Challenges for AI Regulation in Health and for Healthcare Organizations: Notes from the University of Florida's NSF-sponsored Workshop on AI Governance

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Abstract

In February 2023, the University of Florida, sponsored by the U.S. National Science Foundation, organized an international workshop to discuss Artificial Intelligence (AI) governance in both for-profit and non-profit organizations. AI is no more confined to computer science and has permeated daily life in many aspects, with strong economic and social impact. AI is used to determine insurance coverage, selection for job interviews, tailoring content for news and entertainment, medical recommendations, and clinical decision support. Since the data used for developing AI algorithms can contain multiple biases, e.g., gender prejudice,

AI can inadvertently become discriminatory to certain groups, especially socioeconomic disadvantaged minorities, that can further widen disparities and drive inequity concerns. In this workshop, we engaged with multiple stakeholders (academia, public sector, industry) from multiple domains, including business, human resources, and health sciences. We discussed how organizations can deal with conflicting goals optimized by AI (e.g., procedural and distributional justice vs. instrumentality in the name of efficiency). Renowned speakers and a specific international panel discussing AI governance in health and healthcare were organized. In this newsletter, we report key outcomes from the health-related discussions. The workshop details, agenda, and presentations can be found at https://warrington.ufl.edu/nsf-workshop/.

1 Introduction

Artificial intelligence (AI) has impacted human life at many levels, entailing economic and societal changes. AI algorithms are increasingly used by organizations to generate predictions that feed into decisions (e.g., who is eligible for insurance coverage, approved for bank loans, selected for job interviews). Since the data used for developing the algorithms can contain bias such as gender or racial prejudice, AI predictions can become discriminatory. For-profit and not-for-profit organizations face the hurdles of developing, applying, and maintaining governance of AI, making sure that goal optimization responds to ethical and fairness values.

To gain insights on the outlook of AI governance for organizations, in February 2023, the University of Florida, sponsored by the US National Science Foundation, organized an international workshop with keynote talks and round tables. This workshop aimed to develop interdisciplinary theories that could usefully guide organizations about not only how value is co-created through relationships with stakeholders but also how the value is ultimately distributed, and how its distribution could influence value creation in the context of developing and deploying AI. Two important themes discussed were goal conflict and trade-off codification. We tried to reason around questions such as: How does an organization achieve commitment from multiple stakeholders when they have conflicting goals (e.g., procedural and distributional justice vs. a focus on instrumentality in the name of efficiency)? What factors create the codification of trade-offs, assigning weights across competing objectives such as cost minimization vs. opportunity maximization?

One portion of the workshop focused on health organizations, both for-profit (e.g., healthcare providers) and not-for-profit, public health entities (e.g., departments of health). Here, we report key outcomes from the health-related discussions.

2 AI governance for healthcare and public health organizations

2.1 US perspectives

The US-based speakers and panelists covered two layers of healthcare AI governance needs: (1) the data infrastructure, and (2) the clinical decision level. Dr. Lucila Ohno-Machado (Yale University) showcased the rise in data sharing initiatives, the risks to privacy, and why clear informed consent is critical in the perspective of sharing and integrating healthcare and biological data. She provided an overview of data obfuscation methods, highlighting pros and cons. Dr. Emma Spencer (Florida Department of Health) further elaborated on the expansions of surveillance data (usually consent-exempt) collection efforts, linkage with social-ecological sources, and implications of massive data reuse. She illustrated how the US Centers for Disease Control and Prevention have invested heavily in the data modernization efforts of public health institutions at both the federal and state level, to bolster and unite public health data, building a strong foundation for surveillance, data collection and analysis, accelerating the use of data for action including the use of predictive analytics, strengthening the skills of the public health workforce, improving partnerships, and working on change management and governance activities. However, even with the opportunities that AI poses for more precise public health, there are many considerations to factor to ensure that there are no misuses of data that may generate harm for individuals or populations. Dr. Genevieve Melton-Meaux (University of Minnesota) dived into clinical AI governance in patient care, and its importance to minimize potential harm. Regulatory guidance, risk frameworks, governance models, and local exemplars are only emerging particularly when considering the full life cycle of clinical AI and the dynamic and complex nature of healthcare delivery.

2.2 Global world perspectives

The international panel expanded the view on AI governance in healthcare globally, bringing examples across the continents.

