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Risk-based assessment of AI in medicine

A recent article by Prof. Dr. Martin Haimerl and Prof. Dr. Christoph Reich of Furtwangen University shows that machine learning (ML) in medicine is often evaluated without a comprehensive risk assessment. The authors investigated the extent to which current scientific papers include risk-based metrics in the evaluation of AI models for medical devices.

The result: most publications use classic metrics such as accuracy or sensitivity without sufficiently considering the clinical risks of misclassification.

Lack of risk assessment - a critical problem

Haimerl and Reich emphasize that different types of errors in the use of ML models – in particular false-negative (overlooked diseases) and false-positive (misdiagnosis) results – can have serious and sometimes very different consequences. While a false-negative result can lead to omitted treatment, a false-positive result may cause unnecessary interventions. A risk-based assessment could help to improve the safety and effectiveness of AI-supported diagnostic models.

Regulatory requirements and necessary adjustments

The authors refer to the EU Medical Device Regulation (MDR) and the risk management standard for medical devices ISO 14971, which prescribe a systematic risk assessment for medical devices. Nevertheless, many ML models do not take these regulatory requirements sufficiently into account. The authors show that a stronger focus on risk-based performance metrics could significantly improve patient safety and this approach should be considered an essential building block for the approval of AI-based medical devices.

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