Researchers Unveil Framework for Sharing Clinical Data in AI Era

Released: March 24, 2020

OAK BROOK, Ill. — Clinical data should be treated as a public good when it is used for secondary purposes, such as research or the development of AI algorithms, according to a special report published in the journal *Radiology*.

David B. Larson, M.D., M.B.A.

"This means that, on one hand, clinical data should be made available to researchers and developers after it has been aggregated and all patient identifiers have been removed," said study lead author David B. Larson, M.D., M.B.A., from the Stanford University School of Medicine in Stanford, California. "On the other hand, all who interact with such data should be held to high ethical standards, including protecting patient privacy and not selling clinical data."

The rapid development of AI, coming on the heels of the widespread adoption of electronic medical records, has opened up exciting possibilities in medicine. AI can potentially streamline and improve the analysis of medical images, but first it must be trained on large troves of data from mammograms, CT scans and other imaging exams. One of the current limitations of the advancement of AI-based tools is the lack of broad consensus on an ethical framework for sharing clinical data.

"Now that we have electronic access to clinical data and the data processing tools, we can..."
dramatically accelerate our ability to gain understanding and develop new applications that
can benefit patients and populations," Dr. Larson said. "But unsettled questions regarding
the ethical use of the data often preclude the sharing of that information."

To help answer those questions, Dr. Larson and his colleagues at Stanford University
developed a framework for using and sharing clinical data in the development of AI
applications.

Arguments regarding the sharing of clinical data traditionally have fallen into one of two
camps: either the patient owns the data or the institution does. Dr. Larson and colleagues
advocate for a third approach based on the idea that, when it comes to secondary use,
obody truly owns the data in the traditional sense.

"Medical data, which are simply recorded observations, are acquired for the purposes of
providing patient care," Dr. Larson said. "When that care is provided, that purpose is
fulfilled, so we need to find another way to think about how these recorded observations
should be used for other purposes. We believe that patients, provider organizations, and
algorithm developers all have ethical obligations to help ensure that these observations are
used to benefit future patients, recognizing that protecting patient privacy is paramount."

The authors' framework supports the release of de-identified and aggregated clinical data for
research and development, as long as those receiving the data identify themselves and act as
ethical data stewards. Individual patient consent would not be required, and patients would
not necessarily be able to opt out of allowing their clinical data to be used for research or AI
algorithm development—so long as their privacy is protected.

"When used in this manner," the article states, "clinical data are simply a conduit to viewing
fundamental aspects of the human condition. It is not the data, but rather the underlying
physical properties, phenomena and behaviors that they represent, that are of primary
interest."

According to the authors, it is in the best interest of future patients for researchers to be able
to look "through" the data available in electronic medical records to develop insights into
anatomy, physiology and disease processes in populations, as long as they are not looking
"at" the identity of the individual patients.

The framework states that it is not ethical for clinical providers to sell clinical data for
profit, especially under exclusive arrangements. Corporate entities could profit from AI
algorithms developed from clinical data, provided they profit from the activities that they
perform rather than from the data itself. In addition, provider organizations could share
clinical data with industry partners who financially support their research, if the support is
for research rather than for the data.

Safeguards to protect patient privacy include stripping the data of any identifying
information.

"We strongly emphasize that protection of patient privacy is paramount. The data must be
de-identified," Dr. Larson said. "In fact, those who receive the data must not make any
attempts to re-identify patients through identifying technology."

Additionally, if a patient's name was unintentionally made visible—for instance, on a
necklace seen on a CT scan—the receiver of the information would be required to notify the

party sharing the data and to discard the data as directed.

"We extend the ethical obligations of provider organizations to all who interact with the data," Dr. Larson said.

Dr. Larson and his Stanford colleagues are putting the framework into the public domain for consideration by other individuals and parties, as they navigate the ethical questions surrounding AI and medical data-sharing.

"We hope this framework will contribute to more productive dialogue, both in the field of medicine and computer science, as well as with policymakers, as we work to thoughtfully translate ethical considerations into regulatory and legal requirements," Dr. Larson said.

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"Ethics of Using and Sharing Clinical Imaging Data for Artificial Intelligence: A Proposed Framework."
Collaborating with Dr. Larson were David C. Magnus, Ph.D., Matthew P. Lungren, M.D., M.P.H., Nigam H. Shah, M.B.B.S., Ph.D., and Curtis P. Langlotz, M.D., Ph.D.

Radiology is edited by David A. Bluemke, M.D., Ph.D., University of Wisconsin School of Medicine and Public Health, Madison, Wis., and owned and published by the Radiological Society of North America, Inc. (http://radiology.rsna.org/)

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