Thesis Project Portfolio

Volumetric Assessment of Pulmonary Artery Thrombus Burden

(Technical Report)

The Analysis of Relevant Social Groups Dynamics:

Influences on the Development of AI/ML based Medical Device Regulations

(STS Research Paper)

An Undergraduate Thesis

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Sociotechnical Synthesis

Advancements in artificial intelligence (AI) and machine learning (ML) have opened new possibilities in the field of medicine. These technologies, when harnessed effectively, have the potential to revolutionize healthcare delivery and patient outcomes. However, they also introduce a new set of challenges. My technical and STS topics delve into these challenges and explore potential solutions. My technical research focuses on overcoming the technical difficulty of medical image segmentation by developing a novel AI model to segment and calculate the volume of blood clots based on medical images. For my STS topic, I investigated the concerns of AI/ML-based medical devices through different social groups' perspectives on this technology and how the social dynamics impacted the selection of regulatory solutions, specifically the US Food and Drug Administration (FDA)'s AI/ML-based medical device regulations. By addressing both the technical hurdles and the social dynamics surrounding their implementation, we can navigate the challenges posed by AI/ML-based medical devices while maximizing their potential to revolutionize healthcare delivery and patient outcomes.

With the booming growth of AI, the application of advanced AI algorithms to improve the analysis of medical images has been popularized. Despite this progress, technical challenges persist in optimizing effectiveness. One example is detecting and analyzing pulmonary embolism (PE) from medical images. PE is one of the critical cardiovascular diseases that demands the development of AI image software to improve its treatments. PE is caused by blood clots blocking blood flow from the heart to the lungs. To treat severe PE, healthcare professionals conduct catheter-directed thrombectomy procedures to remove blood clots. However, the current treatment can lead to complications due to a lack of precise endpoints for determining the

success of clot removal. To address the challenge of segmenting PE on medical images and the lack of clinical endpoints for PE treatments, our technical project used U-Net, one of the advanced AI neural networks, and finely tuned parameters to create a reliable AI-based volumetric analyzing software. This novel AI model allowed us to segment and measure the volume of blood clots automatically, providing a potential endpoint to evaluate the success of PE treatments. Through the technical project, I was able to experience the benefits of automation in the healthcare system. Yet, I recognize the potential safety and effectiveness risks of AI/ML-based medical devices that still need to be addressed during the technical project.

The regulatory landscape surrounding AI/ML-based medical devices is evolving parallel to technical advancements. The adaptability of these technologies posed regulatory challenges. As a result, federal regulations do not address some potential risks, such as algorithmic bias and cybersecurity threats. Recognizing these complexities, the FDA has proposed a new regulatory framework with the contribution of stakeholders to accommodate the evolving nature of AI/ML algorithms while ensuring safety and effectiveness. Employing the Social Construction of Society (SCOT) framework, my STS research underscores the significant role of social factors in influencing the development of these regulations, highlighting the impact of societal perspectives on shaping AI/ML-based medical device policies. Through policy analysis and discourse analysis of stakeholder feedback, the study finds the substantial contributions of various societal views, desires for innovation, and safety concerns converge on shaping regulatory frameworks for AI/ML-based medical devices. By engaging social groups in the regulatory process, the new regulations aim to strike a balance between fostering innovation and safeguarding public health, thereby valuing the input of all stakeholders.

Working on both my technical and STS projects, I have gained a more holistic perspective on AI/ML-based medical devices and a better understanding of how societal views influence the prioritization of challenges and the selection of regulatory solutions. While my technical project allowed me to experience the great potential of improving diagnosis and treatments with AI/ML-based medical devices, it also underscored the urgent need to address safety and efficacy risks associated with AI/ML applications in healthcare. This realization prompted me to explore these risks further through my STS research. Exploring societal perspectives revealed the significant role of social groups in shaping the regulatory framework for AI/ML-based medical devices, ultimately addressing societally prioritized concerns of these technologies. Integrating insights from both projects has shown me the crucial interplay between social factors and technological advancement. It has reinforced the understanding that effective regulation must strike a delicate balance between fostering innovations and safeguarding public health and well-being. Thus, addressing safety and efficacy concerns emerges not only as a technical imperative but as a crucial facet for responsible innovation that aligns with societal perspectives.