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AI Insurance: How Liability Insurance Can Drive the Responsible Adoption of Artificial Intelligence in Health Care

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Despite enthusiasm about the potential to apply artificial intelligence (AI) to medicine and health care delivery, adoption remains tepid, even for the most compelling technologies. In this article, the authors focus on one set of challenges to AI adoption: those related to liability. Well-designed AI liability insurance can mitigate predictable liability risks and uncertainties in a way that is aligned with the interests of health care's main stakeholders, including patients, physicians, and health care organization leadership. A market for AI insurance will encourage the use of high-quality AI, because insurers will be most keen to underwrite those products that are demonstrably safe and effective. As such, well-designed AI insurance products are likely to reduce the uncertainty associated with liability risk for both manufacturers — including developers of software as a medical device — and clinician users and thereby increase innovation, competition, adoption, and trust in beneficial technological advances.

There is a gap in much of the conversation about medical artificial intelligence (AI) that fails to account for the ways in which insurance products play a key role in health care. Despite growing interest and enthusiasm for AI, there is little discussion about the role of AI liability insurance in AI uptake for health care. However, the market for AI liability insurance products is likely to impact incentives for the development and adoption of high-quality AI tools and products. These insurance products could also play an important role in supporting regulatory sandboxes, depending on risk categories, as envisaged by some policy makers.[1] Health care leaders would benefit from discussing how a market for AI liability insurance could help foster the growth of AI in health care more broadly.

Much of the recent adoption of AI has been driven by advances in machine learning (ML), a subfield of computer science.[2-4] There are a number of health care settings in which AI-based solutions (e.g., for diagnosis) already demonstrate a level of performance comparable to that of expert clinicians.[5,6] In other settings (e.g., risk stratification), ML models may outperform existing paradigms, although comprehensive evidence is still pending.[7]

Despite the development of hundreds of systems that have been cleared by the U.S. FDA and European Union (EU) notified bodies, the adoption of AI in medicine has been slower than many expected.[8,9] There are a number of likely reasons for this pace, including unclear, nonexistent, or misaligned financial incentives, difficulties in accessing high-quality, unbiased data for building ("training") algorithms, difficulties in workflow integration and implementation at scale, privacy concerns, and uncertain legal doctrine on liability (i.e., responsibility for harms that occur during use).[8,10-11]

The question of AI liability has received some attention by policy makers and legislators, most notably in the European Parliament.[12,13] There is also an ongoing debate about the appropriate form and degree of liability and responsibility. This reveals that legal uncertainty and unpredictability are still dominant features of the medical AI landscape, yet strategies for the management of this legal uncertainty and unpredictability are typically required for research and development investments, marketing, product adoption, and, ultimately, ongoing user trust. Physicians and health systems may be liable under malpractice and other negligence theories, while manufacturers and algorithm developers may be subject to product liability.[14]

Our purpose in this article is to address how AI liability insurance can facilitate adoption of AI tools that will, by design, reduce the margin of error for a human decision-maker, whether those tools involve full automation or keep a human in the loop. We do not explore how care delivery should be modified for (each/every) application of an AI product. Thus, we focus on liability-related challenges to AI adoption in health care. We propose that, as discussed in other industries,[15] well-designed AI liability insurance has the potential to mitigate liability risks and uncertainties for stakeholders, and to do so in a way that is aligned with patient, physician, and health care organization leadership interests. Without liability insurance, medical practitioners and health care organization leaders will hesitate to use AI tools — including software as a medical device (SaMD) — to support diagnosis and treatment. Technology developers will similarly hesitate to commercialize and deploy such products when liability issues persist and/or when they remain uncertain or unaddressed by insurance.

> " *Legal uncertainty and unpredictability are still dominant features of the medical AI landscape — yet strategies for the management of this legal uncertainty and unpredictability are typically required for research and development investments, marketing, product adoption, and, ultimately, ongoing user trust.* "

Yet the corollary is that refining and adapting AI insurance models can offer opportunities to provide a risk-mitigating environment in which medical AI tools could evolve and thrive. Such insurance can enable health care practitioners to take on *appropriate* risks in light of the care setting, the patient's individual circumstances, and the technological tools available. It can also serve a certification role, over and above that of a national regulator, enabling adoption of those technologies that can be demonstrated to have limited and/or quantifiable risk and are, therefore, actuarially assessable, thus creating a potential market for insurance products. Perhaps most importantly, a market for AI insurance will encourage the use of high-quality AI in health care delivery, because insurers will be most keen to underwrite those products that are demonstrably safe and support evidence-driven medical practice. This, in turn, will also have an impact on the cost of insurance policies and hence on broader adoption not only of AI, but also of liability insurance for its use, creating a virtuous cycle for the development and deployment of evidence-based AI products. Such virtuous cycles are most likely to emerge first in the specialties in which AI tools are already providing the most conspicuous diagnostic value, such as radiology and dermatology. In these contexts, insurance can help de-risk technology adoption for health care providers and organizations of all sizes, potentially making adoption more attractive, in particular, when the AI manufacturer holds an insurance policy and, therefore, offers a product that comes with (some) insurance "built in," one possible construct discussed below.

