MEDINFO23

8 – 12 JULY 2023 | SYDNEY, AUSTRALIA

Automating the Identification of Safety Events Involving ML-Enabled Medical Devices

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Background

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1. Machine learning (ML) enabled systems have the potential to improve healthcare del
2. With use in clinical settings and by consumers, safety events involving ML-enabled medical devices are emerging.

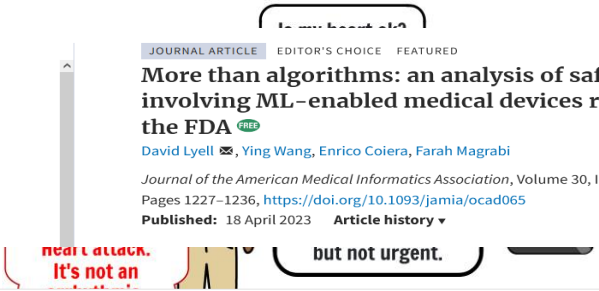
Volume 30, Issue 7
July 2023

JOURNAL ARTICLE EDITOR'S CHOICE FEATURED

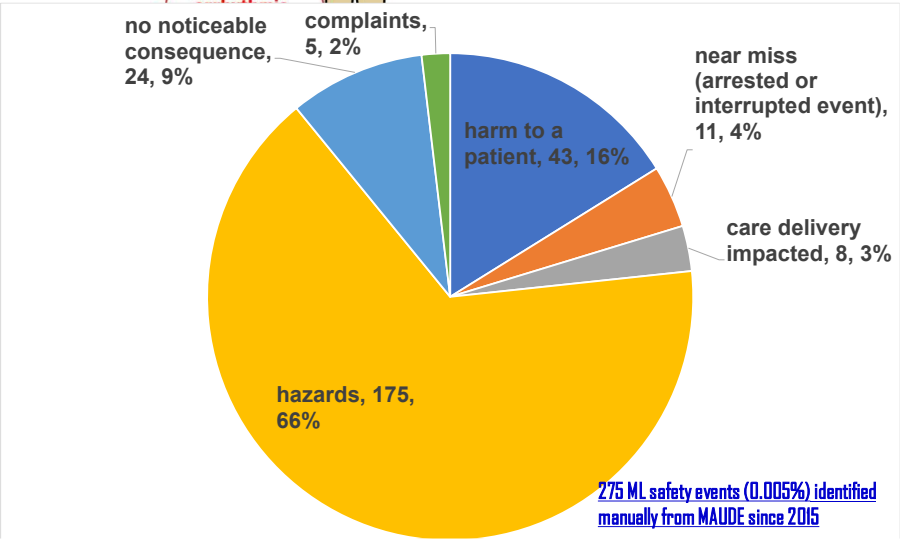
More than algorithms: an analysis of safety events involving ML-enabled medical devices reported to the FDA FREE

David Lyell ✉, Ying Wang, Enrico Coiera, Farah Magrabi

Journal of the American Medical Informatics Association, Volume 30, Issue 7, July 2023, Pages 1227–1236, https://doi.org/10.1093/jamia/ocad065
Published: 18 April 2023 **Article history**



3. FDA MAUDE database is a valuable resource to understand patient safety risks associated with ML medical devices in real worlds.
4. Considering over 2 million events were reported to MAUDE in 2021, manual review on an ongoing basis is not feasible.



Machine Learning driven solution

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Data collection

- Data processing: bag of words
- Numeric representation: term frequency–inverse document frequency (TF-IDF)

Feature representation

- Event reports including updates and follow-up investigations
- Brand names plus reports
- Manufacture names plus reports

Model training and testing

- Binary discriminative classifiers of SVM with radial-basis function kernel
- 10-fold subsampling cross-validation
- Four stratified classifiers with varied feature sets above

Error analysis and verification

- Performance measures: precision, recall and F1 score
- Verification of classifier identified positives

