Generative AI in Health Care and Liability Risks for Physicians and Safety Concerns for Patients

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Generative artificial intelligence (AI) is a quickly emerging subfield of AI that can be trained with large data sets to create realistic images, videos, text, sound, 3-dimensional models, virtual environments, and even drug compounds. It has gained more attention recently as chatbots like OpenAI's ChatGPT or Google's Bard display impressive performance in understanding and generating natural language text. Generative AI is being heralded in the medical field for its potential to ease the long-lamented burden of medical documentation by generating visit notes, treatment codes, and medical summaries. Physicians and patients might also turn to generative AI to answer medical questions about symptoms, treatment recommendations, or potential diagnoses.[1] While these tools may improve patient care, the liability implications of using AI to generate health information are still in flux. To date, no court in the United States has considered the question of liability for medical injuries caused by relying on AI-generated information.

How Does Generative AI Work?

Large language models like ChatGPT or Bard are generative AI systems designed to create human-like language responses to a wide range of user questions and prompts. While ChatGPT and Bard were not specifically designed to be used in health care, there is a realm of opportunities to deploy generative models in health care, ranging from taking notes for physicians, to providing treatment recommendations, to making medical decisions.

It is important to understand how ChatGPT, Bard, and other generative AI systems work. Generative AI typically uses deep learning algorithms to generate new content. Deep learning models, often considered "black boxes," use many layers of complex algorithmic reasoning that make it impossible or extremely challenging for users, and even developers, to understand how they arrived at their answer.[2] This can be contrasted with "white-box" models that are transparent and interpretable.[2]

The ability of black-box generative AI systems to provide users with quick health-related information raises the question of whether, and if so how, health care professionals, such as physicians, and patients should use this technology. To answer this question, it is important to understand the potential liability risks for physicians using generative AI in health care and the risks for patients seeking medical advice from such tools.

Liability Risks for Physicians Using Generative AI

Crucially, no generative AI systems, including ChatGPT and Bard, have been reviewed by the US Food and Drug Administration (FDA) so far. These systems could trigger FDA review if they are "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease" and do not fall under a medical device exception laid out in the Federal Food, Drug, and Cosmetic Act (see sections 201(h)(1) and 520(o)).[3] It currently appears that while ChatGPT will generate a list of differential diagnoses in response to a user's description of symptoms, it also warns users to seek

advice from a medical professional. But what if the user is a medical professional? Can ChatGPT assist them in making medical decisions?

OpenAI's terms of use warn that ChatGPT can "result in incorrect [o]utput that does not accurately reflect real people, places, or facts."[4] ChatGPT also warns that "it can occasionally produce incorrect answers ... and may also occasionally produce harmful instructions or biased content."[5] Additionally, ChatGPT can confidently present users with information that it hallucinates. For example, when asked for sources to support potential diagnoses, ChatGPT might provide seemingly real citations to fake sources. To minimize liability risks, even medical professionals must exercise caution when relying on AI-generated information. This is because when physicians cannot understand how a black-box generative AI system reached its conclusions, it may be impossible for the physician to independently evaluate the accuracy of the AI's output.[6]

Whether physicians might be liable for patient injuries when using generative AI to support their clinical decisions depends on the applicable standard of care, which requires physicians to provide treatment in accordance with generally accepted medical standards in their specialty.[7] When evaluating the physician's actions, this standard of care considers the circumstances under which the decision was made, along with the information available to the physician at that time.[8] Depending on how medical experts interpret the applicable standard during testimony in a future case involving the use of generative AI, physicians might be liable if their reliance on information generated by a black-box AI system is considered to breach the standard of care. On the other hand, if the use of generative AI becomes commonplace, and especially if these systems receive marketing authorization by the FDA, reliance on the AI's output might only breach the standard of care if the physician should have known that the output was incorrect.

Risks for Patients Using Generative AI for Medical Advice

When used directly by patients for medical advice, black-box generative AI is even riskier because, in addition to not being able to understand the basis for the AI's information, patients also generally lack the medical expertise necessary to understand the health risks of relying on the AI's output. Users should be aware that despite ChatGPT's warnings to seek medical attention or consult with physician, it will usually proceed to confidently answer patients' medical questions. This is particularly concerning because, unlike general medical information published on the internet from a single source, ChatGPT appears to give personalized advice in response to user-specific questions. This increases the risk that patients will rely on AI-generated advice to avoid either the cost or time associated with visiting a physician.

Currently, if a patient experiences harm as a result of relying on AI-generated medical advice information, there may be no one liable for the patient's injury. An AI system is not a legal person subject to professional liability rules. If the AI system is considered a product and it is reasonably foreseeable that patients would rely on the information it provides, the manufacturer might still escape or limit its liability by claiming that the patient either assumed the risk or contributed to their own injuries by relying on the AI's information despite the manufacturer's warnings (see Restatement (Second) of Torts, §§ 496D, 402A).[9] Outside of professional or product liability laws, consumer liability laws might apply in the case of patient injuries caused by deceptive AI-generated content, but whether manufacturers will be immune under the Communications Decency Act is still unknown.[1]

Suggestions for Safeguards

As generative AI systems become more prevalent in health care, it is essential to consider the liability implications of this technology and to ensure that there are appropriate safeguards to protect patients. Physicians must continue to follow the standard of care, which currently does not include the use of black-box generative AI systems to treat patients.[7] While physicians and patients may use generative

AI to obtain information, they should remain skeptical of AI-generated information that they cannot independently confirm.

Physicians should also be aware that patients rely on AI-generated health information despite warnings against it. As a result, physicians should continue to make patients aware of the risks associated with relying on AI-generated medical information, including the fact that there may be no one held liable for potential injuries. As always, physicians should carefully document crucial aspects of patient care, including advice to patients and their reasons for medical decision-making.

Overall, there is a need for more information and advice for physicians and patients concerning the use of generative AI for health care. The American Medical Association should consider developing a guidance document for physicians and patients to help fill this information gap.

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