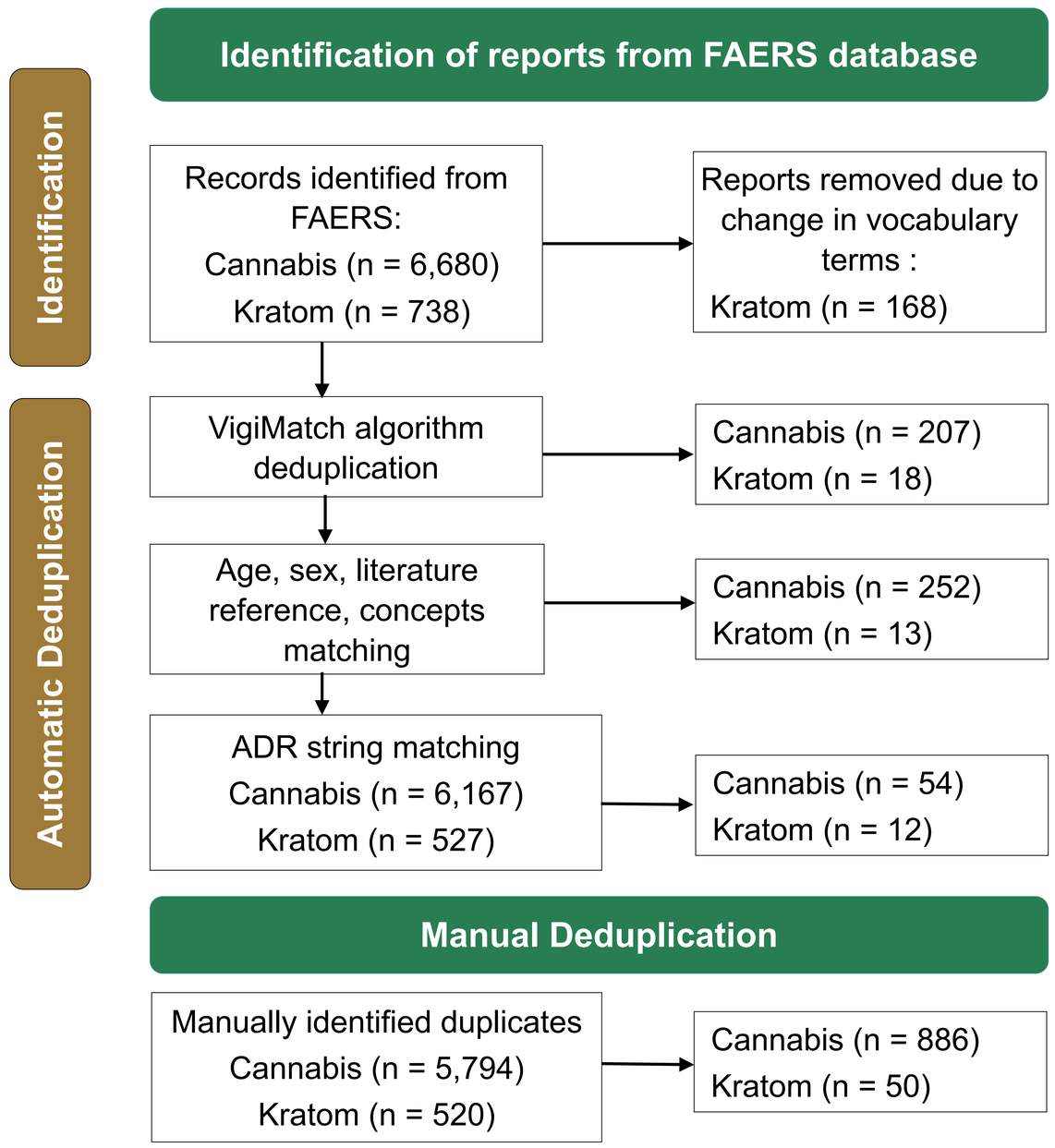
To develop a method that extends probabilistic record matching (VigiMatch[2]) for deduplication in FAERS and evaluate the methods with a focus on cannabis and kratom reports using FAERS report details and embeddings.

METHODS



1. https://open.fda.gov/data/faers/
2. Tregunno PM, Fink DB, Fernandez-Fernandez C, Lázaro-Bengoa E, Norén GN. Performance of probabilistic method to detect duplicate individual case safety reports. Drug safety. 2014;37:249–58.

RESULTS



- Literature references included in 4.7% of the reports; normalized to PubMed IDs (68.4%) and custom IDs (31.6%).

CONCLUSION

- First study to focus on deduplication in FAERS for botanicals combining VigiMatch, approximate matching with literature references, and adverse event reports details.
- Better deduplication with combination of approaches. Embedding similarity could potentially improve deduplication but is more aggressive.
- Manual review showed that extreme duplication remains an issue, specially for reports with missing details.

FAERS: FDA Adverse Event Reporting System
ADR: Adverse Drug Reaction

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