General challenges for development and implementation of AI healthcare algorithms. Dr. Jens Kleesiek put forward three provocative statements considering current challenges when developing and implementing AI algorithms for clinical routine. *1) Physicians do not need explainable AI (xAI).* Historically, medicine is evidence based. For many medications we don‘t know how they work, e.g., metformin a widely prescribed oral medication for the treatment of type 2 diabetes mellitus [4]. Based on evidence that is gathered in clinical trials the efficacy of drugs can be determined. The same rational could be applied for AI algorithms and commonly physician do not demand an explanation of the inner working of an algorithm. Yet, he argued that we need xAI to build

theories, for improving algorithm development as well as for creating novel hypotheses from data. *2) We do not need new regulations for 99% of what we call AI today.* Most (if not all) currently FDA approved algorithms are locked-in algorithms that do not learn continuously and their output does not change over time. This makes them suitable for an evaluation in a clinical trial, i.e., creating evidence how good they perform and under what conditions they should be employed. Hence, similar processes and regulations as for approving novel medications could be employed for algorithms. *3) Bureaucracy hinders progress.* Here he pointed out that an over-regulation can hinder and even stop progress. This neither should mean, that privacy rights can be ignored nor that patients should be put at risk when using AI algorithms in healthcare. Yet, especially in Europe / Germany, he observed that people tend to focus on thinking about everything that hypothetically could go wrong, stopping them from acting. This might lead to a delay of progress that would allow for a better and more efficient treatment of patients.

Health prediction models in primary care: experiences in Slovenia Dr. Gregor Stiglic discussed his group's experience with the implementation of prediction models at the primary care level in Slovenia. Modern Healthcare Information Systems (HIS) rely on the establishment of an infrastructure for utilizing the data produced as a consequence of healthcare to promote continuous quality improvement.

Most of the time, healthcare professionals manually identify and classify diseases, which could in many instances be assisted by various machine learning techniques that can accomplish results comparable to those of humans. Such models can significantly assist healthcare professionals engaged in preventive care. The flaw of the majority of these models, which are frequently quite complex, relates to the interpretation of their results and the end-users' comprehension of the logic underlying the predictions. Consequently, interpretable prediction models are required. Dr. Stiglic outlined the initial difficulties caused by missing data, which were resolved by educating healthcare professionals on the impact of missing data on prediction model performance. Later, he demonstrated how they created models with a greater level of interpretability for end users.

Integrated ecological and health infrastructure in Italy Data availability in large scale can lead with topics that can be related to health. Dr. Pierangelo Veltri presented experiences in acquiring and analyzing data from agricultural, environment and their relation with wellness. Acquiring data from water sources, zoonotic lands pressure (and thus land filtering and absorbing capacity), as well as from food production may help in designing environmental protocols for defining long term environment parameters and thus improving life quality. In south of Italy, Dr. Veltri and colleagues are developing integrated data infrastructure able to link information from different sources, agricultural, medical, social and and behavioural, to inform public health and welfare pro-

gram planning. Yet, data alone are not enough, and traditional statistical approaches are not suited to model complex multi-domain reality. AI techniques –backed up by interdisciplinary expertise and domain knowledge– can exploit big, heterogeneous dataset focusing on individual/community health, ecological conservation and energy use efficiency, food production targets, and social improvements. Latest generation AI, e.g., large language models like ChatGPT, may be able to draw informed reports for public officials to inform decisions on public health matters, such as pandemic response or chronic disease management.

Upstreaming the healthcare system through Artificial intelligence (AI) technology in low/middle and upper-middle income countries AI has become essential and are driving the development of the healthcare standard in high income countries. However, many low-, middle-, and upper-middle-income countries are facing significant challenges and obstacles to integrating AI into their healthcare systems. Thailand has heavily invested in improving healthcare services using AI in various areas, such as disease diagnosis, image interpretation in radiology, and health outcomes prediction. These efforts have helped healthcare providers in enhancing effectively patient care (Davenport and Kalakota, 2019). However, Thailand still needs a better understanding of the healthcare context at different levels, particularly in primary, secondary, and tertiary health services, which presents serious limitations for AI implementation. In addition, policy-driven approaches are likely to be a crucial factor in improving the quality of care by stipulating policies for integrating AI technology into health services throughout the country. Another component for effectively implementing AI in healthcare is for government agencies to invest in AI research and develop human resources to develop health professionals' competencies in AI (Park et al., 2020). This strategy, in addition to improve the overall health outcomes for Thai citizens, could project the country into the competitive global market of AI research and development and AI-skilled jobs.

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