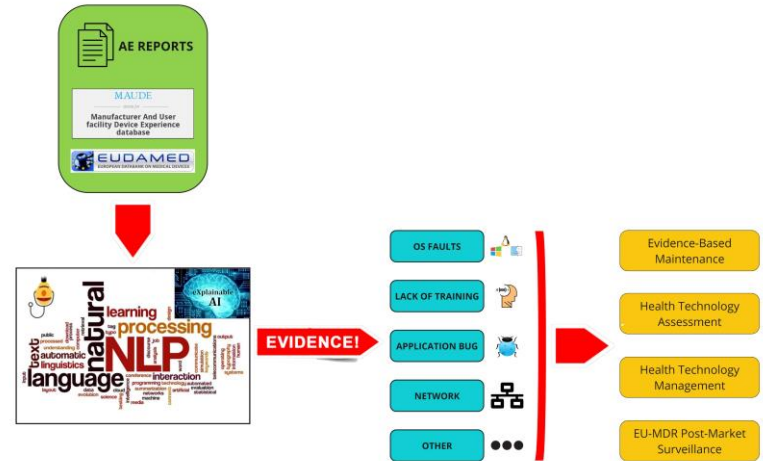**Università degli Studi di Firenze
Dipartimento di Ingegneria dell'Informazione**

**Università degli Studi di Siena
Dipartimento di Biotecnoligie Mediche**

Designing and developing a dedicated Natural Language Processing framework for Healthcare Information Technology Management and Assessment

Evidence-Based Maintenance and Real-World Data

Evidence-Based Maintenance consists of the continuous performance monitoring of equipment, starting from the evidence (i.e., the current state in terms of <u>failure</u> history) and improvement of its effectiveness by making the required changes.
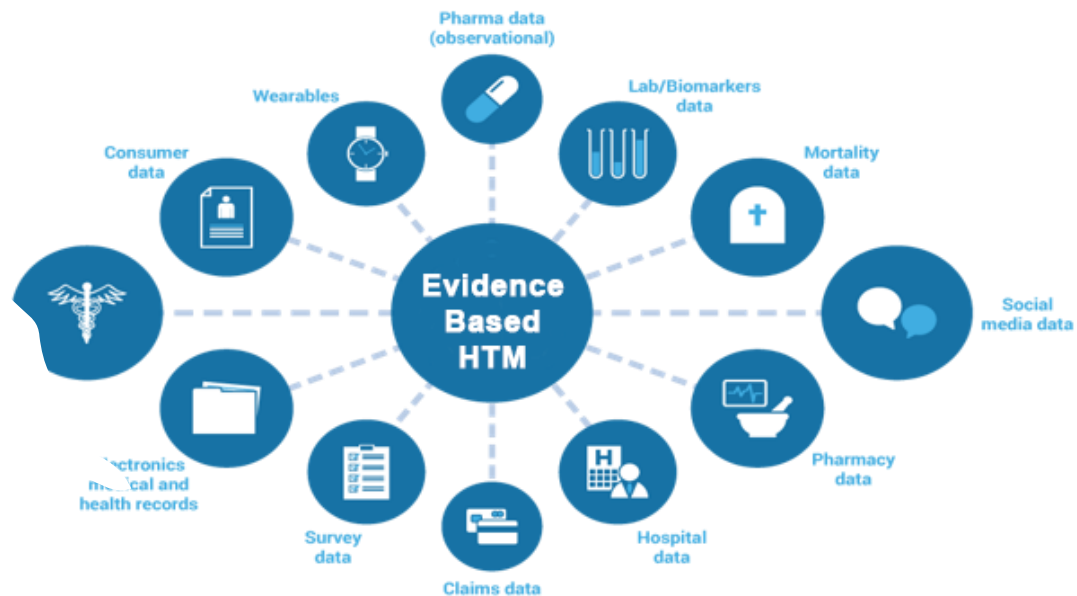
Existence and type of official nomenclature system for medical devices by country

The data for this graph was collected by WHO during 2021 and 2022.

The data is part of the up-date of the 2022 Global Atlas of Medical Devices.

None (do not have)	75
More than one system	15
Based on UMDNS	16
Based on GMDN	15
Based on EMDN	27
Nationally developed	32
No answer	14

World Health Organization

Existence and type of official nomenclature system for medical devices

- No answer 7%
- Nationally developed 16%
- None (do not have) 39%
- Based on EMDN 14%
- Based on GMDN 8%
- Based on UMDNS 8%
- More than one system 8%
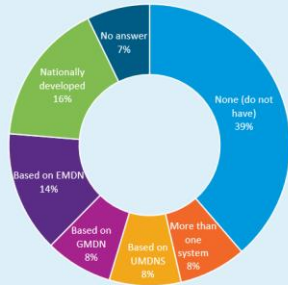
N= 194

