

DAY ONE PROJECT

Elevating Patients as Partners in Management of Their Health Data and Tissue Samples

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Summary

From HIPAA to doctor-patient confidentiality, the U.S. healthcare system is replete with provisions designed to ensure patient privacy. Most people are surprised, then, to hear that patients in the United States do not legally own nearly any of their health data: data as diverse as health and medical records, labs, x-rays, genetic information, and even physical specimens such as tissue and blood removed during a procedure.

Providing patients with agency over their health data is necessary for elevating patients as partners in their own health management—as individuals capable of making genuinely informed and even lifesaving decisions regarding treatment options.

The next administration should pursue a two-pronged approach to help do just that. First, the administration should launch a coordinated and comprehensive patient-education and public-awareness campaign. This campaign should designate patient data and tissue rights as a national public-health priority. Second, the administration should expand provisions in the Cures 2.0 Act to ensure that healthcare providers are equally invested in and educated about these critical patient issues. These steps will accelerate a needed shift within the U.S. healthcare system towards a culture that embraces patients as active participants in their own care, improve health-data literacy across diverse patient populations, and build momentum for broader legislative change and around complex and challenging issues of health information and privacy.

Challenge and Opportunity

Patient perceptions of what the U.S. healthcare system is are often at extreme odds with reality. Half of all U.S. patients believe they own their medical records, but this is only true in the state of New Hampshire.¹ Tissue ownership is even more opaque due to the lack of state or federal laws governing this issue.² Ethical and moral debates³ abound as to who should own healthcare data and/or tissue.

Patient rights regarding their health data are currently largely governed by the Health Insurance Portability and Accountability Act (HIPAA),⁴ the Health Information Technology for Economic and

¹ Health Information & the Law. (2015). Who owns medical records: 50 state comparison.

<http://www.healthinfolaw.org/comparative-analysis/who-owns-medical-records-50-state-comparison>.

² Petrini, C. (2012). Ethical and Legal Considerations Regarding the Ownership and Commercial Use of Human Biological Materials and Their Derivatives. *Journal of Blood Medicine*, 3: 87–96. <https://www.dovepress.com/ethical-and-legal-considerations-regarding-the-ownership-and-commercial-peer-reviewed-article-JBM>.

³ Ozair, F.F.; et al. (2015). Ethical Issues in Electronic Health Records: A General Overview. *Perspectives in Clinical Research*, 6(2): 73–76. <https://doi.org/10.4103/2229-3485.153997>.

⁴ HHS (2020). Individuals' Right under HIPAA to Access Their Health Information. Office for Civil Rights. <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>.

Clinical Health (HITECH) Act,⁵ and the Interoperability and Patient Access final rule.⁶ However, more than 40% of individuals have never viewed their health data, only a portion of patients are aware of their right to request their data, and an even smaller portion understands the potential benefits of viewing their data firsthand.⁷ Patients also face barriers in exercising and fulfilling their health-data rights at every turn, from requesting to receiving to managing their information.^{8,9} A recent analysis of the top 83 U.S. hospitals found widespread violation of patients' rights, including blatant misinformation about requesting records, exorbitant costs for fulfilling data requests (for example, \$542 for a 200-page record), incomplete provision of requested records, and limitations on the ways patients could receive their data.¹⁰ Patients also typically experience extended delays in receiving their medical information after requesting.

These problems have real consequences. An estimated 20% of preventable medical errors are due to the lack of immediate access to health information.¹¹ This equates to approximately 80,000 deaths every year in the United States.¹² Improving the accessibility of health data could do much to reduce this number. In addition, providing patients ready access to their health data enables patients to become active participants in their care. Data access allows patients to monitor their chronic conditions, ask informed questions, flag discrepancies and errors in their medical records, ensure their care is coordinated across providers, adhere to treatment plans, share files for more rapid second opinions, and directly donate their information research. According to a survey conducted by the National Coordinator for Health Information Technology, 8 out of 10 patients who have accessed their records found the information useful.¹³

