

OR Manager

The monthly publication for OR decision makers

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SPECIAL SERIES

Legal and ethical questions temper excitement about AI—Part 1

As part of a special series on artificial intelligence (AI), OR Manager is taking a deep dive into the many facets of this new technology and its impact on patient care. Part 1 and Part 2 of the introduction to AI (May 2019 and June 2019) defined types of AI and described its many current and potential surgical applications. The series has also presented examples of AI in practice: the OR Black Box® (June 2019) as well as an interactive surgical

playbook and a system for quantifying blood loss (see articles in this issue on pages 10 and 12). In part 1 of a two-part article, we examine legal and ethical challenges related to AI.

Artificial intelligence will likely have a dramatic impact on healthcare, including surgery, but the nature of that impact depends on how challenges are addressed. Data management and

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Performance improvement

Partner with IT to produce the highest quality data

"What we have right now, quite frankly, in healthcare are islands—visible islands of excellence in a sea of invisible failures, with risk lurking just below the waterline. We need to widen those islands of excellence. We need to connect these islands with more dry land. We need to address these areas of risk. That is going to require transparency, it's going to require data, it's going to require personal story telling, and it's going to require effective use of health IT."

These words were written not by a healthcare strategist or information technology (IT) expert but

by retired airline pilot Chesley Burnett "Sully" Sullenberger, who, on January 15, 2009, landed US Airways Flight 1549 in the Hudson River after a bird strike disabled both engines. All 155 people on the plane survived.

Sullenberger is now a lecturer on the importance of aviation and patient safety.

Safety in aviation has often been compared with safety in healthcare, but nowhere are there more similarities between the airlines and healthcare than in the OR. And nowhere are there more islands of data, processes, and personnel that need to be connected,

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Artificial intelligence

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analysis, ethical issues, legal and regulatory questions, and user impact are some of the issues being discussed not just in the United States but internationally as well.

This article takes an in-depth look at some of these issues. Part 2, which will be published in August, will discuss the additional challenges.

Data challenges

AI systems require large amounts of data to “learn,” and that learning is only as good as the data used to teach it. Both volume and quality create challenges related to data protection and analysis.

Data protection



Michael Matheny, MD, MS, MPH

“In healthcare, we put a lot of value, and rightfully so, on maintaining patient privacy and patient confidentiality,” says Daniel Hashimoto, MD, MS, surgical artificial intelligence and innovation fellow at Massachusetts General Hospital in Boston. Laws such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that are meant to protect privacy can also hinder access to the wealth of data needed to build effective AI systems.

What is the role of data privacy and protection in the age of AI? Experts are calling for a dialogue to answer that question. “These algorithms have the potential to be very high performing, can provide public good, and can provide [significant] health benefits,” says Michael Matheny, MD, MS, MPH, associate professor of medicine, biomedical informatics, and biostatistics at Vanderbilt University Medical Center, Nashville, Tennessee. “People will have to decide where the balance is between allowing that data to be more accessible for the public good

versus keeping it private and personal.”

Dr Matheny cochairs the National Academy of Medicine (NAM) Artificial Intelligence in Healthcare Working Group, which will be releasing a report on AI (sidebar, p 7).

These types of discussions go beyond US borders, and viewpoints vary. Dr Matheny notes that a country’s culture determines the balance of public good versus privacy and data protection. “[The viewpoint] is based on the risks and benefits they see to themselves, the risks and benefits they see to society, and how they weigh their own personal rights relative to society,” he says. For example, people in the US and China have very different views on data usage.

Some institutions are already taking steps to address data protection. Johns Hopkins in Baltimore, for example, has created a secure platform for storing research data in the cloud.

“We’re creating an environment where the data is as secure as we know how to make it,” says Ferdinand Hui, MD, associate professor of radiology and radiologic science, director of interventional stroke, and codirector of the Radiology Artificial Intelligence Lab at Johns Hopkins. “That way, we can do analytics on large amounts of data with as little risk of breach as we know how.”

Researchers can access a variety of data, including electronic health record data, images, genomics, and physiological monitoring data.

But Dr Hui, along with Wendell Wallach, senior advisor to the Hastings Center in Garrison, New York, acknowledges that advances in information and technology make data de-identification—traditionally viewed as sufficient for protecting a person’s privacy—difficult.

“In reality, if you have enough pieces of information about a person, you can probably reconstruct who that individual is, and that would violate their rights,” says Wallach, who is also chair of technology and ethics studies at the Yale

Interdisciplinary Center for Bioethics in New Haven, Connecticut, the author of *A Dangerous Master: How to Keep Technology from Slipping Beyond Our Control*, and principal investigator for the Hastings Center’s Control and Responsible Innovation in the Development of Autonomous Machines Project (<https://dev-the-hastings-center.pantheonsite.io/who-we-are/our-research/current-projects/control-and-responsible-innovation-in-the-development-of-autonomous-machines/>) (sidebar, p 8).

