



Artificial intelligence in medicine creates real risk management and litigation issues

By Matthew P. Keris

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Abstract: The next step in the evolution of electronic medical record (EMR) use is the integration of artificial intelligence (AI) into health care. With the benefit of roughly 15 years of electronic medical records (EMR) data from millions of patients, health systems can now leverage this historical information via the assistance of complex mathematical algorithms to formulate computer-based medical decisions. With AI spending in health care forecasted to increase from \$2.1 billion currently to \$36 billion by 2025,¹ we sit on the precipice of the next revolution in health care. Now is the time to consider the potential risks, liability and litigation issues of using AI in health care.

WHAT IS “AI” AND HOW IS IT BEING USED IN HEALTH CARE?

There are many definitions of AI, but essentially it is the attempt to have computers achieve human-level intelligence through the use of data and mathematical algorithms to make decisions.² AI has already begun its integration into health care, assisting health care providers in diagnosis, patient monitoring, administration, and treatment recommendations. AI algorithms are prepared by humans and computer systems use these equations to process large volumes of data and ultimately make a decision based on the information provided. In some nonhealthcare instances, AI has outperformed humans. The algorithms are sometimes referred to as the “black box” because it makes complex decisions without explaining why it did so and how it came to its conclusion.³

In the health care context, the algorithms are applied to historic health care data that has been captured by the EMR. Using “data mining,” AI is applied to the health information by a computer to assist health care providers in making recommendations to the patient. In other words, the equations suggest health care options by leveraging preexisting health data and making recommendations based on mathematical analysis.

Algorithms provided by a vendor are proprietary in nature and each owner of the “black box” will want to protect it from their competition and demand that it not be shared publicly. An algorithm may be modified by a health care provider after it has been provided by a vendor.⁴ Like getting a cooking recipe and then adding new additional ingredients, it could enhance or ruin the end product. If there are several people contributing to the recipe, it will be difficult to determine who is responsible for an AI algorithm’s success or failure.

Currently, health care AI is being used to assist in diagnosis, patient monitoring, administrative recommendations, and treatment options. For example, AI can be used in the interpretation of imaging studies and pathologic slides (Computer Assisted Diagnosis or CAD). In some instances, computers are outperforming their human counterparts in reviewing these studies. Further, smart watches are allowing patients to be remotely monitored for cardiac issues, provide continuous glucose monitoring to prevent hypoglycemic episodes, and assess the ambulation of patients with deteriorating neurologic conditions. Home assistants monitor elderly patients for deteriorating behavioral and emotional conditions. Administratively, AI is being used in voice-recognition dictation into the EMR.⁵ By reducing time spent interacting with the record, physicians are able to spend more time with the patient.

From a health care risk perspective, AI in these instances is of benefit. AI can provide a “second set of eyes,” provide real time health data, and provide physicians more time to meaningfully interact with their patient. Distant monitoring, computerized dictation, and use of CAD complements the medical decision makers. However, just as electronic medical records were initially hailed as a method of reducing errors and improving care, it would be foolhardy to believe that AI use will be without risk. Some medical errors will be eliminated, but others will emerge. There are several areas where AI use could be of great risk to patient care.

HEALTH CARE RISK IN CAD

CAD in imaging and pathology interpretation is where AI has been of great assistance to health care providers to date. Computers learn anatomy from reviewing prior similar images. Comparing patient imaging to what the computers have learned to recognize as “normal” anatomy, AI is identifying abnormalities in both imaging and pathologic slides. If abnormalities are detected by the computer, it is “flagged” for the radiologist or pathologist to specifically review to determine whether the finding is suspicious. Some imaging-based systems have been proven to be fairly accurate, but humans are still tasked with making the final diagnosis.⁶

CAD in these instances can increase diagnosis accuracy. In the setting where the human clinician misses a suspicious

finding and the computer recognizes it, this obviously is a positive from a health risk perspective. If the image is reviewed again, for a third time (by a human) and this person confirms a suspicious finding, AI prevented a negative outcome.

