Physicians and Hospitals Law Institute

Understanding the Impact of "Artificial Intelligence" on the Future Practice of Law and Medicine[1]

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Whether searching for new uses of existing drugs, making a diagnosis, or recommending the "best" treatment option, the use of Artificial Intelligence in numerous settings poses unique challenges for health care lawyers and providers in understanding just what it is, what are its benefits and, just as importantly, what are its risks and inherent limitations. Terms such as "computer science" and "scientific discipline" spark terror in the hearts of many lawyers, but given the incredible pace at which AI is charging into the fields of medicine and the law, these and other phrases are ones which lawyers must become conversant to understand and face the significant challenges that AI will present on so many different levels.

I. Exploring Key concepts and the Vocabulary of AI

Health lawyers need to gain a 101 level of understanding of what AI is, what common terminology is used to describe AI applications and a basic knowledge of how AI will be used by their clients so they can then begin to understand and address its legal implications at both the macro and micro levels.

Artificial Intelligence

The noun "Artificial Intelligence" is defined by Webster's as:

> **1:** a branch of computer science dealing with the simulation of intelligent behavior in computers
> **2:** the capability of a machine to imitate intelligent human behavior[2]

To imitate intelligent behavior, a computer has to learn. This learning is called "machine learning." Webster's defines machine learning as "[t]he process by which a computer is able to improve its own performance (as in analyzing image files) by continuously incorporating new data into an existing statistical model. Webster further notes that "[a]n entire subspecialty known as *machine learning* is devoted to building algorithms that allow computers to develop new behaviors based on experience. — Adam Piore"[3]

The American Medical Association (AMA) has offered a more expansive definition of Artificial Intelligence in Health Care stating:

> Computational methods and techniques for data analysis have been evolving for decades. A number of these methods have come to be known collectively as "artificial intelligence." Artificial intelligence constitutes a host of computational methods that produce systems that perform tasks normally requiring human intelligence. These computational methods include, but are not limited to, machine image recognition, natural language processing, and machine learning. However, in health care a more appropriate term is "augmented intelligence," reflecting the

[2] https://www.merriam-webster.com/dictionary/artificial%20intelligence

[3] https://www.merriam-webster.com/dictionary/machine%20learning

> enhanced capabilities of human clinical decision making when coupled with these computational methods and systems.[4]

Machine Learning (Supervised and Unsupervised)

An explanation that describes AI in the context of medicine is provided by Rahul C. Deo, MD, PhD in his paper "Machine Learning in Medicine."[5]

> Machine learning is the scientific discipline that focuses on how computers learn from data. It arises at the intersection of statistics, which seeks to learn relationships from data, and computer science, with its emphasis on efficient computing algorithms. This marriage between mathematics and computer science is driven by the unique computational challenges of building statistical models from massive data sets, which can include billions or trillions of data points.[6]

The two most common types of machine learning are "supervised learning" and "unsupervised learning." Although a bit simplistic, to understand the different concepts it might be useful to think of the how children grow into adults. On one level, they are supervised by the various adults in their lives and teachers who are able to help them learn the basics based on known data, and outcomes and a semi-controlled environment. On another level, however, children learn based on their experience in interacting with other children, pets, people and the wider world around them without supervision of any kind. In terms of medicine, Dr. Rao provides the following explanations of supervised and unsupervised learning:

> Supervised learning starts with the goal of predicting a known output or target. In machine learning competitions, where individual participants are judged on their performance on common data sets, recurrent supervised learning problems include handwriting recognition (such as recognizing handwritten digits), classifying images of objects (e.g. is this a cat or a dog?), and document classification (e.g. is this a clinical trial about heart failure or a financial report?). Notably, these are all tasks that a trained person can do well and so the computer is often trying to approximate human performance. Supervised learning focuses on classification, which involves choosing among subgroups to best describe a new data instance, and prediction, which involves estimating an unknown parameter (such as the temperature in San Francisco tomorrow afternoon). …
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> In contrast, in unsupervised learning, there are no outputs to predict. Instead, we are trying to find naturally occurring patterns or groupings within the data. This is inherently a more challenging task to judge and often the value of such groups learned through unsupervised learning is

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[4] AMA Board of Trustees 2018 Annual Report: Report #41, Augmented Intelligence (AI) in Health Care, page 182 https://www.ama-assn.org/system/files/2019-12/a18-bot-reports.pdf.

[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5831252/

[6] Wikipedia defines algorithm as follows: In mathematics and computer science, an **algorithm** is a finite sequence of well-defined, computer-implementable instructions, typically to solve a class of problems or to perform a computation. Algorithms are unambiguous specifications for performing calculation, data processing, automated reasoning, and other tasks. https://en.wikipedia.org/wiki/Algorithm

> evaluated by its performance in subsequent supervised learning tasks (i.e. are these new patterns useful in some way?).[7]

An example of supervised machine learning in health care is discussed in a recent New York Times article "A.I. Is Learning to Read Mammograms." As noted in the article:

> Tested on images where the diagnosis was already known, the new system performed better than radiologists. On scans from the United States, the system produced a 9.4 percent reduction in false negatives, in which a mammogram is mistakenly read as normal and a cancer is missed. It also provided a lowering of 5.7 percent in false positives, where the scan is incorrectly judged abnormal but there is no cancer.[8]

Deep Learning

The term "Deep Learning" relates to a type of machine learning. Wikipedia defines it as follows:

> Deep learning is a class of machine learning that uses multiple layers to progressively extract higher level features from the raw input. For example, in image processing, lower layers may identify edges, while higher layers may identify the concepts relevant to a human such as digits or letters or faces.[9]

In the article "Scalable and accurate deep learning with electronic health records,"[10] the authors discuss how Google, though its access to de-identified EHR data involving over 216,000 adult patients 46 billion data points was able through deep learning models to achieve "a high accuracy for tasks such as predicting: in-hospital mortality, 30-day unplanned readmission, prolonged length of stay, and all of a patient's final discharge diagnoses (and claimed) that [t]hese models outperformed traditional, clinically-used predictive models in all cases." [11]

Biased Data

A key issue relative to machine learning is the potential bias of the training data sets. The AMA Board of Trustees in their annual report for 2018 provided a succinct summary of the issue.

> One of the most significant implications for end users of AI systems is that these systems sets can, invisibly and unintentionally, "reproduce and normalize" the biases of their training data sets. In health care, the result can be models that "reflect the conditions only of the fortunate" and yield "an aggregate understanding of health and illness that fundamentally excludes the marginalized" in a way that risks exacerbating existing health disparities. Minority populations can be disadvantaged in the context of AI systems in a second way as well in that "by definition, there is proportionately less data available about minority predictions," while the accuracy of decision making, a proxy for fairness, will be higher for majority groups. Addressing fairness is

[7] Id at p. 2
[8] https://www.nytimes.com/2020/01/01/health/breast-cancer-mammogram-artificial-intelligence.html
[9] https://en.wikipedia.org/wiki/Deep_learning

[10] https://www.nature.com/articles/s41746-018-0029-1.pdf

[11] Id.