Training and testing datasets

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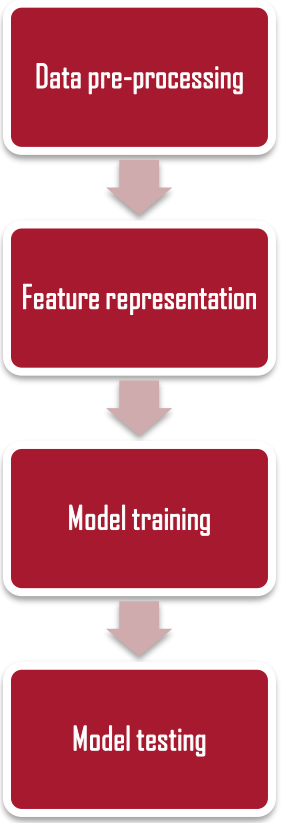
Datasets	Event type	Stratified dataset (n=)
Training set (75%) From 1 January 2018 to 31 October 2021	ML safety events	207
	General safety events	4,044,796
	Total	**4,045,003**
Testing set (25%)	ML safety events	68
	General safety events	1,348,266
	Total	**1,348,334**
External testing set From 1 November 2021 to 31 March 2022		895,627



Results: performance of four classifiers

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Dataset		Report classifier	Generic type classifier	Brand name classifier	Combined classifier
Testing set	False negative (n)	27	22	23	4
	False positive (n)	4	2	5	0
	Total (n)	**31**	**24**	**28**	**4**
	Precision (%)	94.4	97.1	93.2	100
	Recall (%)	71.6	75.6	74.7	93.9
	F1 score (%)	81.4	**85**	82.9	**96.9**
External testing set	Classifier identified MLSEs (n)	43	38	38	7,707
Verified as	MLSEs (n)	31	38	38	/
	Data input issues attributed to non-ML	5	0	0	/
	False positives (n)	7	0	0	/

Table: Performance of report classifier, generic type classifier, brand name classifier and combined classifier on testing and external datasets.

Report classifier

Generic type classifier

Brand name classifier

Combined classifier

Results: error analysis

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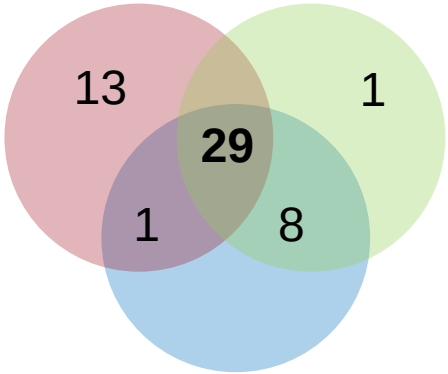
Classifier identifications

- 52 ML safety events identified by three classifiers on external testing set.
- 29 (56%) identified by all three involving known ML devices.
- 9 events identified by two classifiers
  - 8 events by brand name and generic type
  - 1 event by report and generic name
- 13 events identified by report alone and one by brand name



True and false positives

- 40 of 52 events (77%) manually verified as true positives (TP).
- 5 false positives (10%) did not involve ML devices but associated with device input problems, such as poor data acquisition.
- 7 false positives (13%) neither HIT problems nor ML devices.
- All 29 events overlapped by the three classifiers were verified as TPs,
  - Data acquisition problems: 90% (n=26) from imaging systems.
  - Algorithm errors: two TPs (6.9%) with an ECG device designed for detecting normal sinus rhythm and sever arrythmias.

Discussion

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Feasibility

Model performance

- Stratified text classifiers can be used to identify rare ML events from large collections of data.

Generalizability

Real-world use of AI

- Current classifiers don't generalize well to identify rare class events from highly imbalanced dataset.

Device input problems

Common safety risks

- Mostly identified by classifiers and made up the bulk of the training set.

Algorithm errors

Critical safety risk for ML devices

- One user's device suggested atrial fibrillation during heart attack.
- Another user experienced atrial fibrillation, but the device indicated a normal rhythm.

Future work

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Active learning

Data annotation

- iteratively ask safety experts to verify events identified by the classifier and label more ML safety events.

Large Language Models

Generative AI

- pre-trained or fine-tuned on a dataset of safety events to identify ML safety events.

SafeHealth.ai

Knowledge sharing

- Insights on medical AI devices
- Safety risk analysis of ML events

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Thank you and comments?

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