From a health care liability standpoint, CAD use in imaging and pathology raises the issue of “reviewer bias” which occurs when the computer’s AI finding is known to the clinician reviewing the image. It is well-documented that clinicians are more likely to find something suspicious on a study if they know beforehand that there may be an issue.⁷ A positive finding based on a CAD review may influence a subsequent human reviewer to also see a suspicious image, which contributes to an increase of false positive findings. If the CAD and physician are both wrong, and the study is truly normal, the false positive could lead to unnecessary treatment. In a cancer setting, it could lead to unnecessary chemotherapy and radiation treatment, which is a common medical negligence claim.

To avoid reviewer bias, it would require the human reviewer to ignore the screening CAD and do a blind review. However, this may defeat the benefit of an initial CAD screening. To avoid reviewer bias and maintain the CAD benefit, it may require three reviews: one by the computer; one by a physician with knowledge of the CAD study, and one by a physician who reviews the image blindly.

Along with reviewer bias, a negative finding by a computer may provide a false reassurance that the image is problem-free. Overreliance on CAD may breed apathy in terms of providing a thorough review of a study. A study that should be acted upon for further follow up may not occur, resulting in a missed or untimely diagnosis. This may be particularly true with respect to newer physicians, and physicians in training. If the next generation of imaging specialists or pathologists are solely trained to interpret studies with CAD, how might their interpretations differ from those who had traditional medical training? Will they be able to differentiate a suspicious finding from a benign image without the assistance of an AI? From a training perspective, in order to properly educate the next generations of specialists it may be wise to limit their reliance on AI in reviewing patient studies.

Another unintended consequence of the use of CAD may cause clinicians to disregard their use altogether. CAD that routinely provides false positives may breed contempt of the system and clinicians may simply disregard the computer’s finding. If a clinician actively disregards the recommendations of the CAD, the benefit of a “second set of eyes” is being wasted. If the institution knew or should have known that clinicians were ignoring the CAD recommendations, it could lend to the argument that the hospital was liable for corporate or administrative

negligence. That is, the administration knowingly allowed its physicians to eliminate a safeguard that increases a chance of diagnosis, which jeopardized patient safety. In other words, if you have the ability to have an image or slide reviewed with CAD and for some reason, you do not, an argument can be made that the negligence was in not using all of your tools to provide an accurate diagnosis.

An initial suspicious finding by the CAD that is disregarded or disagreed upon by the clinician on further review could be problematic in circumstances where the computer was right, and the physician was wrong. That is, the image tagged by the CAD turned out to be a mass, lesion, aneurysm, or clot but the human imaging specialist disagreed. If there is a subsequent medical malpractice claim, the computer is a built-in expert for the patient. A gross negligence allegation could be made against the human image reviewer where it is argued that the suspicious finding was so prevalent, the computer identified it, but the physician could not. It is similar to having two physicians within the same practice examining the same image and coming up with a completely different finding. The inherent conflict may be too difficult to overcome if a jury were to determine liability.

An institution that is sued for corporate liability and for the actions of its vicarious imaging specialist will also be placed in a difficult predicament in this scenario. A missed diagnosis by a human agent implicates the hospital negatively on the agency claim. But the positive CAD finding helps the hospital's corporate case and precludes an argument that the CAD was incorrect. This is a "no-win" scenario for an institution that precludes it from arguing both a good CAD review and good human review. In short, CAD use can further complicate medical defenses in failure to diagnose cases.

Lastly, there are some smartphone applications that evaluate skin lesions for possible melanoma without the inclusion of a clinician's input. People take pictures of the suspected lesions on their smart phone, which is transmitted electronically and evaluated by an AI program, without any human input. The computer application will then make a recommendation to the user whether to see a physician based on its review of the pathology. Obviously, the absence of a trained medical professional's involvement in evaluating skin lesions is ripe with risk management concerns. The Cochrane database for systemic reviews has concluded that smartphone AI-based analyses have not yet demonstrated sufficient accuracy in their diagnosis and are associated with a high likelihood of missing melanomas.⁸ Persons using these types of applications may be lulled into a sense of security if the application does not recommend further follow-up with a physician. Obviously, it would not be wise for a health system or an application to exclusively rely on an AI in providing diagnosis of potential melanomas.