> essential, even if doing so may be costly for developers when it requires them to seek more complex decision rules." (Citations omitted) [12]

Automation Bias and "Black Box" Medical Decisions

Sometimes being too comfortable with an automated system can lead to problems. An example of this phenomenon is overreliance on automatic systems in cars by their drivers that lead to accidents and sometimes death.[13] The same is true for autopilot systems in airplanes.[14]

With respect to AI in medicine, the article "Artificial intelligence, bias and clinical safety" published in the BMJ Journal of Quality and Safety[15] notes that "**automation bias** describes the phenomenon whereby clinicians accept the guidance of an automated system and cease searching for confirmatory evidence, perhaps transferring responsibility for decision-making onto the machine—an effect reportedly strongest when a machine advises that a case is normal." (Emphasis added)[16]

The article above also reviews the issue of Black Box decision making and notes:

> One of the key differences between rule-based systems and the multitude of ML algorithms is the degree to which the resulting prediction can be explained in terms of its inputs. Some ML algorithms, particularly those based on artificial neural networks, make inscrutable predictions and for these algorithms it is harder to detect error or bias.[17]

The article goes on to give the example of where an "X-Ray analysis AI system could be inaccurate in certain scenarios because of a problem with training data, but as a black box this is not possible to predict and will only become apparent after prolonged use.[18] (Id at p. 234) As discussed below, the black box problem is a critical factor in whether or not certain types of AI will be regulated by the FDA.

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[12] AMA Board of Trustees 2018 Annual Report: Report #41, Augmented Intelligence (AI) in Health Care, page 184 https://www.ama-assn.org/system/files/2019-12/a18-bot-reports.pdf.

[13] https://www.ntsb.gov/news/press-releases/Pages/NR20190904.aspx

[14] https://www.nytimes.com/2019/03/14/business/automated-planes.html

[15] Challen R, Denny J, Pitt M, et al. BMJ Qual Saf 2019;28:231–237; https://qualitysafety.bmj.com/content/28/3/231 See also: "How Should AI Be Developed, Validated, and Implemented in Patient Care?" https://journalofethics.ama-assn.org/article/how-should-ai-be-developed-validated-and-implemented-patient-care/2019-02

[16] Id. at 234.
[17] Id. at 233.
[18] Id. at 234.

II. AI and Emerging Legal Challenges

A. AI and Standards of Care.

The question arises as to whether and how AI will adjust, or not, the standard of care. At the outset we must subdivide this question to develop a useful answer. First, we must ask whether AI is likely to help produce better processes and outcomes of care. As we will see, the current answer is: maybe, maybe not – it depends. Second, we need a deeper dive into how the medical standard of care is set and how/whether that might be affected by the emergence of AI. Because physicians and their medical malpractice standard of care are pivotal in healthcare, that will be the focus here, although it is recognized that other participants in healthcare (e.g. allied providers, hospitals, drug/device manufacturers) will likewise have their own standards of care.

1. Will AI produce better processes and outcomes of care.

The simplest answer at this time is: we don't yet know, since AI is very new and still evolving. That said, a few things are becoming clearer. On one hand, certain kinds of tasks that are somewhat repetitive and monotous may be better performed by AI. This includes, e.g., reading radiology and pathology images such as mammograms, Pap smears or lung cancers.[19] Where human fatigue or distraction can impair accuracy, computerized, deep-learning services can potentially be of great value.

However, even here we begin to encounter caveats. The AI results will be only as good as the information provided at the outset, and that information is not always pristine. One kind if important database for healthcare, for instance, comes from electronic health records (EHRs). However, EHR data are well known to be flawed. Physicians and nurses often complain that they spend so much time with log-in procedures and box-checking for "quality" data, that there is little time to write the narrative information that may actually be more important – and where boxes are endlessly being checked, the box-checker's sheer annoyance can further inhibit the quality of data. Copy-and-paste entries, while roundly discouraged, are also common and further deleterious.

Additionally, AI's supposedly superior capacity for reading images and slides presupposes that we already have a "gold standard" against which the AI judgments can be appraised as correct, or not. And yet for many kinds of cancer we simply do not have a histopathological "gold standard."[20] Hence we cannot entirely know whether AI is leading or misleading us.

We also note other sources of data inadequacy. Persons with reduced access to care, including minorities and those with lower socio-economic status, will accordingly provide less input for those databases. And where funds are limited, then fewer diagnostic interventions may be undertaken, again limiting the database. Black women, for instance, have a lower likelihood of being tested for high-risk germline mutations for breast cancer, even though actual risk of those mutations is similar – hence an AI analysis

[19] Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. Nature Medicine 2019; 25: 44–56; Ardila D, Kiraly AP, Bharadwaj S et al. End-to-end lung cancer screening with three-dimensional deep learning on low-dose chest computed tomography. Nature Medicine published online April 5, 2019; McKinney SM et al. International evaluation of an AI system for breast cancer screening. Nature 2020; 577: 89-94.
[20] Adamson AS, Welch HG. Machine Learning and the Cancer-Diagnosis Problem — No Gold Standard. NEJM 2019; 381: 2285 – 87.

could be artificially limited in that direction.[21]

Worse, it is at least possible that where large amounts of money are at stake, small manipulations of images or other data could mean distorted AI analysis that, in turn, could fuel approving insurance payments, even new medical devices, based on inaccurate information.[22]

In sum, a biased or inaccurate dataset can produce a comparably stilted analysis, not always recognized as such. Garbage in, garbage out. The jury is still out, with respect to where and when AI will truly be a boon to healthcare.

2. In what ways, if any, will or should AI change the standard of care.

Healthcare's standard of care, particularly for medicine, has long been a complex and confusing subject, and AI will not make that reality disappear. An increasingly familiar scenario seen in intensive care units will highlight a basic question.

The patient is quite clearly near death – end-stage cancer, perhaps, with multi-organ system failure. The physicians and nurses, united, believe it is time abate aggressive life support and shift toward comfort measures. But the family are adamant: "do everything! you must keep dad alive as long as possible."

These situations cause great angst within the team. Aggressive care can cause suffering and, where the patient is dying, suffering that is needless. Yet the family is also aggressive. "Can we unilaterally withdraw care, even without the family's consent?" physicians ask.

A number of states, e.g. Tennessee's Healthcare Decisions Act, appear to offer an answer. Per T.C.A. § 68-11-1808, a physician should generally comply with a patient's advance directive (or surrogate's decisions), except that:
"(e) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution." [23]

So what are we to make of "medically inappropriate" and "contrary to generally accepted health care standards applicable to the health care provider"? This poses, in essence, a classic issue surrounding the medical standard of care, transposed to a different setting. If "generally accepted" refers to what physicians intellectually endorse then endless, hopeless life support in a case like this is arguably contrary to those standards.[24] However, if "generally accepted" refers to what physicians actually do, then aggressive care is the standard, simply because highly aggressive care typically does continue so long as any member of the family might possibly sue.

