Suggestions to the Legislation about Medical Ethics and Ethics Review in the Age of Medical Artificial Intelligence

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Abstract : In recent years, the rapid development of Artificial Intelligence (AI) has extensively promoted medicine, pharmaceutical, and other related fields. The medical research and development of artificial intelligence by scientific and commercial organizations are on the fast track. The ethics review is one of the critical procedures of registration to get the products approved and launched. However, the SOPs for ethics review is not enough to guide the healthy and rapid development of artificial intelligence in healthcare in China. Ethical Review Measures for Biomedical Research Involving Human Beings was enacted by the National Health Commission of the People's Republic of China (NHC) on December 1st, 2016. However, from a legislative design perspective, it was neither updated timely nor in line with the trends of AI international development. Therefore, it was great that NHC published a consultation paper on the updated version on March 16th, 2021. Based on the most updated laws and regulations in the States and EU, and in-depth-interviewed 11 subject matter experts in China, including lawmakers, regulators, and key members of ethics review committees, heads of Regulatory Affairs in SaMD industry, and data scientists, several suggestions were proposed on top of the updated version. Although the new version indicated that the Ethics Review Committees need to be created by National, Provincial and individual institute levels, the review authorities of different levels were not clarified. The suggestion is that the precise scope of review authorities for each level should be identified based on Risk Analysis and Management Model, such as the complicated leading technology, gene editing, should be reviewed by National Ethics Review Committees, it will be the job of individual institute Ethics Review Committees to review and approve the clinical study with less risk such as an innovative cream to treat acne. Furthermore, to standardize the research and development of artificial intelligence in healthcare in the age of AI, more clear guidance should be given to data security in the layers of data, algorithm, and application in the process of ethics review. In addition, transparency and responsibility, as two of six principles in the Rome Call for AI Ethics, could be further strengthened in the updated version. It is the shared goal among all countries to manage well and develop AI to benefit human beings. Learned from the other countries who have more learning and experience, China could be one of the most advanced countries in artificial intelligence in healthcare.

Keywords : biomedical research involving human beings, data security, ethics committees, ethical review, medical artificial intelligence

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