Patient tissue is just as valuable as patient data. Excised tissue specimens (such as a tumor) are critical for translational and clinical research, which in turn is critical for discovery and development of new and novel therapeutics. Tissue banks and large research programs (e.g., the "All of Us" Research Program sponsored by the National Institutes of Health¹⁴ or the "Count

⁵ HHS (2017). HITECH Act Enforcement Interim Final Rule. Office for Civil Rights. <https://www.hhs.gov/hipaa/for-professionals/special-topics/hitech-act-enforcement-interim-final-rule/index.html>.

⁶ U.S. Centers for Medicare & Medicaid Services (2020). Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>.

⁷ Health Data Basics (n.d.) Health Data Education. <https://www.healthdatabasics.org/>.

⁸ HHS (2017). Improving the Health Records Request Process for Patients: Insights from User Experience. Office of the National Coordinator for Health Information Technology. https://www.healthit.gov/sites/default/files/onc_records-request-research-report_2017-06-01.pdf.

⁹ Murphy-Abdouch, K. (2015). Patient Access to Personal Health Information: Regulation vs. Reality. *Perspectives in Health Information Management*, 12: 1c. <https://pubmed.ncbi.nlm.nih.gov/26807075/>.

¹⁰ Lye, C.T.; et al. (2018). Assessment of US Hospital Compliance With Regulations for Patients' Requests for Medical Records. *JAMA Network Open*, 1(6): e183014. <https://doi.org/10.1001/jamanetworkopen.2018.3014>.

¹¹ Fickenscher, K.M. (2013). President's Column: Interoperability—the 30% Solution: From Dialog and Rhetoric to Reality. *Journal of the American Medical Informatics Association*, 20(3): 593–594. <https://doi.org/10.1136/amiajnl-2013-001768>.

¹² Kish, L.J.; Topol, E.J. (2015). Unpatients—Why Patients Should Own Their Medical Data. *Nature Biotechnology*, 33(9): 921–924

¹³ HHS (2017). Improve Patient's Access to Health Information. <https://doi.org/10.1038/nbt.3340>.

¹⁴ HHS (n.d.) National Institutes of Health (NIH) — All of Us Research Program. National Institutes of Health (NIH). <https://allofus.nih.gov/>.

Me In” initiative sponsored by the Broad Institute¹⁵) rely on crowdsourced data and tissue specimens donated by patients to advance lifesaving research.

However, the U.S. healthcare system makes it very difficult for a patient to donate tissue to research studies conducted outside of the patient’s treating institution. Hurdles include exorbitant handling and shipping costs charged to the patient, inconsistent tissue storage and handling, moral and ethical questions surrounding tissue ownership, and legal issues surrounding material transfer agreements (especially at universities). These barriers are especially important to overcome in light of the fact that 90% of patients who participated in the National Cancer Institute focus groups said they would be willing to donate their tissue for research purposes—there is a large gap between the number of patients willing to donate their tissue and the number who actually do so.¹⁶

A first step is educating patients about tissue donation. Proactively raising awareness empowers patients to pursue donation opportunities. For instance, patients can come to appointments prepared to ask about their treating institution’s tissue-disposal policy and about procedures in place if the patient decides to donate tissue to a research study outside of the treating institution. An informed patient is one of the most powerful scientific resources available.

The goal of the policy proposal outlined herein is to educate the public about their health-data and tissue rights as defined by HIPAA, the HITECH Act, and the Interoperability and Patient Access final rule, thereby empowering and informing patients to assume agency *before* they sign consent forms. This proposal aims to help patients understand how to request and access data to improve their health outcomes, as well as to use or donate health data and tissue to advance research. This proposal also aims to expose gaps in patient rights related to biospecimens and to raise awareness about the many benefits of being informed. Focusing on health literacy in all components of this proposal will ensure that no patient is left behind, and that marginalized and underserved patient populations have the knowledge and tools to fight for their health.