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[21] Parikh RB, Teeple S, Navathe AS. Addressing Bias in Artificial Intelligence in Health Care. JAMA online Nov 22, 2019; E1-E2, at E1.

[22] "If an insurance company uses A.I. to evaluate medical scans, for instance, a hospital could manipulate scans in an effort to boost payouts. If regulators build A.I. systems to evaluate new technology, device makers could alter images and other data in an effort to trick the system into granting regulatory approval." Metz C, Smith CS. Warnings of a Dark Side to A.I. in Health Care. New York Times March 21, 2019; available at https://www.nytimes.com/2019/03/21/science/health-medicine-artificial-intelligence.html.

[23] T.C.A. § 68-11-1808(e). *See also* T.C.A. § 68-11-1808(c): "A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience."

[24] Bosslet GT, Pope TM, Rubenfeld GD. An Official ATS/AACN/ACCP/ESICM/SCCM Policy Statement: Responding to Requests for Potentially Inappropriate Treatments in Intensive Care Units. American Journal of Respiratory and Critical Care Medicine 2015; 191: 1318 – 1330.

As Joseph King captured this perennial issue nearly a half century ago, our choice seems to be between an empirical standard (physicians' *customary* practices), versus a more theoretical standard (physicians' *accepted* practices) – i.e., what doctors do versus what they endorse.[25] We will consider custom first, finding it seriously flawed, then turn to a more theoretical guidelines-based approach. The latter, which is also deeply flawed, is where AI may have its greatest impact.

a. Customary practice: a flawed approach for setting the standard of care

Unlike much of tort law, which defers to the "reasonable person," malpractice law looks to the profession to set its own standard of care.[26] The empirical "customary practice" standard, established by an expert's testimony regarding what his colleagues do, is traditional, albeit with adjustments for reputable minorities and localities.[27]

Unfortunately, custom is problematic in many ways. As a practical reality, day-to-day medical practice reflects the incentives that surround it. Fee-for-service payment encourages do-more, charge-more, hence a fairly extravagent approach to resources.[28] And defensive medicine, when in the form of needless tests and treatments to ward off hypothetical lawsuits, likewise distorts what would be a medically optimal standard of care.[29] Indeed, the more that physicians actually engage in excessive intervention and defensive medicine, the more a custom-based standard *requires* such excess.

As a result of these well-known weaknesses, a number of commentators argue that medical custom should

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[25] King JH. In search of a standard of care for the medical profession: the 'accepted practice' formula. Vanderbilt Law Review 1975: 28: 1213 – 1276.

[26] Price WN, Gerke S, Cohen IG. Potential Liability for Physicians Using Artificial Intelligence. JAMA 2019; 322: 1765 – 66, at 1765; King JH. In search of a standard of care for the medical profession: the 'accepted practice' formula. Vanderbilt Law Review 1975: 28: 1213 – 1276, at 1218, 1234 ff

[27] Blumstein JF. Medical malpractice standard-setting: developing malpractice 'safe harbors' as a new role for QIOs? Vanderbilt L R 2006; 59: 1017 – 1049, at 1023, 1030; King JH. Vanderbilt Law Review 1975: 28: 1213 – 1276, at 1218, 1234 ff;

[28] "A particular reason for concern about liability standards for medical malpractice is the prevalence of third-party payment for medical care, which both creates incentives for increased utilization of services10 and provides the financial vehicle for implementing that increased level of utilization. … the medical malpractice system, which is linked to practice styles already influenced upward by the prevalence of third-party payment, may result in sub-optimal over-deterrence and higher costs unjustified by their correlative benefits." Blumstein JF. Medical malpractice standard-setting: developing malpractice 'safe harbors' as a new role for QIOs? Vanderbilt L R 2006; 59: 1017 – 1049, at 1020. *See also* Atul Gawande, The Cost Conundrum: What a Texas Town Can Teach Us about Health Care. The New Yorker, June 1, 2009; available at http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande.

[29] Studdert DM, Mello MM, Sage WM, Des Roches CM, Peugh J, Zapert K, et al. Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. JAMA. 2005;293:2609–17; Sekhar MS, Vyas N. Defensive medicine: A bane to healthcare. Ann Med Health Sci Res. 2013 Apr-Jun; 3(2): 295–296. In one study, physicians' use of advanced imaging rose, simply because someone they knew had been sued. See Ly DP. Rates of advanced imaging by practice peers after malpractice injury reports in Florida, 2009-2013 (research letter). JAMA Intern.Med. 2019; (online 5/20/19); E1-E2.

In one study, 86% of physicians acknowledged that a major reason for providing unnecessary care was fear of being sued. Lyu H, Xu T, Brotman D et al. Overtreatment in the United States. PLoS ONE 12(9): e0181970. published September 6, 2017. *See also* Carroll AE. The High Costs of Unnecessary Care. JAMA 2017; 318: 1748-49, at 1748.

be, and is being, gradually abandoned as the chief source for the standard of care.[30]

b. Guidelines: a flawed approach for setting the standard of care

It has been suggested that evidence-based guidelines, rather than professional custom, should steer the standard of care. Surely we should incorporate the best of our science, it is thought, rather than simply demand that physicians echo each other. And to the extent that AI becomes reliably useful, AI could play a strong role.

Unfortunately, such guidelines are also problematic. First, serious questions have been raised regarding the quality of the evidence – the science – on which many guidelines are based. Although medicine purports to be, and in many ways is, a science-based field, the reality is that much of the funding for RCT research (randomized controlled trial) comes from drug and device manufacturers seeking approval for, or expanded use of their products.[31] Since World War II, medicine has effectively become "the science of the expensive,"[32] because the majority of research funding is from industry. On the other hand, where research simply suggests ways that physicians can improve patient care, it takes about 17 years for those findings to be incorporated.[33]

Moreover, a broad range of clinical issues have never been directly researched, and the applicability of existing research is often limited. Gold-standard, randomized controlled trials, e.g. to test new drugs, tend to have very narrow eligibility criteria, so that the results will not be a mish-mosh of all the other medical problems and drugs the research subjects are taking. When the drug is then approved and used on the broader population, we can often see unanticipated problems from drug interactions, side-effects and the like. Hence to become guidelines for general application, most research must be supplemented with opinion. And often those opinions come from eminent physicians who receive substantial funding from industry – hence the guidelines they produce can reflect significant conflicts of interest.[34]

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[30] Philip G. Peters, Jr., The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium, 57 Wash. & Lee L. Rev. 163, 164 (2000), at 170-72; Philip G. Peters, Jr., The Role of the Jury in Modern Malpractice Law, 87 Iowa L. Rev. 909, 920 (2002); James A. Henderson, Jr. & John A. Siliciano, Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice, 79 Cornell L. Rev. 1382, 1393 (1994); Blumstein JF. Medical malpractice standard-setting: developing malpractice 'safe harbors' as a new role for QIOs? Vanderbilt L R 2006; 59: 1017 – 1049.