Liability Risk and Technology Adoption

Developers of health care AI products face the risk of product liability lawsuits when their products injure patients, whether injuries arise from defective manufacturing, defective design, or failure to warn users about mitigable dangers.[16] Physicians may also face risks from patient injuries stemming from the use of AI, including faulty recommendations or inadequate monitoring. Similarly, hospitals or health systems may face liability as coordinating providers of health care or on the basis of inadequate care in supplying AI tools — an analogy to familiar forms of medical liability for providing inadequate facilities or negligently credentialing a physician practicing at the hospital.[17] Such risks may reduce incentives to adopt AI tools.

These boundaries are malleable. Hospitals are often held vicariously liable for the actions of physicians (employed or affiliated) working in the hospital. Liability can also be shifted via contract (although there are limits on waiver of liability by patients). Notably, the firm Digital Diagnostics, whose IDx-DR product was the first AI product cleared for marketing by the FDA to provide an independent diagnosis, contracts to accept liability for hospitals and physicians resulting from faulty diagnosis by the system[17] and carries its own insurance for that assumed risk.[18,19]

The AI liability landscape is in flux. As of the start of 2022, neither U.S. courts nor legislatures have weighed in specifically on the issue because of the novelty of AI technology. The European Commission announced its proposal for an AI legal framework on April 21, 2021.[1] Under this proposal, which would also have to be read in combination with an ongoing re-evaluation of the EU Product Liability Directive (85/374/EEC) and increasingly strict regimes for privacy protection, *high-risk AI systems* — those "that pose significant risks to the health and safety or

fundamental rights of persons,"[1] such as safety components of AI applications in robot-assisted surgery — would be subject to rigorous regulatory obligations, high fines for noncompliance, and strict(er) liability regimes. Lower-risk systems would benefit from "regulatory sandboxes" with gradually fewer obligations and fault-based liability regimes. As of the start of 2022, the final details of these regimes remain to be clarified.

> " *While a single malpractice claim against a surgeon is likely to be specific to one procedure or medical encounter, a single AI liability claim against an algorithm's developer or user organization may involve medical errors associated with hundreds of patients or more, such as a drug-dosing algorithm that systematically calculates excess doses for patients across an entire health system."*

Furthermore, legal liability has been shown to impact both developer incentives and clinician behavior.[20,21] When clinicians face the risk of liability, they tend to avoid adopting new, higher-risk technologies, but they also tend to increase adoption of new technologies that mitigate risk. In addition, uncertainty about liability can itself negatively impact developer innovation.[22] New regulatory developments, including recent EU proposals, suggest a tendency toward elevated liability for high-risk AI systems, making it likely that liability concerns will reduce their adoption and use.

Insurance and Liability Risk

AI liability insurance would reduce the liability risk to developers, physicians, and hospitals. Insurance is a tool for managing risk, allowing the insurance policy holders to benefit from pooling risk with others. Insurance providers are intermediaries that play an organizing role in creating these pools and performing actuarial assessment of associated risks.[23] While many types of insurance exist in the health care context, our focus in this article is entirely on AI liability insurance rather than coverage for health care services.

In some respects, liability insurance for algorithms is similar to medical malpractice insurance. Both can involve unlikely (assumed unintentional) idiosyncratic errors that can occur at random, but for which aggregate probabilities are well known for insurance policy providers. This is where insurance excels and creates value.

However, AI liability insurance will differ from medical malpractice insurance given the issue of scale — in particular, the software-specific phenomenon in which problems may propagate widely to many/all users.[24] While a single malpractice claim against a surgeon is likely to be specific to one procedure or medical encounter, a single AI liability claim against an algorithm's developer or user organization may involve medical errors associated with hundreds of patients or more, such as a drug-dosing algorithm that systematically calculates excess doses for patients across an entire health system.

To some extent, the issue of scale can be managed. With known and/or predictable error rates, it should remain straightforward to assess risk and, therefore, to write actuarially fair insurance policies for medical AI products. Further, as is the case in other insurance markets, a market for reinsurance may play a particularly large role in settings with correlated risks, as in medical AI.

However, insurance will not solve all liability issues. The economics of insurance break down in settings where error rates are unknown, particularly if the errors occur at scale — meaning the same issue can affect many patients. This is especially likely when AI recommendations are opaque, when cybersecurity concerns are difficult to identify,[25] when new legislation and standards are evolving rapidly, and when the types of potential damages are poorly defined ex ante.

