FSMB Symposium on Artificial Intelligence
in Health Care and Medical Regulation
Washington, DC
January 17, 2024

The Federation of State Medical Boards' (FSMB) Symposium on Artificial Intelligence in Health Care and Medical Regulation was held on Wednesday, January 17, 2024, at the Hamilton Hotel, Washington, DC.

The meeting was attended by 133 individuals, including members and staff of state and territorial medical and osteopathic boards, representatives of the health technology sector, the legal profession, venture capital, government and several partner organizations.

Humayun "Hank" Chaudhry, DO, President and CEO of the FSMB, and Jeffrey Carter, MD, Chair of the FSMB's Board of Directors and member of the Missouri Board of Registration for the Healing Arts, opened the meeting. Dr. Carter reminded attendees that this was not FSMB's first public discussion of the subject. Working with the law firm of McDermott Will and Emery, the FSMB sponsored a symposium in 2018 about the role of artificial intelligence and technology in health care. Dr. Carter also noted that a significant reason for the symposium this time is to better inform the ongoing work of the FSMB's Ethics and Professionalism Committee. The Committee, chaired by FSMB Board Member Mark Woodland, MS, MD, of the Pennsylvania Board of Medicine, is drafting guidance and recommendations related to

artificial intelligence in health care for consideration by FSMB's House of Delegates in April, 2024 in Nashville, Tennessee.

Opening Keynote Speaker

The opening keynote speaker was Jeffery Smith, MPP, Deputy Division Director, Certification and Testing Division in the Office of Technology at the Office of the National Coordinator (ONC) for Health Information Technology in the U.S. Department of Health and Human Services. He shared a brief primer about the ONC and its statutory role in the federal government, noting that the Government Accountability Office (GAO) had looked at clinical applications and administrative applications of AI as early as 2020. Mr. Smith's presentation highlighted the potential benefits and challenges of AI in healthcare, including the possibility of widespread harm by misuse or misapplication of AI.

Mr. Smith spoke at length about the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, which will become effective on January 1, 2025, noting that the ONC's focus on transparency has been characterized as a fundamental first step towards governance of AI in healthcare. The rule defines Predictive DSI (Decision Support Intervention) as "technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis." He also discussed the alignment of this rule with President Biden's Executive Order on the Safe, Secure, and Trustworthy Developmnet and Use of Artificial Intelligence, issued October 30, 2023.

Mr. Smith concluded by addressing what medical regulators, educators and accreditors need to be focused on: basic AI education at the medical student level, with an overarching aim of ensuring basic AI literacy for all practitioners.

Perspectives Panel

The first panel featured a discussion with Marc Paradis, MS, Vice President of Data Strategy at Northwell Health, Marc Succi, MD, a radiologist at Massachusetts General Hospital-Harvard Medical School and Associate Chair of Innovation and Commercialization at Mass General Brigham, and Alya Sulaiman, JD, a Partner at McDermott Will & Emery. Frank Meyers, JD, FSMB's Deputy Legal Counsel, served as moderator.

Panelists outlined current AI usage for ambient clinical documentation, diagnostic assistance, patient communication and care coordination. Challenges include physician reluctance to adopt recommendations, determining accountability, and avoiding introducing biases. The panelists highlighted both risks and benefits associated with greater incorporation of AI into the clinical setting, such as acceleration of diagnoses and individualized treatment models.

Collectively, the panelists reconzied the importance of regulatory approaches focused on addressing those harms we are most interested in avoiding, rather than adopting vague principles. Multiple panelists noted that the pace of AI advancement necessitates rapid adoption while addressing ethical concerns. Action items from this panel center on further testing of current AI tools in clinical settings and developing education accompanied by incentives to drive responsible clinician usage.

The panel also addressed the challenges of attributing liability with AI usage across developers, organizations, and clinicians, and discussed potential exploration of shared responsibility models. Panelists noted that distributive responsibility models of regulation tend to be less favorable than those focusing on shared responsibility and that such regualtory models would require clear measures on intended functionality, performance degradation risks and appropriate human oversight.

Panelists also observed that generative AI could be a solution to balancing workforce concerns and burnout by enhancing our ability to assess clinical risk and improve care. The panel also discussed that the transformative impact of AI on healthcare will take longer than 5-10 years and expressed a hope that there is an effort to look not only at AI that improves quality of health care but also improves access to care, as with rural health care.

The panel concluded by commenting on a newly introduced piece of state legislation that would require a licensed physician to oversee and review all uses of AI in healthcare.

Key Ethical Challenges for Medical Regulation

Jeremy Petch, PhD, Director of Digital Health Innovation at Hamilton Health Sciences and an Assistant Professor at the University of Toronto and McMaster University, reviewed what is meant by "Black Box" AI models, noting that a "black box" is an engineering term that refers to algorithms that are sufficiently complex that they are not easily interpretable by humans (and sometimes not interpretable at all). He noted that black boxes are often cited as a barrier to the adoption of AI in medicine, given that they impact clinician ability to trust the models.

Dr. Petch reviewed limitations of explainability: explanations are approximations, so they may produce only an imitative understanding of the functioning of black box AI. Interpretability, on the other hand, implies that a human can understand exactly how a model arrived at a specific output. He proposed a guideline for deciding when to require interpretable models, as opposed to merely explainable ones, suggesting that the decision should be based on the stakes of the clinical decision and how significant a tradeoff it offers in terms of interpretability and performance. If there are no meaningful differences in performance or accuracy between interpretable and explainable models, then an interpretable model should be used. However, if there is a significant improvement in performance with an explainable model, then its use may be justified. As the stakes of a decision are raised, the improvement in performance should also rise significantly for ongoing acceptance of an explainable black box model to be justified. If significant improvement in performance is not offered, then interpretability should be required.