[31] Ioannidis JPA. How to make more published research true. PLoS Med 11(10): e1001747; Edwards MA, Roy S. Academic Research in the 21st Century: Maintaining Scientific Integrity in a Climate of Perverse Incentives and Hypercompetition. Environmental Engineering Science 2016; 00: 1 – 11.

[32] Morreim EH. Saving lives, spending money: shepherding the role of technology. In: Ethical Issues in Health Care on the Frontiers of the Twenty-First Century. Wear S, Bono JJ, Logue G, McEvoy A, editors; Philosophy and Medicine Series; Dordrecht: Kluwer Academic Publishers, 2000; 65-112; at p. 65.

[33] Morris ZS,Wooding S, Grant J. The answer is 17 years, what is the question: understanding time lags in translational research. J R Soc Med. 2011; 104 (12): 510-520; Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. 2001, National Academy of Sciences [executive summary], at p. 13 (citing Balas, E. Andrew and Suzanne A. Boren. Managing Clinical Knowledge for Health Care Improvement. Yearbook of Medical Informatics National Library of Medicine, Bethesda, MD:65–70, 2000); available at http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf. Full text available at https://www.nap.edu/download/10027

Per Joseph King, "the strict customary practice rule appears incompatible with a rapidly changing science and may glorify medical custom without due regard for advances in the state of the art … " King, Vanderbilt Law Review 1975: 28, at 1244.

[34] "Financial conflicts of interest among organizations and experts creating practice guidelines are highly prevalent, can in some instances be quite large, are often unreported or reported inaccurately, are subject to inadequate or

As summarized by John Ioannidis: "Influential randomized trials are largely done by and for the benefit of the industry. Meta-analyses and guidelines have become a factory, mostly also serving vested interests. National and federal research funds are funneled almost exclusively to research with little relevance to health outcomes."[35] Indeed, from the perspective of close statistical analysis, the majority of published research findings may actually be false.[36]

These problems were sufficiently well-recognized that in 2011 the Institute of Medicine (now the National Academy of Medicine) released a set of "best practices and quality standards to inform the development of clinical practice guidelines, including managing conflicts of interest, engaging adiverse set of stakeholders, conducting systematic reviews, rating evidence . . . , and articulating recommendations."[37] Based on that analysis the federal National Guidelines Clearinghouse (NGC), applying those standards, removed nearly 50% of its guidelines between 2014 and 2018. [38]

Unfortunately, in 2018 the NGC lost its federal funding,[39] hence such formal evaluation of guideline quality has been discontinued. Nevertheless, academicians' evaluations continue. Recently "Molino and colleagues appraised 421 primary care–oriented guidelines using the validated AGREE-II (Appraisal of Guidelines for Research and Evaluation Instrument, version II) tool, rating fewer than 25% of guidelines as high quality."[40] And "Schumacher and colleagues characterized the evidence supporting American Thoracic Society guidelines, finding that among the subset of strong recommendations, fewer than 20% were based on high-quality evidence."[41]

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nonexistent policies on disclosure, and in some cases have been associated with differences in recommendations.6 The concern about financial conflicts of interest extends beyond whether panel members receive money from vested industry interests. A guideline that recommends more visits and procedures may beregarded as beingpotentially self-serving when the guideline committee consisted solely or predominantly of members of the clinical group likely to benefit from the increased demand." Shekelle PG. Clinical practice guidelines: what's next? JAMA. 2018; 320(8): 757-758, at 758.

[35] Ioannidis JPA. Evidence-based medicine has been hijacked: a report to David Sackett. Journal of Clinical Epidemiology 73 (2016) 82e86.

[36] Ioannidis JPA. Why most published research findings are false. PLoS Medicine 2005; 2 (8): e124 (0696 – 0701); available at https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124.

[37] Incze M, Ross JS. On the Need for (Only) High-Quality Clinical Practice Guidelines. JAMA Intern Med 2019; 179: 561 at 561.

[38] Incze M, Ross JS. On the Need for (Only) High-Quality Clinical Practice Guidelines. JAMA Intern Med 2019; 179: 561 at 561. *See also* Greenfeld S, Steinberg EP, Auerbach A, Avorn J, Galvin R, Gibbons R. Clinical Practice Guidelines We Can Trust. Washington, DC: Institute of Medicine; 2011; Shekelle PG. Clinical practice guidelines: what's next? JAMA. 2018; 320(8): 757-758.

[39] "The NGC was originally created in 1998 by AHRQ in partnership with the American Medical Association and the American Association of Health Plans (now America's Health Insurance Plans). This partnership ended in 2002. The contract that supported the NGC ended August, and funds to continue support for the NGC were unavailable" as of July 16, 2018. AHRQ. Information about the National Guideline Clearinghouse (NGC); available at https://www.ahrq.gov/gam/updates/index.html.

[40] Incze M, Ross JS. On the Need for (Only) High-Quality Clinical Practice Guidelines. JAMA Intern Med 2019; 179: 561 at 561; Molino CGRC, Leite-Santos NC, Gabriel FC, et al. Factors associated with high-quality guidelines for the pharmacologic management of chronic diseases in primary care: a systematic review [published online February 18, 2019]. JAMA Intern Med. doi:10.1001/jamainternmed.2018.7529.

[41] Incze M, Ross JS. On the Need for (Only) High-Quality Clinical Practice Guidelines. JAMA Intern Med 2019; 179: 561 at 561; Schumacher RC, Nguyen OK, Desphande K, Makam AN. Evidence-based medicine and the American Thoracic Society clinical practice guidelines [published online February 18, 2019]. JAMA Intern Med. doi:10.1001/jamainternmed. 2018.7461.

The upshot is discouraging. Yes, evidence-based guidelines and other learned treatises can be provided as evidence of the standard of care during malpractice litigation.[42] And findings from AI could be encompassed within this allowance. But if the quality of those treatises and guidelines, and the evidence on which they are based, are as deeply biased and conflicted as these commentaries suggest, it is not clear whether current guidelines and evidence would actually be superior to custom.

c. Deliberate guidelines: also a flawed approach for setting the standard of care

If guidelines summarizing existing evidence are flawed, perhaps better-quality guidelines could be constructed *ex ante*, by people less burdened with conflicts of interest.[43] Perhaps AI, if it can overcome the challenges identified above,[44] could be particularly useful in such an effort.

Indeed the *ex ante* guideline approach has been tried . . . but with little success.

