

Creating a Learning Health System

► Standard Health Record

How Standard Health Records (SHRs) May Hold the Key to Dramatically Better Patient Outcomes

What does cancer have in common with opioid addiction, heart disease, and diabetes? Unfortunately, numbers—very large numbers.

According to the [National Cancer Institute](#), approximately 38.5 percent of men and women will be diagnosed with cancer at some point during their lifetime. In 2014, an estimated 14.7M people were living with cancer in the United States.

While numbers for cancer and other major diseases are staggering in terms of human suffering, as a specialist in open source software tools for healthcare, I recognize that such large figures also provide potential solutions.

Here's why: odds are that most of those 14.7M people have electronic health records (EHRs) of some kind. And while each patient's record contains a wealth of information about symptoms, treatments, and results that are important to him or her personally, that data also holds potentially valuable information that could help researchers identify better treatments for other people, as well. Essentially, each patient's real-world record may provide clues to help solve real-world problems for many.

There's a big barrier, however, to achieving the promise of using vast quantities of real-world data to achieve better patient outcomes: incompatible data across the many EHR systems. In the following pages, I'll outline:

- The major issues that impact researchers, patients, and healthcare providers
- MITRE's potential solution of combining data from multiple patient records into a patient-centric, standard health record (SHR) for healthcare in general
- How these SHRs could benefit cancer research and clinical treatment specifically.

I'll also offer some thoughts about how the Veterans Health Administration's (VHA) goal to use the same EHR platform as the Defense Department may drive additional insights into the need for, and opportunities that come from, data standardization.

One Human, One Health Record

For perspective, consider that there are more than 1,500 different electronic medical and health record (EMRs and EHRs) IT system products certified as part of “meaningful use” regulations issued by the U.S. Department of Health and Human Services. To be flexible in a variety of clinical settings, most products are highly configurable—which only adds to the complexity and incompatibility across different systems. In addition to capturing too much information as free text, the fundamental problem is that today’s health IT systems contain semantically incompatible information. Because of the great variety of the data models of EMRs/EHRs, transferring information from one health IT system to another frequently results in the distortion or loss of information, blocking of critical details, or introduction of erroneous data. This may explain why, even after health IT has been almost universally adopted, clinicians still routinely share information using old-school methods—such as [fax machines](#).

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At MITRE, our mission is to solve problems for a safer world. As a public interest, not-for-profit organization, we have a unique vantage point working across federal, state and local government, as well as with industry and academia. MITRE is uniquely positioned because we are a conflict-free organization that can provide objective insight; we are often given access to proprietary data because we do not compete with industry or manufacture products. My colleagues at MITRE and I have spent 15 years working on health data interoperability and standards, collaborating with clinicians, provider organizations, health information exchanges, EHR vendors, and standards development organizations to research the practical uses of health data. We have built dozens of prototype open source tools, supporting the development of several major national health IT standards. We have also executed several large-scale clinical studies and pilots in partnership with EHR system developers and integrators, quality measure developers, clinicians, and government health officials, which has helped shape health data standards and open source health information solutions.

Through these efforts, we have found a critical gap in realizing the full potential of EHRs to empower patients and reduce doctor burden. Specifically, patients lack a way to capture a holistic view of their health information spanning multiple care provider EHRs. This gap makes it difficult for patients to own their records and share them with doctors in a portable and secure manner. This, in turn, puts more burden on doctors to ask more questions and re-enter information about a patient’s condition.

In 2017, MITRE launched a global effort to address these challenges, which we call the Standard Health Record Collaborative. The Standard Health Record Collaborative’s central focus is

to establish standards for the structure and content of health record information. Initial implementations will prioritize patient identification, primary care, and emergency care providers.

Our hypothesis: By creating a flexible method for combining a patient's health data from multiple health IT systems and care providers, we could create a single, high-quality health record for every individual in the United States—what we term a Standard Health Record (SHR). This record is standard in the sense it compiles data from multiple existing health records that store a part of a patient's history into a single, comprehensive standard record for the patient throughout his or her lifetime.

Bear in mind, creating an SHR does not mean eliminating the beneficial competition of having multiple EHR systems. It means these systems will share a consistent set of structures and content. The promise of SHR is that no matter where patients go—including among different healthcare systems—they and their providers will have access to a complete and accurate set of the same data. The resulting SHR is patient- and provider-centric, and addresses the dynamic data needs of providers, patients, and caregivers by including data specifications for many areas related to social determinants of health. In fact, the standardization of the data will give us a greater understanding of the variation in patients' stories and experiences.

Each EHR system may present the information in different ways, but the underlying data will be apples to apples, readily accessible to patients and to those providers given permission to share it. This will ease the burden on providers, greatly reduce the "starting all over again" process for patients whenever they see new specialists, and empower researchers with relevant, more easily analyzed data. SHR will also accelerate secondary uses in public health, such as disease "early-warning" surveillance, post-approval monitoring, and patient-centered outcomes research.

Collecting High Quality Oncology Data for Better Treatments and Patient Outcomes

While SHR has the potential to improve outcomes for virtually any disease or healthcare problem, my colleagues and I believe that cancer research is the best place to focus early efforts.