Dr Hui uses mammograms as an example of the challenges, saying that each mammogram has a unique pattern of tissue, stroma, and blood vessels.

“If I had a copy of another mammogram to compare against, I could probably figure out who you are, like a fingerprint,” he says, adding that it’s possible to use CT scans to reconstruct what a person looks like.

Data analysis

Sound AI algorithms depend on sound analysis. “The problem with many published algorithms is that when we evaluate the performance of that algorithm on a new set of data or a new set of patients, it doesn’t do as well,” Dr Hui says.

The challenge is the variables inherent in data, for example, different surgeons, different hospitals, different patient characteristics, and different procedures.

“We don’t know whether the patients and decision points that got programmed into an algorithmic system to provide care align with the patient populations in a different area of the country from where the system was programmed,” says Danton Char, MD, assistant professor of anesthesiology, perioperative and pain medicine at Stanford University Medical Center in Stanford, California. “What works in Palo Alto might not work in Akron

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Artificial intelligence

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[Ohio],” says Dr Char, who has written about the ethical issues inherent in AI.

“There’s a lot of work that needs to be done to make sure that the algorithms that we develop on one set of patients in one part of the country and one part of the world are valuable and still accurate in other patient groups,” Dr Hui says.

Dr Char adds that external pressures could lead to the development of inappropriate algorithms. “Profit-driven pressures and regulatory compliance-driven pressures could cause people to create algorithms that skew toward providing the kind of data that regulators want to hear, or that maximize profits, but at the expense of healthcare or delivering quality health.”

The current emphasis on basing reimbursement on outcomes could lead to the creation of algorithms that guide users toward clinical actions that would improve quality metrics but not necessarily improve patient care. For example, there might be indicators that encourage the ordering of unnecessary testing.

Clinical decision-support systems could also be programmed to boost profits for stakeholders without clinicians having any knowledge of that. This might take the form of recommending medications or devices that the creator or purchaser of the AI algorithm holds a stake in.

“Healthcare exists in this tension between maximizing profit and maximizing health, and those two things don’t always line up,” Dr Char says.

Addressing these data challenges is key to ensure that AI researchers have what they need to build better algorithms. Dr Hashimoto calls for a central database that researchers can access, but notes that it’s important to consider modifying certain rules so that data util-

National Academy of Medicine and AI

The National Academy of Medicine (NAM) is taking a leading part in investigating the role of artificial intelligence (AI) through its Digital Learning Collaborative. In addition to oversight and regulation, a work group for the collaborative has identified the following issues related to patient ownership of data:

- health data definition and use
- case identification
- exploration of data ownership and sharing models
- principles for data stewardship
- enhancing patient health literacy
- understanding patient preferences

In the summer of 2019, NAM plans to release a special report about AI based on the work of an interprofessional committee. “We hope that this will help everyone come to a consensus around the safest and most effective way to implement these things in healthcare,” says Michael Matheny, MD, MS, MPH, committee cochair and associate professor of medicine, biomedical informatics, and biostatistics at Vanderbilt University Medical Center in Nashville, Tennessee.

“Our hope is that this compilation will engage the range of stakeholders to delve more deeply into the shades of gray and be more engaged and involved in helping drive legislation and self-governance,” adds Sonoo Thadaney, MBA, committee cochair, executive director for presence, and executive director for the program in bedside medicine at Stanford University School of Medicine in Stanford, California.

ity can be optimized without compromising patient privacy.

Ethical issues

Ethical issues include bias, monetizing patient data, and access.

Bias

AI algorithms should be based on unbiased data, but ensuring that can be challenging. “We’re now realizing that a lot of the data we collect reflects biases from the past, and those are just carried forward,” Wallach says. “Either the data itself is not complete, or it’s based on historical materials that were intrinsically collected in ways that may reinforce biases.”

Some bias has its roots in research. “So much of our medical research is based on the average, 50-year-old Caucasian male,” says Sonoo Thadaney, MBA, executive director for presence and executive director for the program in bedside medicine at Stanford University School of Medicine in Stanford,

California. “We don’t have access to large data sets that represent the populations they aim to serve—with sufficient breadth and depth of diversity in gender, race, and age.”

Wallach adds that other forms of bias include patient infirmities such as mental health conditions and how humans think about various issues, such as politics. “Biases can be very broad,” he says. “They go beyond basic racial, gender, or cultural prejudices.”



