

Research Project

Ethical and Legal issues of Mobile Health-Data – Improving understanding and eXPLAINability of digital transformAtion and data technologies using artificial IntelligeNce [EXPLaiN]

Third-party funded project

Project title Ethical and Legal issues of Mobile Health-Data – Improving understanding and eXPLAINability of digital transformAtion and data technologies using artificial IntelligeNce [EXPLaiN]

Principal Investigator(s) [Elger, Bernice Simone](#) ;

Co-Investigator(s) [Thouvenin, Florent](#) ; [Steiner, Luzius A.](#) ; [Eckstein \(usb\), Jens](#) ; [Vogt, Julia](#) ; [Pena, Carlos](#) ;

Project Members [Arbelaez Ossa, Laura](#) ; [Lorenzini, Giorgia](#) ;

Organisation / Research unit

Ethik / Bio- und Medizinethik (Elger)

Department

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Status Active

This project explores the highly important topic of mobile data (mData) uses in medicine and the employment of machine learning (ML) and deep neural networks (DNN) in this context. Clinical, research or other secondary uses involving mobile health data or ML, and even more the combination of mData and ML, have raised a panoply of new concerns creating legal and ethical barriers which interfere with trust of patients and society. Data protection concerns increase disproportionately with mData. In addition, the use of ML could be incompatible with the new EU General Data Protection Regulation (GDPR, Art. 22) that postulates a right to explanation while ML algorithms function like a “black box” in spite of efforts to improve interpretability and explainability. Given the complexity of regulatory issues related to mData and ML, research ethics committees (REC) worldwide struggle with establishing criteria how to approve such projects. These concerns significantly impede advances in research: health care institutions collect high volumes of very useful data, including an increasing amount of mData, but beneficial analysis, in particular of mobile data, remains scarce. While appropriate infrastructures are currently being developed, there is an urgent need for (i) clarification of the new pressing questions related to the ethical and legal governance of mobile data research and the use of ML algorithms and (ii) an in depth exploration of patient concerns. The topics of mData and ML are intrinsically related as the volume of mData collected during health care has recently started to explode. Examples are smartwatch apps used in cardiology and non-invasive home-ventilators (continuous positive airway pressure, CPAP) collecting a variety of sleep, breathing and activity related parameters. Artificial intelligence (AI) such as ML is a promising tool to analyze this high data volume for research or clinical purposes. While the global importance of AI technology is generally recognized for the interpretation of digitalized data in the clinical and/or research context - f. ex. scans, skin lesions, electrocardiograms, faces, and vital signs - challenges such as bias, data protection, and lack of transparency and explainability raise concern. Access to data is debated, as manufacturers and health insurers are highly interested in the use of mData. These unresolved issues interfere with trust and the efficient and beneficial implementation of these promising technologies. Ethical and legal issues, including risks and benefits related to ML in medicine, vary enormously between different examples. Therefore, it is important to study them in concrete applications. This project will fill an important gap through a pragmatic approach on mData research and ML, by examining these questions related to two existing types of data collected in Swiss University hospitals.

The first type concerns mobile data collected in cardiac patients via smartwatches. The second type consists of perioperative data (POD) collected via existing patient data management systems: PDMS, Copra 6 at Swiss University hospitals (BS, BE; VD in prep.). Both datasets are producing high amounts of interoperable data (ECG, vital signs etc.) where ML is highly useful for research and clinical purposes. The two datasets will be compared to examine which type of additional issues exist for the use of mData as compared to clinical and secondary uses for more classical in-hospital data. Objectives and milestones: i. Define needs and barriers in practice to advance data analysis in two case studies- Use two existing types of data collected in Swiss hospitals (mData from smart watches used in cardiology at the University Hospital Basel and POD data from PDMS) to (a) describe scientifically meaningful clinical and research or other secondary uses and (b) clarify the ethico-legal framework and ML explainability to advance cutting-edge analysis. Our applicants from the field of computer science will contribute their experience on explainability as they not only use ML algorithms to build predictive models from biomedical data, but also investigate approaches allowing to understand reasons behind the models. ii. Review the existing ethical and legal frameworks- Analyse the current research ethics framework for data analysis involving ML, in particular for new types of mobile data collected via apps on smart watches.- Analyse the legal framework, in Switzerland and Europe (in particular the European data protection regulation: GDPR), including (a) existing law and how it should be interpreted, (b) legal barriers or gaps and (c) a de lege ferenda approach, i.e. how the law and research ethics framework should regulate mobile data and the use of AI/ML.

Financed by

Swiss National Science Foundation (SNSF)

Add publication

Published results

4643234, Lorenzini, Giorgia; Shaw, David Martin; Arbelaez Ossa, Laura; Elger, Bernice Simone, Machine learning applications in healthcare and the role of informed consent: Ethical and practical considerations, 1477-7509 ; 1758-101X, Clinical Ethics, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

4657381, Lorenzini, Giorgia; Shaw, David Martin; Elger, Bernice Simone, It takes a pirate to know one: ethical hackers for healthcare cybersecurity, 1472-6939, BMC Medical Ethics, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

Add documents

Specify cooperation partners

ID	Kreditinhaber	Kooperationspartner	Institution	Laufzeit - von	Laufzeit - bis
4614385	Elger, Bernice Simone	Tamò-Larrieux, A. Dr. iur.	University of Zurich	01.10.2020	30.09.2024
4614388	Elger, Bernice Simone	Shah, Dipen, Prof.	Univ. Hosp.Geneva	01.10.2020	30.09.2024
4614390	Elger, Bernice Simone	Sticherling, C., Prof.	Univ. Hosp. Basel	01.10.2020	30.09.2024
4614391	Elger, Bernice Simone	Stübler, F., Prof.	Inselspital Bern	01.10.2020	30.09.2024

ID	Kreditinhaber	Kooperationspartner	Institution	Laufzeit - von	Laufzeit - bis
4614392	Elger, Bernice Simone	Kern, C. Prof.	CHUV Lausanne	01.10.2020	30.09.2024
4614393	Elger, Bernice Simone	Müller, H. Prof.	Univ. of Geneva	01.10.2020	30.09.2024
4614396	Elger, Bernice Simone	Papaux, M.L.	Univ. of Geneva	01.10.2020	30.09.2024
4614397	Elger, Bernice Simone	Celi, L. A., Prof.	Harvard Medical School	01.10.2020	30.09.2024