Science Distributed February 20, 2020 Volume 1 Issue 6

INTEGRATED FUTURE(S)

ARTIFICIAL ETHICS

Putting the A-I in lawsuit

Welcome to Integrated Future(s), IF.

IF is a weekly newsletter about the future of emerging technology and the impact on science, medicine and society. We'll look at how artificial intelligence, blockchain, quantum and neuromorphic computing, neurotech and more will integrate with each other and with ***technoscience***, the technological infrastructure of science in our society.

This week we'll look at who is watching the innovators of artificial intelligence on protected health information from a regulatory perspective. Artificial intelligence or AI is a catch all term for an array of machine algorithms and learning applied to data sets to give predictive analytics and augment or automate decision making. These are being narrowly applied to specific areas (chess, cancer diagnosis, driving, etc.) today and it's anticipated that there will be more general applications in the future.

In health, there have been some uses explored and related problems that have arisen. From a regulatory perspective, who is responsible for safeguarding patients and their data? I argue that it is the human research protection elements in the United States, but most don't even recognize that they should be involved.

Please remember that the map is not the territory.

- Sean

THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH

https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

This is the foundational report for guidelines regarding medical/health research in the U.S. It was commissioned by an act of Congress in large part a direct response to what a federal whistleblower revealed about the egregious ethical and moral failures of federal researchers and administrators in the Tuskegee Syphilis Experiment from 1932-72.

THE NEXT BELMONT REPORT

The Belmont Report, upon which our ethical and legal framework of health research is based, is more than 40 years old. When the report came out in 1978/9, it was the culmination of 4 years of monthly meetings for key contributors before wrapping up their findings and drafting the report in a four-day consensus meeting. Given the rapid emergence of technology and privacy opportunities and challenges, it seems the ideal time to start on a new, updated report of similar comprehensive quality and lasting value. If this is happening and I missed it, let me know. If not, let's do it.

Required reading for anyone that does research, medicine, or touches health data.

FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS ('COMMON RULE')

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

These are the more detailed federal guidelines for protection of human subjects in research, more commonly known as the Common Rule. This policy including its recent updates have shaped my still developing thoughts on the matter.

Sean's IF/Take:

If one takes health care data, including de-identified and/or anonymized data, and uses it in a hospital or health system for quality assurance or process improvement (QA/PI), this is not research. It is good practice to get a non-research determination from an approved authority (e.g. HRPA or IRB), but if the use is only internal you will generally not run into a problem even if you don't. IF, however, you plan to make the results **generalizable**, meaning findings can be applied to other places, it is probably research. It might be exempt research, but it is probably research. Even if by some chance it is not research, you are definitely going to want to have that non-research determination by an approved authority. And that authority in most places is usually not the researcher, clinician, technologist, administrator, informaticist, or whoever is crunching the numbers or calling the shots (CDC and some other exceptions to this exist, where steps have been taken to instill determination authority at the operational level).

Generalizability is the key concept as we start to look at AI use of health (including behavioral) data. Traditionally, generalizability has been closely related to plans to publish findings. You can publish QA/PI findings as not generalizable by picking the right framing, title, journal, etc. But if you want to say, "here's what we found about X and we think it applies elsewhere," you are generalizing.

With AI, particularly machine learning, the usual methodology of science: hypothesize, analyze, conclude, report, and repeat is rapidly iterated without the reporting portion. This is done internal to the system using whatever data it is fed. If it is being fed data from a single hospital or health system to augment quality assurance or process improvement, ok, that's not research. But if the plan is to create a tool to generalize the learning to a different population, that's probably research. Maybe exempt, maybe even ruled non-research, IF you get the authorized determination.

Who cares? Those concerned with Belmont Report's 3 principles: respect for persons, beneficence, and justice. Those who police related laws and regulations (i.e. IRBs, HRPOs, OCR). And everyone whose data you used for that health AI you made millions on when they learn you broke the law doing so allowing them to file class action lawsuits.

That's all this week. Share at will. Questions/comments to seanmanion@sciencedistributed.com. Thanks for reading.

Sean T Manion PhD is a technoscientist with a focus on blockchain and other emerging tech, neuroscientist, former federal researcher/admin and bureauscientist. He is a Chief Editor at Frontiers' Blockchain for Science, a Fellow of the British Blockchain Association and co-author of the book Blockchain for Medical Research: Accelerating Trust in Healthcare with Yaël Bizouati-Kennedy (CRC Press, April 2020). He is currently performing the duties of self-appointed strategic planner for science.

Science Distributed **is a start-up recently turned non-profit focusing on improving science and its impact to society with emerging technology. More soon at sciencedistributed.com (pardon our dust).**