Sonoo Thadaney, MBA

Thadaney, who co-chairs the Artificial Intelligence in Healthcare Working Group, adds that focusing too much on currently available data can lead to unexpected consequences. For example, in the last century there was a well-meaning focus on addressing world hunger by increasing yield per acre,

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without considering nutrition per acre. “Fast forward to today, and we see that the yields per acre on our planet have certainly gone up, but there are [significant] nutritional differences [among zip codes and countries],” she says.

Some have access to high-nutrition food, but others do not. “We have a food apartheid thanks to our food deserts; we can’t end up with a healthcare apartheid because we only focus on matrices such as efficiency and costs, ignoring criteria such as inclusivity and equity.”

Combining a focus on efficiency with a biased data set could lead to disparities, Thadaney says, especially for those who can’t afford second opinions and concierge medicine. “The people who end up with algorithmic medicine are the ones who will likely be people for whom the data set is not relevant and that prioritizes efficiency rather than outcomes,” she says.

Monetizing patient data

Thadaney notes that patients give permission for a healthcare system to use their data for treatment, billing, and academic research. “Patients have not explicitly given permission to use that data to monetize it for either one institution or a number of institutions,” she says.

Dr Char says that many people will need to volunteer their health data so there is sufficient information to develop AI. “What they should get in return for giving up their data is not clear,” he says. “Certainly I think that to do right, there should be some kind of clear benefit to the patient [as opposed to profit for the institution or application designers.]”

He notes that in 2017, London’s Royal Free Hospital was found to have breached the Data Protection Act when it gave data for 1.6 million patients to DeepMind, a Google subsidiary. The data transfer was part of a partnership to create Streams, a healthcare app for

How private is private?

The difficulty of maintaining data privacy varies between fixed and free text in an electronic health record (EHR). Fixed text refers to what is contained in pull-down menus with preset fields. Free text refers to the notes that clinicians type into the EHR.



Jennifer Geetter, JD

“Fixed text is easy to de-identify: You just tell the computer, ‘don’t pass along the following fields that would constitute identifying information,’” says Jennifer Geetter, JD, a healthcare attorney

with McDermott Will & Emery in Washington, DC. “Free text is much harder to de-identify because what constitutes identifiable information in free text often depends on context.”

Geetter uses the example of a provider who notes that a patient is particularly concerned about shoulder surgery because he is a pitcher on the local minor league team. “While you can tell a scrubbing tool to take out proper names or location, how do you tell the scrubbing tool to take out that type of

information?” she says. “Tools are getting more sophisticated, but it’s still difficult to assess successful de-identification, and aggressively removing content and context needs to be balanced with retaining a rich and informative data set necessary for creating and running effective algorithms and other machine learning analyses.

“There’s no real legal obligation that AI [artificial intelligence] technologies only receive de-identified information if there is a legal pathway where they could permissibly receive identifiable information,” Geetter adds.

She notes that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) permits digital health tools to receive identifiable information in many circumstances, and that entities can receive the information they need to provide the service they contracted for, which could apply to AI. But Geetter says there can be a disconnect between what the law permits and the public’s expectations.

“Probably the law allows things that the public doesn’t expect, and I think it prohibits things that probably the public isn’t bothered by,” she says.

New technology challenges old ways of protecting privacy.

diagnosing and detecting acute kidney injury. Patients were not told that their data would be used for ongoing testing of the app.

Wallach notes that the European Union’s General Data Protection Regulation gives individuals many rights related to who owns data about them, but that’s not the case in the United States. “The rules [in the US] are looser in terms of what businesses can and cannot do with data,” he says. “There’s a lot of concern that the data is being used in unethical ways or inappropriate

ways, and that we should be clarifying the norms on the use of that data.”

Access

Access to AI could be an issue, particularly for smaller hospitals with fewer financial resources. “If I’m in a rural area or a small community hospital, what are the ethical implications of not being able to get the benefits from AI because of the financial outlays?” Dr Char asks.

“This is going to be a pretty significant challenge,” Dr Matheny adds. “There’s a lot of infrastructure that

needs to be in place from health IT [information technology], health record, and data management resources.”

In addition, AI algorithms require updating on a regular basis to be sure they are operating safely and accurately, and those updates contribute to cost.

Dr Matheny says a way to mitigate the financial disparity is to reduce implementation costs through transparent best practices. “That needs to be a conscious effort by stakeholders to encourage national discussion going forward in order to promote standardization and to lower costs of implementation, or only large medical centers will be able to offer the benefits from these technologies,” he says.

“Whether AI will realize the promise of actually helping more people or whether it’s going to enhance affluence and income disparity is not so clear,” Dr Char says. “I think that everybody working in this area acknowledges that we probably don’t really understand all of the social ramifications of a lot of this artificial intelligence.” ❖

Cynthia Saver, MS, RN, is president of CLS Development, Inc, Columbia, Maryland, which provides editorial services to healthcare publications.

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