In summary, CAD with imaging and pathology used in conjunction with physicians may reduce misdiagnosis claims because the computer may pick up a suspicious finding not considered by a human reviewer. However, CAD use in health care will not absolutely eliminate misdiagnosis claims and may create new, complex legal arguments against an institution that may be hard to defend, especially in scenarios where the clinician's and computer's recommendations are not aligned. On top of this, reviewer bias will be even more of an issue in medical malpractice claims. But if CAD can reduce errors, the trade-off is worth it.

HEALTH CARE RISK ISSUES ASSOCIATED WITH REMOTE MONITORING DEVICES

Smartwatch use has proliferated and there are many health care-related applications that can track real-time patient data and predict impending emergency medical conditions.⁹ Further, some integrated voice-activated home computing devices allow for remote monitoring of home-bound elderly patients for depression, falls, and other emergencies. The value of these devices is that they could provide very current information about patients to a health care provider outside a formal consultation setting that can be used in formulating treatment options. However, these positives bring additional risks.

Device calibration is very important to these remote devices. If the information coming from these devices is incorrect due to a calibration error or device placement issue, the AI or physicians using real-time health information to predict an upcoming event can be making incorrect recommendations. Unlike medical devices in a regulated health care setting that is checked, upgraded or replaced, smart devices are only as reliable as the person using it. If they do not know how to ensure proper calibration or device positioning, the data used by others can be wrong.

Remote device settings are equally as important as calibration. If a device is not properly programmed at the onset of use, the AI using the available information may be incorrect. One known concern about smart devices is that they are susceptible to having settings changed during upgrades, or if they are breached and controlled by computer hackers. If the devices fail to work due to a settings change, there could be negative consequences to the patient, especially during an acute event. Likewise, if a remote monitor does not act upon the information being provided when an intervention is required, it could lead to patient mortality. While the mobility of these smart devices can be considered a benefit to its users, it also exposes patients to injury due to simple setting mistakes and breaches by nefarious online hackers.

From a legal perspective, remote monitoring may impact venue in a subsequent malpractice case. For example, if a

Washington-based physician is actively using data from a patient residing in Oregon, the Washington physician may be exposing himself to jurisdiction in an Oregon lawsuit if a claim is filed by his patient. He may also be placing himself in a position where it could be claimed that he is practicing medicine in another state unlawfully.

Use of smart devices for remote patient monitoring provides additional security that a patient is being closely managed for potentially life-threatening acute events. Before embracing this advance in health care, those utilizing these technologies should know that while health care risks can be mitigated by using remote devices, they will not be eliminated.

ADMINISTRATIVE RISK IN USE OF AI APPLICATIONS

Automated scheduling and assistance with EMR documentation are two other ways by which an AI may assist with administrative tasks in health care. While useful, AI should not be completely relied upon to ensure administrative tasks are completed and accurate.

The automated scheduling feature can assist health care providers in calendaring routine follow-up visits based on disease process. Patients with one type of diagnosis may be assigned a standard follow-up schedule in 6 weeks, as opposed to others that may have their next follow-up in six months. Automated reminders and follow up messages may be automatically sent to patients in anticipation of an office visit.

With the automatic calendaring function, AI systems may fail to take into account acute episodes and therefore may not update a return visit date despite clear reasons for an earlier consultation. For example, a cardiology patient with a routine checkup in 6 weeks may have visited an emergency room (ER) in the interim for chest pain complaints. If the ER visit is not acknowledged by the automated calendaring system, when told to follow up with their cardiologist at discharge, the patient may believe that a 6 week follow up is appropriate, even despite the new chest pain complaints. This is particularly true for a patient who becomes dependent on AI-assisted calendaring. The patient may incorrectly assume his cardiologist was made aware of the ER visit, rather than contact the cardiologist, advise him of the change in condition and schedule an earlier follow-up appointment. If the patient does not schedule an earlier visit and suffers a fatal heart attack prior to returning, the patient's reliance and physician's use of the automated scheduling system may be the subject of considerable scrutiny in the subsequent lawsuit.

The use of AI in scheduling increases the opportunity for the patient and physician to overly rely on automation to manage follow-up care. AI in calendaring should not be completely relied upon in managing a patient's

appointments. While convenient, it does not eliminate the need for an active relationship between the physician and patient.

