

Frameworks for Developing Machine Learning Models

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Keywords

machine learning, good practice, best practice, transparent reporting, artificial intelligence, diabetes mellitus

Machine learning (ML) has the potential to revolutionize health care and diabetes care. One of the key benefits of using ML in diabetes care is its flexibility and scalability. This makes it suitable for a wide range of tasks, such as identifying patient risk levels, making diagnoses, and predicting outcomes. In addition, ML algorithms are capable of analyzing various types of data, including demographic information, laboratory results, imaging studies, and physician notes, and integrating that information to make predictions about disease risk, diagnosis, treatment options, and prognosis.^{1,2}

However, its limited adoption in clinical care suggests that current strategies are deficient. Currently, ML solutions are often being developed in silos with a focus on insufficient studies of important aspects from development to validation, implementation, and clinical relevance of the models.³ Good Machine Learning Practice (GMLP) includes aspects such as:

- Ensuring that the data used for training and testing the models are diverse, representative, and of high quality;
- Using appropriate evaluation metrics that are specific to the task and the population being studied;
- Being transparent about the limitations and uncertainty of the models;
- Considering ethical and legal implications, such as ensuring patient privacy and obtaining informed consent;
- Regularly monitoring and updating the models to ensure they remain accurate and current;
- Collaborating with domain experts, such as physicians and health care professionals, to ensure the models are clinically relevant and useful; and
- Regularly assessing the impact and value of the models in the real-world setting and making adjustments accordingly.

Over the last years, several frameworks for good practice and reporting have been proposed. It is important that these frameworks are adopted to a larger degree to ensure that more models are successfully implemented in clinical settings and can improve care, diagnostics, and workflow in a

real-world world setting. In 2021, the US Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) published a framework with 10 guiding principles that can help inform the development of GMLP:

<https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles>

In 2019, Wiens et al³ published a framework titled “Do no harm: a roadmap for responsible machine learning for health care,” which covers important aspects from choosing the right problem and data to ethical considerations and deploying the models responsibly. Recently, FDA has published a document of Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. The document presents an non-exhaustive list of 521 AI/ML-enabled devices across medical disciplines marketed in the United States as of January 31, 2023:

<https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>

Transparent and adequate reporting of published ML models is additionally very important to advance progress in the field and evaluate proposed models. The reporting quality of published ML models has been identified as insufficient in most studies, making it difficult to replicate, assess, and interpret study findings.⁴ Numerous frameworks and checklists, such as the Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD), TRIPOD-Artificial Intelligence (under development), and the *International Journal of Medical Informatics* (IJMEDI) checklist, exist and should be adopted by researchers and journals to ensure adequate reporting for ML models.^{5,6}

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Abbreviations

FDA, US Food and Drug Administration; GMLP, good machine learning practice; IJMEDI, *International Journal of Medical Informatics*; MHRA, United Kingdom's Medicines and Healthcare products Regulatory Agency; TRIPOD, Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis.

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