Professional Standards Review Organizations (PSROs) were created in 1972 amidst Congressional concern about large cost overruns in federal Medicare and Medicaid programs, as well as the defensive medicine practices that helped fuel those overruns.[45] Each regional PSRO would establish professionally developed norms of practice based on typical practice patterns in that region.[46] And then, "[i]n recognition of the relationship between utilization control and medical malpractice exposure, the PSRO legislation specifically addressed the medical malpractice risk … in furtherance of cost-containment objectives,"[47] by immunizing physicians from liability whenever they practiced in conformity with PSRO-issued guidelines.

PSROs were eventually replaced by Professional Review Organizations (PROs), which in turn have been replaced by Quality Improvement Organizations (QIOs).[48] However, QIOs and their predecessor organizations never did exercise their authority to implement standards of care. They evaluate quality, but not quantity of care, and have not issued the sorts of guidelines that would either set standards of care, or immunize physicians where compliance might pose a liability risk.[49]

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[42] Mackey TK, Liang BA. The Role of Practice Guidelines in Medical Malpractice Litigation. Virtual Mentor. 2011; 13(1): 36-41.
[43] Blumstein JF. Medical malpractice standard-setting: developing malpractice 'safe harbors' as a new role for QIOs? Vanderbilt L R 2006; 59: 1017 – 1049.
[44] *See supra*, II-A-1.
[45] Blumstein JF. Medical malpractice standard-setting: developing malpractice 'safe harbors' as a new role for QIOs? Vanderbilt L R 2006; 59: 1017 – 1049, at 1038; King JH. In search of a standard of care for the medical profession: the 'accepted practice' formula. Vanderbilt Law Review 1975: 28: 1213 – 1276, at 1266 ff; Clark C. Havighurst & James F. Blumstein, Coping with Quality/Cost Trade-offs in Medical Care: The Role of PSROs, 70 Nw. U. L. Rev. 6, 8 (1975).
[46] King JH. In search of a standard of care for the medical profession: the 'accepted practice' formula. Vanderbilt Law Review 1975: 28: 1213 – 1276, at 1266 ff.
[47] Blumstein JF. Medical malpractice standard-setting: developing malpractice 'safe harbors' as a new role for QIOs? Vanderbilt L R 2006; 59: 1017 – 1049, at 1039.
[48] Blumstein JF. Medical malpractice standard-setting: developing malpractice 'safe harbors' as a new role for QIOs? Vanderbilt L R 2006; 59: 1017 – 1049, at 1037 ff.
[49] Blumstein JF. Medical malpractice standard-setting: developing malpractice 'safe harbors' as a new role for QIOs? Vanderbilt L R 2006; 59: 1017 – 1049, at 1042.

Hence, just as political considerations apparently caused the de-funding of the National Guidelines Clearinghouse, so may they have been at work since 1972, to thwart Congress' goal of medically reasonable standards that are not inflated by either fee-for-service incentives or defensive medicine fears.

A comparable political story enlightens the rise and demise of the Agency for Health Care Policy and Research (AHCPR). The AHCPR was established in 1989 as a unit of the Public Health Service, to enhance the quality, appropriateness, and effectiveness of health care services. Controversy arose when it produced several guidelines that would reduce the use of certain drugs and surgical services. When another AHCPR guideline concluded that back surgery was unnecessary and potentially harmful for certain kinds of back pain, a lobbying campaign from back surgeons led to replacing AHCPR with the current AHRQ (Agency for Healthcare Research and Quality) and in parallel created the less powerful, now-defunct National Guidelines Clearinghouse.[50] Similarly, when the Patient-Centered Outcomes Research Institute (PCORI) was launched, it was expressly forbidden to consider cost-effectiveness.[51]

3. AI and the standard of care.

If we are incapable of creating and implementing thoughtful, high-quality, un- or at less-conflicted guidelines, even with express protection against liability for guideline adherence, future directions are uncertain. AI currently is far from fulfilling its promise, and that is neither unsurprising nor particularly discouraging. Much will be learned and improvements will follow.

Still, the very same forces that adversely affect both medical custom and evidence- (or eminence-)based guidelines will likely affect AI. Garbage in, garbage out. Economic and political influences will likely exert force throughout. And yet more broadly, the determinants of physicians' and patients' care and outcomes are, in a sense, far simpler. As noted by Ezekiel Emanuel:

> The most pressing problem with the US health care system is not a lack of data or analytics but changing the behavior of millions of patients and clinicians. Physician behaviors, including ordering tests, procedures, pharmaceuticals, and other treatments, are responsible for 80% of health care costs. Similarly, patient behaviors, including eating well, exercising, not smoking, moderate alcohol consumption, and medication adherence, influence more than half of the development of and outcomes related to chronic diseases. A narrow focus on data and analytics will distract the health system from what is needed to achieve health care transformation: meaningful behavior change.[52]

In the end, AI will likely be capable of contributing valuable assistance to improve healthcare. At that point one last issue arises. Like all helpful new technologies, some providers will have access and others will not; some patients will have financially affordable access and others will not. We will then be required to confront yet again a very old issue: how to recognize differential resource access when standards of care traditionally expect the physician to deliver the same quality of care to all they accept for care, regardless of ability to pay. Locality rules and reputable minorities will not save us, because these are resource differences within localities, and those who deviate for financial reasons might be

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[50] Ioannidis JPA. Evidence-based medicine has been hijacked: a report to David Sackett. Journal of Clinical Epidemiology 73 (2016) 82e86, at 83; see also AHRQ/wikipedia https://en.wikipedia.org/wiki/Agency_for_Healthcare_Research_and_Quality

[51] Ioannidis JPA. Evidence-based medicine has been hijacked: a report to David Sackett. Journal of Clinical Epidemiology 73 (2016) 82e86, at 83.

[52] Emanuel EJ, Wachter RM. Artificial Intelligence in Health Care: Will the Value Match the Hype? JAMA 2019; 321: 2281-82, at 2281.

considered disreputable by their peers.[53] That said, the problem is old and familiar, not a new issue triggered by AI.

[53] Morreim EH. Cost containment and the standard of medical care. California Law Review 1987; 75(5): 1719-63.

B. AI and Product Liability – Liability Issues and Regulatory Protections

Liability Issues

A recent article in AMA's Journal of Ethics addressed the question of whether current tort law can adequately address injuries "caused" by AI. The article, "Are Current Tort Liability Doctrines Adequate for Addressing Injury Caused by AI?[54] addressed traditional tort liability in the context of:

- Physician liability: malpractice (negligence);
- Health care organizations: respondeat superior (vicarious liability); and
- Manufacturers and pharmaceutical companies: (products liability).