While computer-based voice-recognition dictation technology has been around for at least two decades, the goal of achieving 100% accuracy remains elusive. However, software startups are now using AI to establish automated transcription in a new push for integration with the EMR.¹⁰ Automated transcription theoretically would allow more time for physicians with patients and reduce burnout associated with the aggravation of interfacing cumbersome EMR systems.¹¹ Acknowledging that even 95% dictation accuracy is unacceptable in health care records, software startups remain aggressive to have health systems use their AI with EMR systems. As a way of closing the accuracy gap, companies are offering to record office visits with automated speech transcription system that is subsequently listened-to by premed students, who then produce a finished transcribed notation. Others rely on speech engine technology only in reviewing the recorded transcription, which is then reviewed by a person, who may or may not be medically trained. In either scenario, it is acknowledged that accuracy is largely dependent on the dictation occurring in optimal recording scenarios. Background noise, an accent, or a poor microphone can drastically reduce the accuracy rates.

While AI may reduce administrative efforts of maintaining an accurate medical record, it will not eliminate the possibility of errors, and will create different problems. The potential risk issues associated with AI transcription are more troubling than the calendaring issues for a number of reasons. First, despite all the developments and proofreading, voice-recognition dictation still has to be done in a pristine environment in order to get close to 100% accuracy. A health care setting is lively with routine interruptions, whether there be a loud noise in the background that is picked up by a dictation microphone or if someone interjects themselves into a recording. The backdrop of the practice of medicine does not afford the silence needed for accurate dictation. Further, physicians will still need to proofread their work and they have the reputation for not giving it the time and attention it requires. If the physician knows there is a "team" of reviewers or AI interpreting his dictation, will that physician be as careful in reviewing the documentation? Likely not. Further, the AI transcription and independent proofreaders may reduce, but not eliminate, errors due to the use of unapproved medical and texting abbreviations in the record and misidentification of drugs by their generic or brand names. Unless the proofreader is the actual one who dictated the entry and used the abbreviation, documentation issues will persist, and errors will continue.

From a litigation standpoint the use of a third-party vendor to assist in documentation may complicate the pursuit and defense of medical error cases. In instances

where patient visits are transcribed and saved electronically, medical malpractice discovery may include a request for the raw audio or video recording. If the recording is not preserved, allegations of evidence tampering or spoliation may follow. The use of inclusion of the third-party vendor may also create another potential defendant, particularly if a transcription error led to a poor patient outcome. Contracts with the third-party vendors should be scrutinized for indemnification or “hold harmless” language in the instance of a transcription error that leads to an injury. If the dictation vendor is not a party, a health care provider could be held legally responsible for the transcriptionists’ errors.

While attempts to simplify record taking for health care providers should be encouraged to make their lives easier and reduce burnout, voice-recognition dictation is not the complete answer and common documentation issues will persist. There is no cure for charting errors other than for those who document to make sure their entries are accurate before finalizing them. AI used to assist with administrative tasks may be of benefit, but is potentially rife with issues. AI should *not* be expected to eliminate errors.

ARE HEALTH CARE AI ALGORITHMS THE NEXT “AUDIT TRAIL”?

Many in health care risk management and claims know that “audit trail” requests have become so prevalent and expensive that potential claims need to be evaluated not only on the medicine, but also on what information can be gleaned from the metadata associated with the record. That is because the audit trail is perceived by many as a way to recreate how the chart was prepared and viewed chronologically. With a true accounting of how the chart was prepared and perhaps altered, patients’ lawyers often attempt to discover from the audit trail if the record has been altered in any way. As a result, it has become more common to include a request to review information from an EMR’s audit trail in litigated cases.

Healthcare AI algorithms making treatment recommendations used by physicians may be the next big thing in terms of scrutiny of health care claims because the issue represents a new avenue for discovery and liability. It is inevitable that an AI algorithm will be involved in a medical error that results in patient harm. If the AI recommendation was approved by the physician, blame may be shared by both the physician and computer program. This is where it gets complicated. It should be anticipated that if litigation follows, there will be attempts to scrutinize the data used by the algorithm as well as the algorithm itself. How far an investigation into the AI will go remains to be seen, but similar to discovery on the audit trail, it could become time consuming, expensive, and considered a waste of time and resources. However, if a negative patient outcome can be traced to a true AI error, it can be a disaster for health care providers.