Code	Description
NPF	No problem found
BATT	Battery failure
ACC	Accessory failure (including supplies)
NET	Failure related to network
USE	Failure induced by use (i.e., abuse, accident, environment conditions)
UPF	Unpreventable failure caused by normal wear and tear
PPF	Predictable and preventable failure
SIF	Induced by service (i.e., caused by a technical intervention not properly completed or premature failures of a part just replaced)
EF	Evident failure (i.e., evident to the user but not reported)
PF	Potential failure (i.e., in process of occurring)
HF	Hidden failure (i.e., not detectable by the user unless special test or measurement equipment)

Nomenclature of Medical Devices and Standardization of Failure Code for maintenance

World Health Organization: **International Classification and Nomenclature of Medical Devices** (ICMD), implemented in the ICD-11.

https://www.who.int/teams/health-product-policy-and-standards/

AIIC associazione italiana ingegneri clinici

Iadanza, E., Luschi, A. (2024). Standardization of Failure Codes and Nomenclature of Medical Devices for Evidence-Based Maintenance. In: IFMBE Proceedings, vol 94. Springer, Cham. https://doi.org/10.1007/978-3-031-49068-2_19
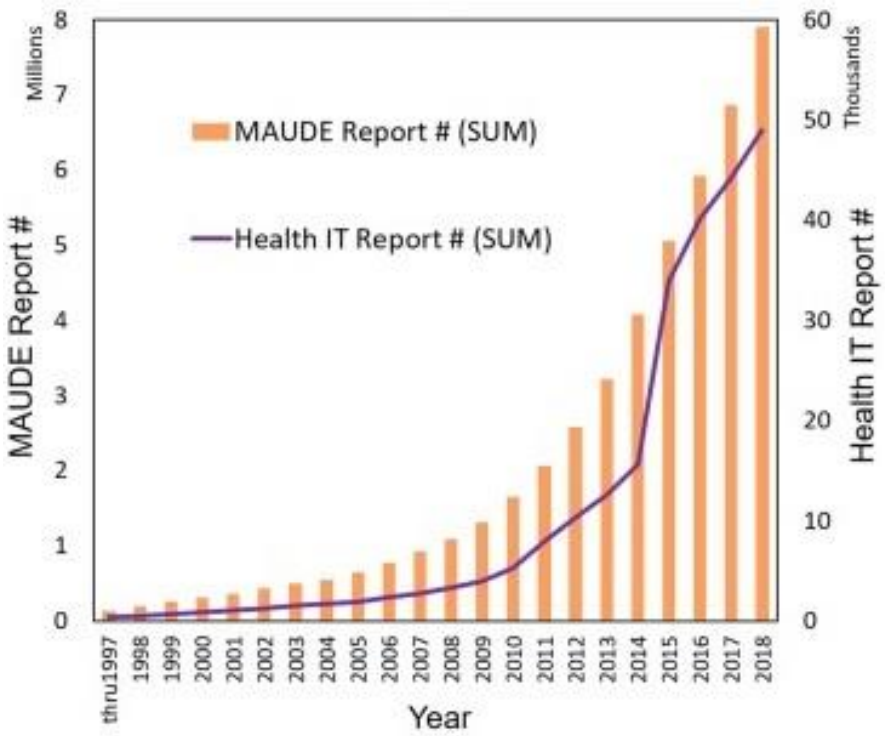
Kang, H., Gong, Y., Creating a database for health IT events via a hybrid deep learning model, Journal of Biomedical Informatics, vol. 110, 2020.
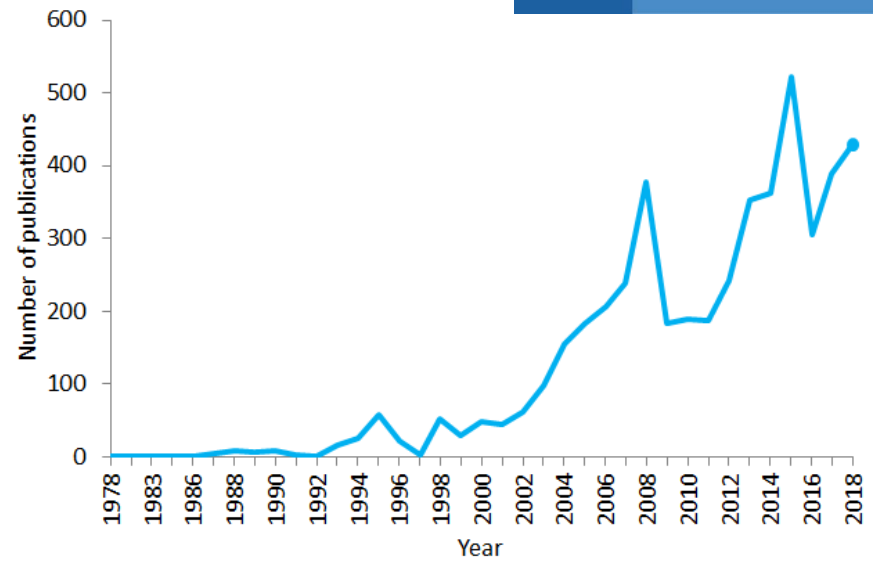
Number of publications containing the sentence "natural language processing" in PubMed in the period 1978–2018. As of 2018, PubMed comprised more than 29 million citations for biomedical literature

NLP in Healthcare and Health Information Technologies

Results and Explainable AI applied to the model

The developed model (**ClinicalBERT**) has an overall classification run-time of:

- 9.73s ± 21.5ms for 1,000 reports.