In addressing the issue of products liability and AI injuries, the authors point to the protection that medical device and drug companies currently enjoy if adequate warning is provided regarding the areas of risk. They note that:

> [A] key difference arises when the products liability doctrine is applied to cases involving medicine and health care, in that such cases are typically subject to the *learned intermediary doctrine.* The learned intermediary doctrine addresses how patient-focused liability doctrines apply to the use of pharmaceuticals and medical devices, wherein physicians intervene between the manufacturer and the ultimate consumer.[55]

In a "Practice Points" published by the ABA litigation section, attorney James Sedgwick discussed the adoption by state courts of the learned intermediary doctrine in reviewing a case before the Arizona Supreme Court in 2016:

> The learned intermediary doctrine has been a part of American jurisprudence since the phrase first appeared in the 1966 decision by the Eighth Circuit Court of Appeals in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). In the ensuing five decades, the vast majority of states have adopted some version of the doctrine, either statutorily or through case law established by state intermediate or Supreme Courts. Essentially, the learned intermediary doctrine provides that the manufacturer of a prescription drug or medical device discharges their duty of care to consumers by providing adequate warnings about the dangerous propensities of the drug or device to the prescribing physician. Recently, on January 21, 2016, the Arizona Supreme Court confirmed that the court is among the majority in *Watts v. Medicis Pharmaceutical Corp*., 2016 WL 237777 (Ariz. Jan. 21, 2016).[56]

There are two obvious issues that come to mind when thinking of the *learned intermediary doctrine* and its application to AI. First, how will the federal regulatory and legal standards evolve regarding the "duty to warn" and "adequate warnings" for designers, developer and vendors of AI products and systems to invoke the doctrine? Second, how will the doctrine evolve in the courts at the state level. One thing that is clear, however, is that both state and national medical associations and medical liability insurers will want to be active participants in helping to shape this evolution whenever possible since it will be their

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[54] https://journalofethics.ama-assn.org/article/are-current-tort-liability-doctrines-adequate-addressing-injury-caused-ai/2019-02

[55] Id.

[56] https://www.americanbar.org/groups/litigation/committees/mass-torts/practice/2016/learned-intermediary-doctrine/

members who plaintiffs will look to for damages if the learned intermediary doctrine duty of care standards applies to AI that may have caused harm.

Another thing for lawyers to ponder with respect to liability is the question of what sort of legal protections can be built into agreements between vendors and purchasers of AI products and services and what warranties and representations will be required in contracts to protect their respective interests.

Regulatory Issues and Standard Setting

A. Food and Drug Administration (FDA)

In September of last year, the FDA issued a new Guidance on Clinical Decision Support Software ("CDS") that replaced an earlier draft that had been issued in 2017.[57] The FDA regulates software that meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including software that is intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of diseases or other conditions (often referred to as clinical decision support software). The guidance notes that "[f]or the purposes of this guidance, the term "CDS" is used to refer to functions that are either Device CDS or Non-Device CDS. FDA uses criteria from the 21st Century Cures Act (Cures to determine if a software function is Device CDS or Non-Device CDS (see Section III)."

Without mentioning the actual term "Artificial Intelligence" the Guidance will regulate the development of AI in health care since it does specifically identify certain issues associated with "machine learning" that will be the focus of its regulations. Under Section C of the Guidance "Device CDS on which FDA intends to focus its regulatory oversight"[58] it notes it will regulate "Device CDS intended for Health Care Providers ("HCPs") that are intended (using the IMDRF Framework[59]) to "inform clinical management" for "serious or critical situations or conditions" and that, in addition, are not intended for the HCP to be able to independently evaluate the basis for the software's recommendations."[60] The Guidance also states it will regulate Device CDS intended for patients under the same standards.

The FDA Guidance has not been finalized as of January 2020, but is likely to come out sometime in the next year after the FDA has reviewed the comments of various affected groups that have a stake in the final FDA position. However, even though the FDA guidance has not been finalized, the FDA has approved numerous AI applications in the past several years.[61]

Finally, it is worth noting that a real question that has arisen is whether the FDA with its limited resources will be up to the task of providing the level of regulatory oversight necessary as the use of AI continues to grow.[62]

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[57] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-so"ftware
[58] Id. at p. 23
[59] IMDRF stands for International Medical Device Regulators Forum which in 2014 developed a framework for risk categorization for software as a medical device. http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf
[60] Supra, FN 23 at p. 23
[61] https://www.docwirenews.com/docwire-pick/future-of-medicine-picks/fda-approved-uses-of-ai-in-healthcare/
[62] https://www.nytimes.com/2020/01/11/opinion/sunday/fda-commissioner-stephen-hahn.html

B. Standard Setting

One key issue being addressed on both a national and international level is the development of recognized standards that will govern AI applications. in general. Lawyers seeking to understand AI should become familiar with the work of ISO, which stands for the International Organization for Standardization. ISO is an independent, non-governmental international organization based in Switzerland with a membership of 164 national standards bodies, including ANSI, which is the American National Standards Institute based in Washington, D.C. ISO in explaining on a very basic level what standards are, notes:

> International Standards make things work. They give world-class specifications for products, services and systems, to ensure quality, safety and efficiency. They are instrumental in facilitating international trade.

It is no surprise that ISO currently has a working group ISO/IEC[63] JTC1/SC 42, which is focused on Artificial intelligence. The scope of their work is Standardization in the area of Artificial Intelligence and to (a) serve as the focus and proponent for JTC 1's standardization program on Artificial Intelligence and (b) provide guidance to JTC 1, IEC, and ISO committees developing Artificial Intelligence applications.[64] To say that the scope of their work is overwhelming, would be an understatement. Current standards under development range from a [framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML) to an [a]ssessment of the robustness of neural networks…"[65]

The corollary to ISO is the American National Standards Institute, ("ANSI") which also has recognized the need for standards to address AI issues in general as well as specific to health care, noting that "[w]ith these new technologies comes the need for standards – both for the development of the tools themselves, and for the use of them in an ethical and productive manner."[66]

C. Privacy and Security of Health Care Data and AI Systems

An issue yet to be confronted on a legal and regulatory basis is whether existing regimes designed to protect the privacy and security of identifiable health data are robust enough in the face of the incredible potential power of AI and, just importantly, the ability of outside actors state and "dark web" actors to develop and implant "malware" in AI systems. Whether one considers research protections that Institutional Review Boards need to think of, regulatory requirements under HIPAA and state laws such as California's more robust protections or international requirements under the EU General Data Protection Regulation or Canada's Personal Information Protection and Electronic Documents Act; all will need to be reviewed and modified to keep pace with AI developments.

