Boston Children's Hospital

Where the world comes for answers

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

United States Senate Committee on Health, Education, Labor and Pensions

Subcommittee on Primary Health and Retirement Security

Avoiding a Cautionary Tale: Policy Considerations for Artificial Intelligence in Health Care

Wednesday November 8, 2023 at 2:30 PM

Testimony by

Kenneth D. Mandl, MD, MPH

Director, Computational Health Informatics Program, Boston Children's Hospital, Boston, MA

Donald A.B. Lindberg Professor of Pediatrics and Biomedical Informatics, Harvard Medical School, Boston, MA

Co-Chair National Academy of Medicine Digital Health Action Collaborative

Subcommittee Chairman Markey, Ranking Member Marshall, and HELP Committee Chairman Sanders and Ranking Member Cassidy, thank you for holding this hearing today and for inviting me as a witness. It is with a deep sense of responsibility and privilege that I offer my testimony as a Professor of Biomedical Informatics and Pediatrics, and Director of a program in Computational Health. I also Co-Chair the National Academy of Medicine's Digital Health Action Collaborative.

With the release of sophisticated large language models like ChatGPT, AI will transform health care delivery sooner than anticipated. These emerging intelligences assimilate vast amounts of information and demonstrate remarkable empathy and profound reasoning. But they are flawed, can produce inaccurate responses, hallucinate, and the precision of their answers changes over time and based on the precise wording of prompts.

Consider AI in the doctor's office. The $48 billion HITECH investment in electronic health records digitized medical information. But these systems also introduced complex and distorted clinical workflows, turning MDs into documentation clerks, contributing to physician burnout and exacerbating the shortage in primary care providers.

An early application of clinical AI attempts to alleviate this self-inflicted problem, placing a microphone in the office, and generating clinical visit notes in real time, just from the overheard doctor-patient dialogue, allowing doctors to face their patients instead of being turned away, crouched over a computer keyboard.

But soon, AI may produce not only the note, but also recommend diagnostics and treatments. Some AI systems may operate independently of physicians, potentially democratizing healthcare access and alleviating physician shortages. But as of now, with no oversight. What if the information is inaccurate? What if a drug company could whisper in the ear of your electronic health record, nudging that AI to favor their pills over a competitor's?

We must anticipate and manage a recalibration of responsibilities within healthcare delivery. How will tasks be allocated between human physicians and their AI colleagues? And will using AI improve care and outcomes. As we speak, patients and doctors are tapping away at keyboards, using ChatGPT to navigate healthcare decisions. But here's the catch — there are no guardrails on this road yet.

As we reshape healthcare around AI, let's remember that today we don't adequately measure whether medical practice is effective. For example, drugs are approved by the FDA with limited data obtained under controlled conditions in a trial.

But, how do approved products fare in the wild, the real world? Do they work like they're supposed to in the messiness of real life? That COVID test you just took, how accurate is it when you're not in a pristine lab, but at your kitchen table? How well did that artificial hip you're about to get work in all the patients who had it before?

The National Academy of Medicine's blueprint for a Learning Healthcare System envisions not just treatment, but learning, and not just from clinical trials but from the vast ocean of real-world data. Each patient's experience informs the care of the next patient by connecting the dots among every visit, treatment, and outcome.

But it's been slow in the making.

The urgency of AI should compel us to accelerate a system that meticulously tracks the real-world accuracy, safety, and effectiveness of not just AI, but also drugs, diagnostics, and devices, procedures, and models of care.

To realize ROI on our $48 billion federal investment we must demand that the data generated are available to support learning. Thanks to the highly bipartisan 21st Century Cures Act and a rule from the Office of the National Coordinator of Health Information Technology, all EHRs must, this year, for the first time, provide a push button export button for their data across what is called an API. Because each hospital or office can produce data in the same format, the care delivery system becomes an interoperable data source in a federated network where the lion's share of data can remain safeguarded at the point of origin. This data can not only drive the development of innovative AI, but also help evaluate AI innovations in real time.

Let's learn from another cautionary tale. The HIPAA privacy rule, passed in 2000, guaranteed patients the right to access their electronic health records. But, without focused enforcement, nearly 20 years went by before this became possible at health system scale.

If the Cures Act APIs are fully supported, we can avoid data monopolies and spark a free market of American innovation in AI, while moving us toward a high performing health system.

Thank you for the opportunity to testify. I look forward to answering your questions.