> "*By "building in" insurance to the product offering, this approach would have the advantage of creating a more attractive AI product for smaller health care providers who do not have the administrative bandwidth to research their own AI insurance policies, at least while AI tools are nascent.*"

Thus, we expect that the best candidates for medical AI insurance will be the subset of AI tools that are actuarially assessable. These include those for which the risks associated with both single and widespread use can be calculated accurately (and/or reasonably estimated ex ante) and where algorithms are *interpretable* and lead to evidence-based recommendations that comply with relevant legislation and align with both the medical literature and professional society practice guidance.

While there are already health care liability insurance products available for cybersecurity and IT-related losses, these products do not cover many potential failures of medical AI, particularly with respect to diagnosis and treatment. If these issues can be overcome and AI liability insurance products can be effectively developed, we expect that some barriers to clinician, hospital, and health care system adoption of AI will be reduced. Overcoming these issues will not be straightforward. It will require substantial investment in risk assessment and AI interpretability, as well as some changes to legal practice. Nevertheless, the development of medical AI insurance will decrease uncertainty about liability, which in turn will increase the likelihood that AI will be adopted.

Insurance and Patient-Centered AI Development

AI liability insurance will create incentives to adopt AI tools and applications while adhering to and supporting patient-centered care — with a focus on AI products that ensure safe, high-quality treatment and outcomes for individual patients. Insurance companies will insure products at rates that are actuarially profitable. Thus, if a product is likely to improve patient safety overall and if the risk of its use can be estimated accurately, then insurance should be

(relatively) inexpensive. Health care providers can then adopt the technology and purchase insurance for its use.

Alternatively, manufacturers could purchase such insurance and build the incremental cost of liability insurance into contracts with health care providers, who would, in turn, not be liable for problems specifically associated with the use of AI tools (this proposal is consistent with that used by IDx-DR, which, as noted above, carries medical malpractice insurance and indemnifies its users). By "building in" insurance to the product offering, this approach would have the advantage of creating a more attractive AI product for smaller health care providers who do not have the administrative bandwidth to research their own AI insurance policies, at least while AI tools are nascent. In contrast, if a product presents an exceptionally high risk or if its risk is not well established, insurance will be expensive, or perhaps not offered at all; whether the manufacturer or the health care provider (organization) holds the policy, its high cost would be a disincentive to adopting the product or developing it in the first place, and perhaps this is for the best.

In this way, insurers can serve a vital credentialing function that complements review by regulators (when relevant) to ensure that AI products are safe and effective. This function of insurance is not unique to AI; the availability and pricing of liability insurance shapes behavior alongside direct regulation in such diverse areas as driving, policing, and the practice of medicine.[26] For example, such "regulation-through-insurance" incentivizes safe driving because the consequences of tickets and accidents include increased insurance premiums. The use of telematic devices to measure driving patterns (and provide insurance discounts when appropriate) further enforces this dynamic.[27]

> " *The credentialing function of insurance will thus reinforce the patient-centered incentives of AI developers. Consequently, this insurance may alleviate health care provider concerns, at least to the point at which they are willing to adopt the AI technology.*"

The credentialing function of insurance will thus reinforce the patient-centered incentives of AI developers Consequently, this insurance may alleviate health care provider concerns, at least to the point at which they are willing to adopt the AI technology. Indeed, this should be the case regardless of whether the AI manufacturer or the health care provider is the holder of the insurance policy, as long as such a policy can be purchased. However, the price and implicit value of insurance are likely to be passed through. For example, a manufacturer selling an AI tool that comes with liability insurance will be able to command a higher price than for the same tool without such insurance. Insurers may also require ongoing performance data from AI developers, whether they are in house or commercial; such data could be well beyond those needed to meet the requirements of regulatory premarket review.[28] While insurers do not provide the same level of centralized review that regulators do, they may well serve a more context-sensitive, hands-on evaluative role focused on both quantifying and reducing risk — a role that may be especially important given the questionable generalizability of many current-generation AI systems.[29]

Once insurance is offered, risks may drop further as product adoption increases real-world performance data availability (including risks) and those data are subsequently used to improve AI tool performance. This has the potential to create another type of virtuous circle, in which insurance reduces uncertainty, which leads to adoption, which enables improved product quality and safety, which further lowers insurance premiums, and in turn leads to more adoption.

Looking Ahead

Liability risk represents one reason why AI adoption in health care has been limited to date. Well-designed insurance products have the potential to reduce the uncertainty associated with liability risk and, thereby, increase adoption of and trust in beneficial technological advances. Insurance providers have incentives to offer affordable insurance policies for AI products that are likely to improve patient outcomes safely and contain the cost of care. Therefore, if liability insurance products for AI in health care can be developed and accurately priced, we anticipate an initial increase in both new AI product development as well as greater AI adoption and an acceleration of this virtuous cycle over time.

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