There is also a real question as to whether regulatory regimes whether in health care or in other areas will ever be able to catch up to uses of AI that some would call dystopian. An example is facial recognition and its uses in surveillance of what was once public, and what we thought were private, spaces to identify people and track their movements. For example, an in the New York Times[67] article on a start-up's`

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[63] The International Electrotechnical Commission (ETC) is the international standards and conformity assessment body for all fields of electrotechnology. JTC stands for Joint Technical Committee. SC stands for Subcommittee

[64] https://www.iso.org/committee/6794475.html

[65] https://www.iso.org/committee/6794475/x/catalogue/p/1/u/1/w/0/d/0

[66] https://www.ansi.org/news_publications/news_story?menuid=7&articleid=41aec2b9-5612-492a-bcc5-b2c04eb7af65

[67] *The Secretive Company That Might End Privacy as We Know It*, New York Times, January 18, 2020: https://www.nytimes.com/2020/01/18/technology/clearview-privacy-facial-recognition.html

application of AI in harvesting of peoples' images from social media which is then to sold law enforcement agencies for identification purposes, a Stanford professor notes:

> "It's creepy what they're doing, but there will be many more of these companies. There is no monopoly on math," said Al Gidari, a privacy professor at Stanford Law School. "Absent a very strong federal privacy law, we're all screwed."

One can only hope that society is up to the challenge.

III. AI and Emerging Ethical Issues

A. Patients - to what extent and in what ways should patients be informed about the use of AI in their care and when and how should patients be consulted about any additional cost of using AI

1. Informed consent to the use of AI.

As with virtually any question of law, there is one correct answer to the question whether patients should be informed about the use of AI in their care: it depends. If, for instance, the software in a medical device is developed with the assistance of AI, and tested in the usual ways before being approved and/or released to the public, then it is not clear why special disclosures would be needed, any more than if an all-women – or all-Tennessee – team happened to have developed the software. If the testing process is no less reliable than usual, then the particular process by which the software was developed may need no special attention.

In contrast, on other occasions AI may introduce special unknowns. Robot-assisted surgery, for instance, has sometimes introduced unknown elements, as the use of the new technology sometimes got ahead of our understanding and skill.[68] Thus, substantial changes to otherwise-standard procedures may deserve special attention during the informed consent process. The pivotal factor seems to be how innovative is the new technology, or its use in the particular case, and what additional risks might arise thereby.

Historically, the pedicle screw litigation provides an example. Orthopedic surgeons had begun to use a particular kind of orthopedic screw in the pedicles of the vertebrae. Although the device was approved for some uses, that particular use was off-label and not well-tested. Nevertheless, by 1995 it had been used in some 350,000 Americans.[69] Thereafter mounting complaints about device failure, plus a widely-seen television report, triggered a broad swath of litigation. In a number of those cases (though not all) courts ruled that the surgeons should have expressly told patients about the investigative nature of the device's use. In *Shadrick v. Coker*, the patient had been told the screws were routine and that his post-operative problems were due to the fact that he had fallen several times.[70] Per the Tennessee Supreme Court:

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[68] Lafranco AR, Castellanos AE, Meyers WC. Robotic surgery: A current perspective. Annals of Surgery 2004; 239(1): 14-21; Alemzadeh H, Raman J et al. Adverse events in robotic surgery: A retrospective study of 14 years of FDA data. PLos ONE 2016; 11(4): e0151470; available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4838256/pdf/pone.0151470.pdf .

[69] Pedicle screws are at the center of controversy. Washington Pose, April 18, 1995; available at https://www.washingtonpost.com/archive/lifestyle/wellness/1995/04/18/pedicle-screws-are-at-center-of-controversy/38060fac-cbec-4703-9abf-17dd88e82b04/

[70] Shadrick v. Coker, 963 S.W.2d 726, 734 (Tenn. 1998).

> When the health care provider performs the treatment or procedure without the requisite informed consent of the patient, liability attaches for the resulting injuries regardless of whether those injuries resulted from negligence ... This is because the doctrine of lack of informed consent is based upon the tort of battery.[71]

Other cases also expect physicians to disclose when a feature of treatment is significantly innovative. In *Retkwa v. Orentreich* the patient received injectable silicone and was not told that it was not approved by the FDA as an injectable substance. Per the court, the patient was entitled to present evidence that physicians working with liquid silicone in dermatology or plastic surgery during that time-frame would have told patients about its investigational status.[72] In *Gaston v. Hunter* a physician injected chymopapain, then an investigational drug, into herniated disks as an alternative to spinal surgery. The court found that the physician must disclose that a procedure is investigational, or it would be battery.[73]

Similarly, in *Estrada v. Jaques* physicians treating a patient recovering from gunshot wound with an embolization procedure that used a percutaneous steel coil to correct a false aneurysm in leg. Inadequate blood supply subsequently caused amputation of the patient's lower leg. Per the court, the surgeon and radiologist failed to mention that this steel coil embolization procedure was 'highly experimental'; such information must be disclosed as part of informed consent, as part of duty of reasonable care.[74]

> [W]e hold that where the health care provider offers an experimental procedure or treatment to a patient, the health care provider has a duty, in exercising reasonable care under the circumstances, to inform the patient of the experimental nature of the proposed procedure. With experimental procedures the 'most frequent risks and hazards' will remain unknown until the procedure becomes established. If the health care provider has a duty to inform of *known* risks for *established* procedures, common sense and the purposes of the statute equally require that the health care provider inform the patient of any *uncertainty* regarding the risks associated with *experimental* procedures. This includes the experimental nature of the procedure and the *known or projected most likely risks*." [75]

2. Informed consent regarding costs specially associated with AI.

The question whether to inform patients regarding any additional financial costs of AI is virtually impossible to answer. In the U.S. healthcare system it is often nearly impossible to discover, in advance, what any particular intervention will cost the patient.

Suppose the AI add-on is a special software package used as back-up for the pathologist's reading of tissue slides. To discern a price we would need first to know whether the over-read is being done on an outpatient or inpatient basis. Supposing it to be inpatient we would need to know:

*whether the hospital is in- or out-of-network for the patient's insurance;

*whether this patient's insurer deems the AI to be "medically necessary";

*if in-network, what the negotiated fee structure is for this specific intervention, between this hospital and this patient's particular insurer;

*whether that structure pays for hospitalization on a per diem or DRG basis (in which case the AI

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[71] Shadrick v. Coker, 963 S.W.2d 726, 732 (Tenn. 1998). See also Corrigan v. Methodist Hosp, 874 F.Supp. 657 (E.D. Pa. 1995). But see Southard v. Temple Univ Hosp, 781 A.2d 101, 104 (Pa. 2001); Blazoski v. Cook, 787 A.2d 910, 919 (NJ Super. AD 2002).

[72] Retkwa v. Orentreich, 584 N.Y.S.2d 710 (Sup. 1992).

[73] Gaston v. Hunter, 121 Ariz. 33, 588 P.2d 326, 351 (Ariz.App. Div 1 1978).

[74] Estrada v. Jaques, 321 S.E.2d 240 (N.C.App. 1984).

[75] Estrada v. Jaques, 321 S.E.2d 240, 254 (N.C.App. 1984).

might add nothing to the charge);

*what percentage of co-insurance the patient must pay;

*how much of the deductible the patient will have met by the conclusion of this episode of care;

*various other factors.

