The Problem: Patients Don't Have Their Own
Digital Health Records

Why aren't medical records freely available for patients' benefit? Why can't patients easily send their health records to doctors and medical researchers? Almost all doctors and hospitals have digital records of their patients. Why don't patients?

The answers are historic, economic, and political.

Medical practices evolved locally and privately. They've never been standardized throughout the United States. There's no standard form of medical record. Doctors properly see themselves as experts, and each hospital and medical office can choose among a variety of formats from the great multiplicity of medical record system vendors. Even the choice of what clinical data elements to record for a given patient varies from practice to practice and specialty to specialty. So do the units in which data are recorded. By tradition, providers as experts do things in their own individual ways. This has been a great strength of our health care system; but as medicine has become more data-intensive and specialized, patient care requires teamwork and coordination across practitioners, specialties, and geographies.

Electronic Health Records (EHRs) for doctors and hospitals were developed with little thought for how they might be exchanged . These computer systems were built by many different companies using different technology plans and different operating rules. Also, each computer system is modified to meet the needs and practices of the hospital or medical office where it is installed. Because of these custom modifications, even two systems from the same vendor typically can't exchange medical records.

File formats and structures are different from system to system. Field lengths (number of binary digits, or bits, in an information unit) vary from system to system. The organization of data in medical records also varies. The recording of lab data, and of crucial metadata for equipment used in diagnosis and treatment, is inconsistent. The only consistently used data standards for *exporting* information from a system are codes used to communicate with payers. No surprise these systems are incompatible. They weren't designed to work together, and they don't.

This is why patients' digital medical records created in one system won't work on, and can't today be routinely transferred to, other systems. They cannot dependably be shared or integrated into a lifetime patient record. As a result, digital medical records are all too often trapped in the systems where they are first written and stored. They're "siloed."

We can't start over and re-build the U.S. medical information infrastructure from scratch so it would all work together. It's too vast and complex. The job would be beyond expensive.

Moreover, patient data is very valuable. It's a goldmine. Hospital systems, insurance companies, and computer system vendors want to keep patient data and use it to build their patient and subscriber bases. It's valuable to universities that conduct medical research, to

pharmaceutical and medical device companies for product development, and to regulators and payers for assessment of products and treatments. So it's jealously guarded.

For all these reasons, medical stakeholders have powerful economic interests in not sharing health data. They want to keep it, for proprietary purposes, in data silos. There exists no institution whose commercial profitability depends on its capacity to store health data that is collected and aggregated on a patient-by-patient basis, securely, for the patient's own benefit and under the patient's control, to help patients shop for and coordinate care, and participate in medical research projects patients care about.

These economic interests translate into politics. Exchanging digital medical records is technologically complicated. Proponents of the status quo in the health industry use that complexity to bog down efforts in Congress and at federal agencies. There is sustained behind-the-scenes lobbying.

It doesn't matter how much patients' groups, clinicians, medical researchers, and academics clamor for making health records exchangeable or "interoperable."   It doesn't matter how valuable interoperable health records would be for better care and faster progress in medical research.

That's why patients don't have their own aggregate, lifetime health records today.

The Solution: A National Health Data Exchange Standard

A mandatory, national, digital, health-data exchange standard will overcome all these obstacles. It will allow all of a patient's information to be collected, aggregated, stored in one place securely under patient control, and be shared with whatever provider or researcher the patient choses.

A nationwide standard is indeed the prerequisite to patients' control and use of their own aggregated digital health records. This standard will herald a new era of faster progress in medical research, better care, better outcomes, lower health care costs, greater patient involvement in care, and more effective patient interaction with the health system.

Why and how would a nationwide exchange standard work? Is it feasible?

Health data in any digital medical record system can be put through an interface to create a data file that is standardized.   The exchange standard would require content (patient data) to be converted to a standardized format. It would also require conversion to a standardized computer code. That file can be sent (output) to any other computer system that has an interface to receive (input) the standardized file's format and computer code.

Once the standardized file is received, another interface converts it to the particular file format and computer code used by the receiving system. The engineering is doable.

Who can write these interfaces? Vendors of all the computer systems used by hospitals and medical offices. What do they need in order to write their interfaces? The national digital health data exchange standard – which would also specify how to send and receive files securely.

Are there legal and political obstacles to doing any of this? Yes, and they can be overcome.

The Office of the National Coordinator for Health Information Technology ("ONC"), part of the Department of Health and Human Services ("HHS"), is already required by statute to develop and enforce a mandatory exchange standard. The 21st Century Cures Act specifies how the standard must be written; engineering features it must contain; and deadlines for ONC to develop the standard, promulgate it, and enforce it.

The Act requires that patients have convenient access to all the elements of their complete digital medical data stored in hospitals, labs, and clinicians' offices, and also generated by the patients themselves. The Act specifies that patients be able to collect and compile their digital health records into one "lifetime," "longitudinal" record.

The records must by statute be "computable," i.e., useable by and exchangeable among various computer systems. Patients must be able to share their lifetime records with others, including clinicians and medical researchers, as they choose. And all this must be doable "without special effort."

To make all this possible, Congress specified the exchange standard as the centerpiece of what the Act calls the "Trusted Exchange Framework and Common Agreement" ("TEFCA"). ONC must create TEFCA under strict deadlines, essentially within a year after preliminary public

comments and meetings that are now past. The clock is running and the deadlines are mandatory.

Obstacles are economic and political. Industry forces want the status quo. No doubt there is political pressure to delay progress. So ONC proposes a collection of voluntary regional standards coordinated by a new, private sector bureaucracy. ONC's plan won't work (it uses disproven technology and failed policy prescriptions), violates the Cures Act's engineering specifications for TEFCA, won't meet the Act's deadlines, and would keep patient data trapped in silos for another decade.

The Cures Act, however, is specific and powerful. If ONC is poised to violate it, patients, clinicians, and medical researchers have standing to rely on the Act to stop the violation. They can force ONC to develop the national health data exchange standard – to comply with the Cures Act – through litigation in federal court. Only then will patients have the means to gather their records easily, aggregate them, and store them securely in accounts the patients own and control.

Nothing else has worked for the last 25 years. Sadly or not, nothing else will work today. Litigation usually is a last resort; but it will succeed now because of the Cures Act. So this is a time for clarity of purpose and action.