Currently, my MITRE colleagues and I are collaborating with Dr. Monica M. Bertagnolli and others from the Alliance for Clinical Trials in Oncology and Dana-Farber/Brigham and Women's Cancer Institute on the "Integrating Clinical Trials and Real-world Endpoints (ICARE)" data study. The goal of the ICARE data study is to enable clinical oncology research by gathering high quality real-world data from patient records.

According to Dr. Bertagnolli, president of the Alliance for Clinical Trials in Oncology Foundation and chief of the division of surgical oncology at Dana-Farber Cancer Institute/Brigham and Women's Hospital, "Highly accurate clinical outcomes data is an element essential to all efforts to improve our nation's healthcare system and the current high cost of data acquisition severely limits our progress."

With only about 3 percent of cancer patients participating in clinical trials, researchers are limited to a small pool of patient data to evaluate the safety and efficacy of cancer treatments. Yet, clinical trials are currently the gold standard for gathering the complete and precise data critical to cancer research. Clinical trials are expensive, time-consuming to set up, and restricted by limited guidelines. For instance, while a researcher may learn how a specific sequence of treatments affects men under the age of 30, how will it affect women over 60? And what if the sequence of treatments changes? What will that do?

With clinical trials, changing parameters requires the expense and time of recruiting a new group of patients. As the parameters become more targeted, it becomes even more difficult and costly to design and run trials against smaller and smaller populations. In contrast, within the tremendous volume of EHR data, myriad combinations and comparisons of parameters are possible. These data have the promise to provide substantial insights into the understanding of cancer and the design of future clinical trials—if we can overcome the barriers of poor quality and incomplete records due to incompatibility.

SHR data is an asset not only for research purposes, but also for the treatment of cancer patients, as it will provide consistent data to a patient's healthcare team, including multiple organizations, sites, and healthcare settings. In addition, SHR will allow patients to participate more easily in their own healthcare, giving them easier access to their records and contributing meaningful data into standardized files, such as through mobile health applications.

"By delivering an accurate method to use routine clinical care to acquire high quality outcomes data, we will dramatically reduce the time and expense involved in all types of clinical research, ranging from drug development to determination of a treatment's overall value to society."

– Monica M. Bertagnolli, M.D., Dana-Farber Cancer Institute/Brigham and Women's Hospital

Gathering real-world data can address six critical needs:

- 1. Inform patient-driven care** – Understand the efficacy and safety of approved therapeutic agents in populations not adequately addressed by randomized clinical trials. These populations often include individuals aged 15 to 19 and those over age 65, underrepresented minorities, patients living in rural locations, and patients without health insurance.
- 2. Drive rare disease research** – Enable research and develop effective treatments for patients with rare tumors or uncommon subtypes.

- 3. Inform therapeutics development** – Understand the course of untreated diseases and response to therapy for diseases where multiple sequential therapeutic regimens are employed. (For instance, instead of drugs in the order of a, b, c, what happens when they are in the order of c, b, a?)
- 4. Optimize resources** – Provide data so cancer caregivers can optimize their limited resources.
- 5. Inform regulatory decision making** – Achieve efficient and accurate post-market surveillance of FDA-approved therapeutics in the real world.
- 6. Lower provider burden** – Reduce provider burden for collecting and viewing patient data.

Insights from within the VA/DoD Electronic Health Records System

The federal government is taking a leading role in seeking greater healthcare benefits from EHR. At a forum hosted by Politico, [Veterans Affairs Secretary David Shulkin](#) said that now's the time to modernize the VA's electronic health records system and create "as great an interoperability solution as is technologically possible." As the VA moves toward the same electronic health records platform as the Defense Department, Shulkin said he saw it as his job to break the gridlock and address the long-standing issue of disparate medical records head-on.

I expect that the healthcare industry will gain a great deal of insight as VA adopts this EHR to deliver a longitudinal health record for more than nine million veterans receiving care in the largest healthcare system in the country. We also expect that Congress, veterans' advocacy groups, and the White House will closely monitor the mission of keeping veterans healthy and their information safe.

While having two major providers using EHR software from the same vendor is a great step forward, it is critical that outside information be incorporated into the records. More and more veterans are using providers from outside the VHA system, and even service members and their families receive substantial care outside the Military Health System. I think a foundation data model such as SHR is crucial to ensuring data interoperability in a bidirectional manner, supporting the safest, most effective care possible.

Collaborating on a Global Scale

Meanwhile, my colleagues and I believe SHR is not only a logical, but vital, leap forward. Compared with traditional clinical trials, the ability to use real-world data provides access to an exponentially greater level of rich and meaningful information that can be analyzed quickly and easily. In terms

of patients, each of us should be able to access and share complete health records with providers across organizations. By harnessing the power of real-world data, we can solve real-world problems for a safer, healthier world.

Are you in a position to help? We welcome perspectives from all stakeholders in the health community, from clinicians and policymakers to patients and informaticists. To learn more about our ongoing work to develop a new healthcare standard, go to the SHR Collaborative [website](#).

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Mr. Quina specializes in creating and managing teams to develop open source tools for healthcare. He is the project lead for the Standard Health Record Collaborative, an initiative defining a U.S. national standard for the logical content for electronic health records. Mr. Quina has led or supported numerous other projects for MITRE, including developing tools for electronic clinical quality measurement. He received a bachelor's degree in computer science from Worcester Polytechnic Institute and a master's degree in computer science from Tufts University.