If the procedure is outpatient we will need to know:

*whether the outpatient facility is in- or out-of-network;

*whether the facility is owned by a hospital, or not (if hospital-owned, a substantial "facilities fee" may be added);

*whether this patient's insurer deems the AI to be "medically necessary";

*negotiated fee schedule between facility and the patient's insurer;

*how much of the deductible the patient will have met by the conclusion of this episode of care;

*various other factors.

The upshot is simple: discerning the patient's additional cost for AI is, like virtually every other cost in healthcare, impossibly complex. Arguably the costs of care ought always to be part of the duty of informed consent.[76] However, this is not currently a common requirement, likely because actual patient costs are so difficult to calculate in a timely way. That said, there still may be an actual legal duty. Particularly in jurisdictions where the "materiality" to the "reasonable patient" is the index for which information should be disclosed, a legal as well as ethical case for financial disclosure can be made. In the past decade, the proliferation of high-deductible plans and large co-insurance obligations has meant that patients' cost-sharing can often run thousands of dollars each year.[77] More recently, thousands of privately insured patients find themselves taken to court, and their wages garnished, over unpaid medical debts.[78] Surely the prospect of large debts, some of which might be avoided by making different

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[76] Morreim EH. Economic disclosure and economic advocacy: New duties in the medical standard of care. The Journal of Legal Medicine 1991; 12(3): 275-329.

[77] Whereas only 7 percent of employers offered exclusively high-deductible health plans in 2009, by 2018 nearly 40% offered only HDHPs. Tozzi J, Tracer Z. Some Big Employers Moving Away from High Deductible Health Plans. Insurance Journal, June 26, 2018; available at https://www.insurancejournal.com/news/national/2018/06/26/493273.htm. Overall, in 2018 almost 30% of people with private insurance had HDHPs, versus only 4% in 2006. See Sloan, Caroline E., and Peter A. Ubel. "The 7 Habits of Highly Effective Cost-of-Care Conversations." Annals of Internal Medicine 170, no. 9_Supplement (May 2019): S33–35, at S33, citing: Kaiser Family Foundation. Employer health benefits: 2016 annual survey. 2016; available at http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2016, and Kaiser Family Foundation. Employer health benefits: 2018 annual survey. 2018; available at http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018.

[78] Kliff S. With Medical Bills Skyrocketing, More Hospitals Are Suing for Payment. New York Times, November 8, 2019p available at https://www.nytimes.com/2019/11/08/us/hospitals-lawsuits-medical-debt.html; Thomas WC. This nonprofit hospital makes millions, owns a collection agency and relentlessly sues the poor. Commercial Appeal June 27, 2019; available at https://www.commercialappeal.com/story/news/2019/06/27/methodist-lebonheur-healthcare-debt-collection-medical-bill-propublica/1577883001/ ; Beil L. The Hospital Treated These Patients. Then It Sued Them. New York Times, September 3, 2019; available at https://www.nytimes.com/2019/09/03/health/carlsbad-hospital-lawsuits-medical-debt.html ; Hancock J, Lucas E. 'UVA has ruined us': Health system sues thousands of patients, seizing paychecks and putting liens on homes. Washington Poast, September 9, 2019; available at https://www.washingtonpost.com/health/uva-has-ruined-us-health-system-sues-thousands-of-patients-seizing-paychecks-and-putting-liens-on-homes/2019/09/09/5eb23306-c807-11e9-be05-f76ac4ec618c_story.html ; Cohn M, Mirabella L. Johns Hopkins Hospital sues patients, many low income, for medical debt. Baltimore Sun, May 17, 2019; available at https://www.baltimoresun.com/health/bs-hs-hopkins-sues-patients-20190516-story.html ; Bannow T. Ballad Health sued thousands of patients in poor, rural area. September 19, 2019; available at https://www.modernhealthcare.com/providers/ballad-health-sued-thousands-patients-poor-rural-area ; Kliff S. Can't Pay the Medical Bill? Your Hospital Might Sue New York Times, November 8, 2019; available at https://www.nytimes.com/2019/11/08/us/hospitals-lawsuits-medical-debt.html. *But*

healthcare choices, would be considered "material" to most reasonable patients.

B. Lawyers – What baseline knowledge will be necessary to advise clients on AI issues?

In many ways, health lawyers today are in the position they occupied almost 20 years ago when they first started paying attention to HIPAA and its security requirements. Many lawyers had to engage in a crash course in computer technology so that they could understand and engage in informed discussions with their clients as to what would be necessary to meet the HIPAA Security rule requirements regarding technical safeguards. Terms such as *authentication, firewall, malware and cloud computing* were not ones that many health lawyers were familiar with and yet today, the vast majority are.

In terms of what baseline knowledge lawyers who want to advise clients on AI need to possess, perhaps the best guidance on what will be required is ABA Model Rule of Professional Responsibility 1.1 Competence.

Model Rule 1.1 states:

> **A lawyer shall provide competent representation to a client. Competent representation requires the legal knowledge, skill, thoroughness, and preparation reasonably necessary for the representation.**

With respect to the requirement of competence under Rule 1.1, comments 1 and 4 to Rule 1.1 provides guidance on these issues.

> *1. In determining whether a lawyer employs the requisite knowledge and skill in a particular matter, relevant factors include the relative complexity and specialized nature of the matter, the lawyer's general experience, the lawyer's training and experience in the field in question, the preparation and study the lawyer is able to give the matter, and whether it is feasible to refer the matter to, or associate or consult with, a lawyer of established competence in the field in question. In many instances, the required proficiency is that of a general practitioner. Expertise in a particular field of law may be required in some circumstances.* (Emphasis added)
>
> *4. A lawyer may accept representation where the requisite level of competence can be achieved by reasonable preparation. ...*

Obviously, the level of competence needed for health lawyers to advise clients will depend on the particular work being done. However, it is clear that given the "complexity and specialized nature" of AI in health care, a great deal of general and specialized continuing education will be necessary for many of us.

IV. Conclusion

From the societal level, to how AI will influence health care in America and the world, to the individual level where it will impact patients in the type and quality of the health care they receive, AI is truly a medium that is a message we all need to understand and heed – not just in the years ahead, but in the

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see: Bannow T. Few hospitals aggressively sue patients to pay bills, and some don't bother at all. Modern Healthcare, October 5, 2019; available at https://www.modernhealthcare.com/revenue-cycle/few-hospitals-aggressively-sue-patients-pay-bills-and-some-dont-bother-all.

immediate future. It was in 1964 that the philosopher Marshall McLuahan first coined the timeless phrase: "The Medium is the Message" and noted with great prescience that "the message of any medium or technology is the change of scale or pace or pattern that it introduces into human affairs."[79] Clearly, the message of AI is a powerful one and the changes in scale and pace that it will introduce into health care and health law are ones we must do our professional best to keep up with.

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[79] *Understanding Media: The Extensions of Man* by Marshall McLuhan ©1964.. https://web.mit.edu/allanmc/www/mcluhan.mediummessage.pdf