Sara Gerke, JD, an Assistant Professor of Law at Penn State Dickinson Law School, discussed the potential liability for physicians using AI. Ms. Gerke analyzed scenarios where physicians face liability risks by not following current standard of care, even if AI recommendations are correct. She also discussed a recent study in the *Journal of Nuclear Medicine* which concluded that a juror may not be more inclined to assign liability if a clinician rejects AI-generated advice that causes harm in comparison to a situation where a clinician follows a non-standard of care approach that causes patient harm. She further discussed that beyond physicians, the law also creates liability risks for hospital systems purchasing and implementing AI tools, and developers involved in creating them.

Both panelists agreed that as AI becomes more widely adopted and complex, the standard of care itself may shift to incorporate AI recommendations. Legal frameworks could also change through case law or legislation like EU directives regulating AI as a product. Analysis of the European Union's AI Act, effective in 2023, illustrates the following points: (1) broad directive gaps exist for healthcare AI; (2) legal causation issues are present; (3) there are unique software product challenges; and (4) evidentiary rule changes on algorithmic opacity are needed.

The panelists also commented that AI learning creates opacity posing trust issues for physicians and informed consent questions for patients, noting that full lifecycle improvements to training data controls, explainability and clinical trials could help address these AI challenges.

FSMB Ethics and Professionalism Committee

FSMB Board Member Mark Woodland, MS, MD, who chairs FSMB's Ethics and Professionalism Committee, provided insight into the Committee's deliberations on the issue of ethical use of artificial intelligence. He noted that the committee discussion reinforced the importance of key traditional ethical principles, such as beneficence, nonmaleficence, autonomy and justice. He noted that these principles will manifest in a policy to help state medical boards and physicians navigate the responsible and ethical incorporation of AI and stressed a need for (1) greater incorporation of AI knowledge in medical education, (2) increased emphasis on human accountability, (3) improved policies on informed consent and data privacy, (4) recommendations to proactively address responsibility and liability concerns, and (5) collaboration with experts. Dr. Woodland concluded by stating that by thoughtfully addressing the opportunities and challenges posed by AI in healthcare, state medical boards can promote the safe, effective, and ethical use of AI as a tool to enhance, but not replace, human judgment and accountability.

Small Group Breakout Sessions

Attendees broke out into small groups to discuss the following topics and issues related to AI adoption and use by licensed health care professionals: (1) What strategies should state medical boards use to keep pace with the rapid advancements in AI technology and its application in medical practice? (2) What steps can state medical boards take to ensure that AI tools trained on biased algorithms cannot be used by licensees? (3) Which use of AI tools in health care can result in patient harm and what are appropriate regulatory responses?

Among the observations reported at the end of the breakout sessions was that it is essential that the FSMB continue to track developments in AI and raise awareness among licensees and members of the public about its potential use. Discussions noted that in the near future state medical boards are going to see complaints about the misuse of AI and potential harms caused because a licensee either followed or did not follow the advice of an AI tool or algorithm. Addressing expert opinions in such cases was identified as an area where medical boards may need improved education and guidance. Attendees suggested that the FSMB could develop educational modules to keep licensees and member boards aware of AI from their perspective. Attendees also identified that requirements for AI-focused CME could be a means of helping licensees keep pace with AI.

Panel: Perspectives on AI in Healthcare and Reflections on the Day

The final panel, moderated by Eric Eskioglu, MD, MBA, Former Executive Vice President, Chief Medical and Scientific Officer at Novant Health, discussed generative AI and its role in health care and medical regulation. Panelists included Sarvam TerKonda, MD, Past Chair of the FSMB and Associate Professor of Plastic Surgery at the Mayo Clinic College of Medicine and Science, Jade Dominique James-Halbert, MD, MPH, a specialist in Obstetrics-Gynecology in Bridgeton, Missouri, who is Chair of SSM Health DePaul Hospital in St. Louis, MO, Alexis Gilroy, JD, partner at Jones Day, and Shannon Curtis, JD, Assistant Director of Federal Affairs for the American Medical Association.

Discussion began by noting that the evolution of AI has been rapid and that many medical professionals and medical boards are deficient in their knowledge of AI and how it is impacting the future of healthcare. Panelists emphasized that AI is already being used every day in our lives and will play different roles for different specialists and specialties.

The panelists debated whether it is best to think about regulating the technology, or use cases where AI plays a role in the practice of medicine. As a corollary, panelists shared their perspectives on whether the current regulatory framework is sufficient to address AI. The panel discussed the notion that the existing legal standard of care cited in existing regulations may suffice, with parallels to how a medical board handles liability, which was highlighted as a major concern for physciains in utilizing AI.

FSMB extends our sincere gratitude to our esteemed panelists, including keynote speaker Jeffery Smith, MPP from the Office of the National Coordinator for Health Information Technology, and the diverse perspectives shared during the informative panels and breakout sessions. This symposium has marked a significant step in advancing our understanding of the ethical and practical implications of AI in healthcare. For further inquiries and continued engagement on this critical topic, feel free to reach out to FSMB's Education Department at edu@fsmb.org

Thank you all for your participation, and we look forward to future collaborations in navigating the evolving landscape of AI in medical practice.