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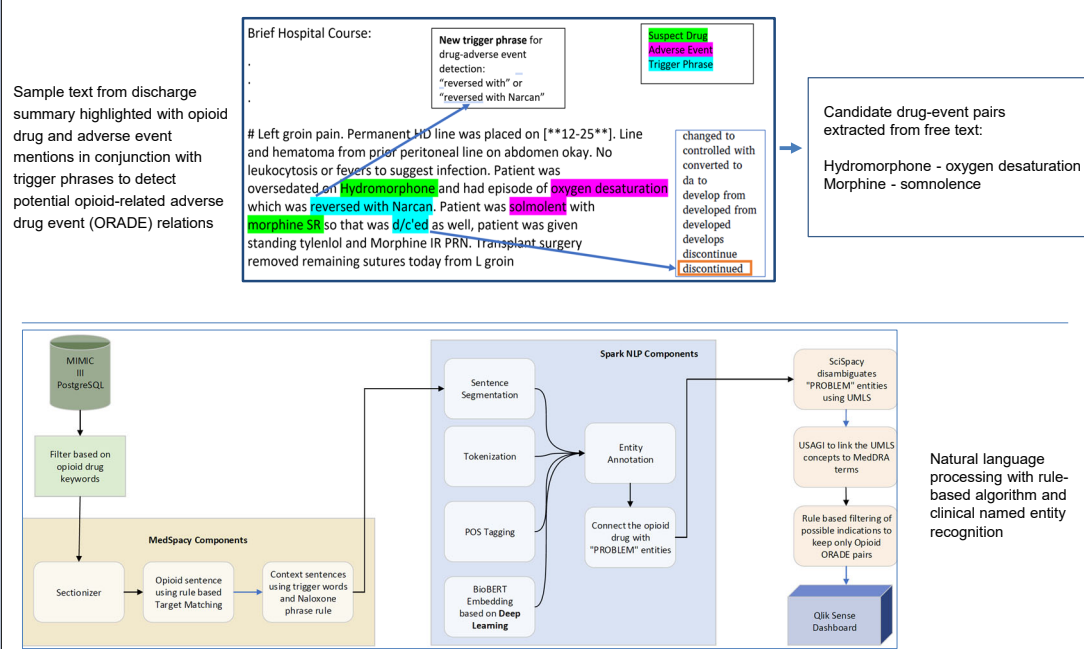
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Introduction

- Electronic Health Records (EHR) are a rich source of real-world information on opioid drug use that could potentially augment drug safety surveillance at the US Food and Drug Administration (FDA). Pharmacovigilance activities at the FDA are oriented to detect, monitor, characterize, and prevent adverse drug reactions for FDA-approved drugs and therapeutic biologic products. Multiple biomedical resources utilized currently include clinical trials data, spontaneous adverse event reports, and published scientific literature reports.

- Electronic health records (EHR) are an important information resource about opioid drug allergies. In a study of drug allergies recorded in EHRs of a tertiary healthcare system, opioids were the third most frequently implicated drug class.¹ In a Veterans Affairs inpatient study, opioids were the second most frequently reported class for drug allergies.²

Methods



Conclusions and Limitations

CONCLUSIONS

- This novel prototype application provides a practical framework to extract ORADE information from unstructured text in EHR discharge summaries.
- ORADE safety signals illustrative of known labeled opioid toxicities can be detected. The application may potentially detect novel emerging ORADEs.

LIMITATIONS

- False positives caused by drug-indication pairs and opioid medication change events
- Concept fragmentation wherein the drug and adverse event do not co-occur in the same sentence
- Complexities in cross-terminology mapping
- Heterogeneity and variable quality of information recorded in the discharge summaries

FUTURE ENHANCEMENTS

- Methodological refinements to increase precision in identifying valid candidate ORADE pairs.
- Assess the application in detecting new emerging safety issues using a larger and more diversified EHR database

Objectives

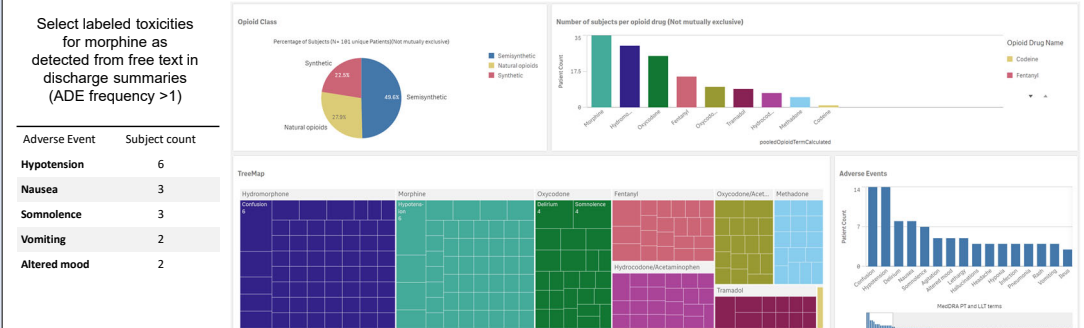
- Garner drug safety insights from EHRs by leveraging rule-based algorithms and deep learning methods to identify opioid-related adverse drug events (ORADE) in discharge summaries from the Medical Information Mart for Intensive Care (MIMIC-III) database³.
- Map drug name and adverse event term mentions from free text to standardized terminologies and ontologies.
- Develop an interactive visualization dashboard to explore structured and unstructured data from the MIMIC-III EHR data to support drug safety review and research

Results

The opioid-ORADE pair detection pipeline was tested on a dataset of 30 opioid-ORADE pairs based on 47 patient's discharge summaries. This test dataset consisted of the remaining 20% of the originally generated dataset. The trained model achieved accuracy/recall/precision/F1 scores of 0.61/0.60/0.64/0.62, respectively.

The extracted candidate drug-event pairs do not indicate causality or absolute risk of an association. Most of the false positives (opioid-ORADE pairs that are detected by the trained model but was not annotated by domain expert) can be attributed to drug regimen change and opioid-indication pairs.

The landing page of the Qlik Sense® ORADE dashboard



References

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