The classification run-time of one report is:

- 9.48ms ± 5.6μs.

Results show better metrics than other existing HIT adverse events reports text classifiers based on non-BERT NLP models
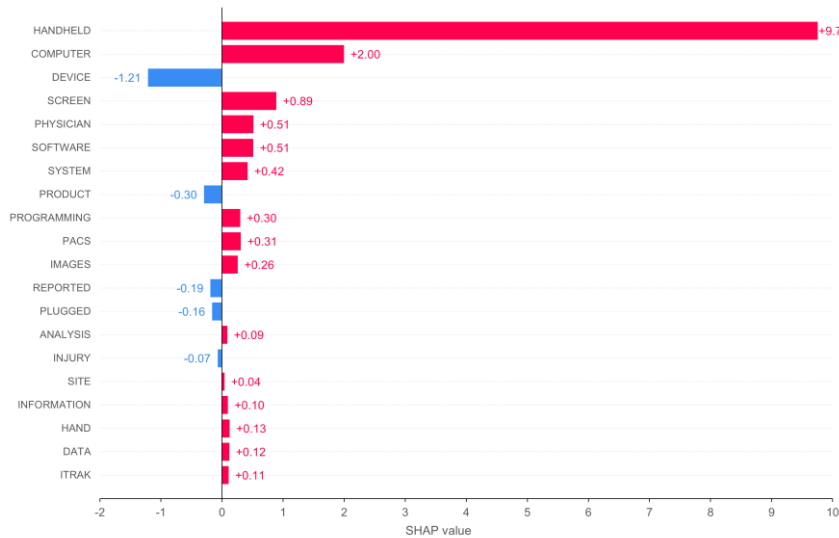

Table 4.2: Comparison of performances of the proposed NLP model (fine-tuned ClinicalBERT) and other non-BERT models. LR - Logistic Regression. SVM - Support Vector Machine. CNN - Convolutional Neural Network. HRNN - Hierarchical Recurrent Neural Network.

Model	Accuracy	Precision	Recall	F1 score
ClinicalBERT	**0.9946**	**0.9893**	**1.0000**	**0.9946**
LR [15]	-	0.9670	0.9420	0.9540
LR [32]	-	0.6940	0.8040	0.7450
SVM+LR+CNN [116]	0.9012	0.8796	0.8606	0.8700
LR+CNN+HRNN [62]	0.9030	-	-	0.8760
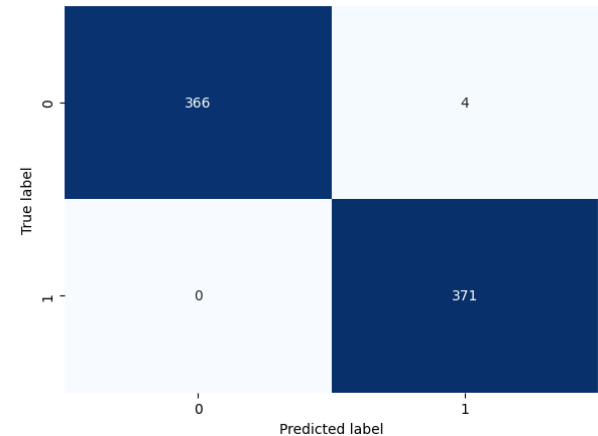
[15] K. Chai, S. Anthony, E. Coiera, and F. Magrabi, "Using statistical text classification to identify health information technology incidents," Journal of the American Medical Informatics Association : JAMIA, vol. 20, 05 2013.

[32] A. Fong, K. Adams, M. Gaunt, J. Howe, K. Kellogg, and R. Ratwani, "Identifying health information technology related safety event reports from patient safety event report databases," Journal of Biomedical Informatics, vol. 86, 09 2018.

[62] H. Kang and Y. Gong, "Creating a database for health it events via a hybrid deep learning model," Journal of Biomedical Informatics, vol. 110, p. 103556, 2020.

[116] E. Wang, H. Kang, and Y. Gong, "Generating a health information technology event database from fda maude reports," Studies in health technology and informatics, vol. 264, pp. 883–887, 08 2019.

A comprehensive review of existing literature has revealed a notable absence of an up-to-date global standard for naming and coding medical devices and their associated fault codes in maintenance work orders. This deficiency poses significant challenges when attempting to collect data from diverse systems, as mapping across disparate nomenclatures becomes exceedingly difficult due to the unique internal organization of each nomenclature and CMMS software.

Semantic ontologies offer the potential to establish a suitable level of abstraction for sharing and reusing concepts in a standardized manner. This ensures that data from diverse sources can be provided with a common nomenclature, facilitating communication among stakeholders and streamlining the integration of the proposed NLP framework for Health Technology Management and Assessment, and Post-Market Surveillance in line with the EU Medical Device Regulation (EU-MDR) 2017/745.

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