First, if a wrong treatment recommendation affects a large group of patients, it can result in a large class of litigants pursuing their individual claims against the hospital, which provided the “black box” treatment recommendation. Second, if it is learned that physicians are adopting AI recommendations over their own judgment, it could result in a claim against an institution for encouraging or allowing an environment to exist where computer judgments are considered superior to human decisions.

Discovery of the “black box” algorithm will be difficult and expensive because of its complexity and proprietary interests of those involved. Again, algorithms provided to a health care institution arguably belong to that party. It should be anticipated that the algorithm developers would seek an opportunity to intervene and object on proprietary grounds for the release of their information to third parties. It gets even more complicated if a health care provider “tweaked” a vendor’s algorithm. How does one discover when and why the algorithm was changed? Who owns the algorithm now? Does the vendor still have proprietary rights to their portion of the altered algorithm? How do you determine which part of the algorithm caused the problem? Because the “black box” gives no reasoning for their treatment recommendation, how can one ever determine with certainty the reason for a decision? Answering these questions will require collaboration with computer and programming engineers and clinically practicing physicians. Deciding these legal issues will be judges who may not have the patience, interest, or time to educate themselves on this topic.¹⁰

Liability for a bad AI recommendation will most likely fall on the institution that brought the technology into the decision-making mix. As a way to mitigate responsibility and damages, health care institutions may consider joining the third-party who created an algorithm in question.¹² Similar to voice-recognition dictation vendors, health care providers may not have a contractual right to join the AI vendor, if there is an indemnification or hold harmless provision in their contract.

In addition to scrutiny of the “black box” algorithm, there could be an investigation into the EMR information that was used by the algorithm. If the information used by the algorithm from the EMR is incorrect, inconsistent, or questionable, the AI could yield a result that is wrong and hurt a group of patients. Consistent with the statement “garbage in, garbage out,” if an AI recommendation is based on bad facts, the algorithm could be incorrect and those who entered the information into the record could be to blame. A likely argument would be against the institution for permitting an error ridden and unreliable EMR to exist and then utilize it in making treatment decisions.

AI used to augment health care decisions will undoubtedly improve care because it can be considered a limited

computerized second opinion. The hope is that through the use of AI, medical claims will be reduced, and care improved. It is anticipated that while some claims will be reduced by harnessing a powerful new medical tool, the ones that persist will be more complex, affect larger classes of patients, increase the costs of litigation and, in some instances, be harder to defend. As health risk management is set to embark in the new world of AI in health care, it should not be lulled to believe that it is a cure for medical errors. While it may eliminate some, it may create more. Be ready.

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ABOUT THE AUTHOR

Matthew P. Keris is a Shareholder in the Health Care department of Marshall Dennehey. He is the Chair of the law firm's Electronic Medical Record and Audit Trail Practice Group and has defended doctors, health systems, long-term care providers and medical device manufacturers for more than two decades. He recently successfully defended the first civil jury trial to occur in Pennsylvania during the COVID-19 pandemic in a socially distanced courtroom. In addition to his litigation practice, Matt's counsel is routinely sought by health care providers, administrators, risk managers, claims professionals, defense counsel, medical societies and governmental entities on issues pertaining to legal, ethical and patient safety matters. He has worked with the U.S. Food and Drug Administration, American College of Obstetricians and Gynecologists, American College of Healthcare Trustees and American Society for Healthcare Risk Management. Matt also serves as an editor of Patient Safety, a journal published by the Pennsylvania Patient Safety Authority. Matt has developed substantial expertise in electronic medical record (EMR) preservation, production and discovery matters, having authored a book on the subject, *Electronic Medical Records and Litigation*, for Thomson Reuters. Known as a national leader of the defense bar, Matt currently serves on the Defense Research Institute's (DRI) Board of Directors as the Atlantic Region Director and is a member of the Steering Committee for its Annual Insurance Roundtable. He is also the Board Liaison to DRI's Lawyers' Professionalism and Ethics Leadership Committee. Matt is a former President of the Pennsylvania Defense Institute and continues to serve as the chair of the Medical Professional Liability Committee. He twice served as President of the Pennsylvania Association for Health Care Risk Management, and is an active member of the Claims & Litigation Management Alliance.