Plan of Action

We recommend a two-pronged approach to improve education and awareness surrounding health-data and tissue rights at the patient and provider levels.

Part 1: Public-health Awareness and Education

¹⁵ Broad Institute (n.d.). Count Me In. <https://www.broadinstitute.org/count-me-in>.

¹⁶ Research Advocacy Network (2005). Importance of Tissue Samples in Research. https://www.roswellpark.org/sites/default/files/Importance_of_Tissue_Samples_in_Research.pdf.

While several useful educational resources have been developed^{17,18} to educate the public about their rights to access their health data, there has yet to be a unified national campaign to raise public awareness on what to do with health data once accessed. In the same vein, public awareness surrounding tissue rights (or lack thereof) and donation options has yet to be addressed at the national level. The next administration can take multiple steps to elevate awareness of health-data and tissue rights from a grassroots effort to a national priority:

Develop a “Patient Data and Tissue Bill of Rights”

A “Patient Data and Tissue Bill of Rights” will lay out all rights that patients have with respect to their health information, including the mandate for compliance by health providers. In addition, this resource will provide suggested questions that patients can ask their providers about their tissue rights, including how many tissue blocks¹⁹ the patient has stored by their treating institution and what the institution’s tissue-disposal policy is. This document will be the cornerstone of the patient-education effort at the clinician and grassroots levels.

Development of this bill of rights should be a collaboration among patient advocacy groups, specific disease organizations, family members, caretakers, and patients, with representation from across geographical areas, household-income levels, ages, educational levels, and ethnicities. The bill of rights should be written in multiple languages and versions should be made in alternative modalities (e.g., audio, video) to ensure accessibility. Finally, people of all health-literacy levels should be able to read and understand the bill of rights. To ensure that this is the case, focus groups should be engaged to provide feedback on the content, readability, and usefulness of the bill of rights once developed. Focus groups should be appropriately compensated for their time and feedback.

Develop use cases to ground educational and awareness initiatives in effective storytelling.

Use cases (i.e., case studies) that illustrate the concrete benefits and value of (1) patient access to health data and (2) agency over tissue fate are effective tools for increasing knowledge and interest in health-data and tissue rights. Examples of use cases include:

- Patients who spotted errors in their health data, allowing them to correct faulty treatment.
- Patients who shared their health data with other providers, enabling second and third opinions to better inform care.
- Patients who donated their health data and tissue to research, supporting breakthrough advances.

Development of use cases would do much to foster a culture of openness within the U.S. healthcare system. This effort would build on findings and recommendations released by the National Academy of Medicine and the Patient-Centered Outcomes Research Institute, which

¹⁷ Office for Civil Rights (OCR) (2008). Your Rights Under HIPAA. <https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html/index.html>.

¹⁸ Health Data Basics. Health Data Education. <https://www.healthdatabasics.org/>.

¹⁹ Tissue blocks refer to patient tissue that is removed by a surgeon during a biopsy or surgery for further examination

recently convened a multi-stakeholder steering committee to identify actions that could stimulate more demand for health-data sharing.²⁰

Launch a national awareness campaign coordinated across U.S. public-health agencies

A national campaign is needed to raise awareness about the importance of health-data and tissue rights among all Americans, not just the current patients at whom most existing education efforts are targeted. Proactive education is especially important for reaching people when they have the bandwidth to internalize the message (by contrast, active patients may understandably be preoccupied with immediate treatment concerns). An effective national awareness campaign will leverage many different media channels alongside traditional methods of communication such as fliers, educational videos, and infographics and approaches to reach all communities and age groups.

The Centers for Disease Control and Prevention (CDC) is best suited to be the primary executor of such a campaign given the agency's historical experience and expertise in conducting similar large-scale awareness campaigns for other public-health priorities. Funding for the campaign should be directed by Congress through the CDC's Prevention and Public Health Fund.²¹ The campaign would ideally receive strategic guidance from the Social and Behavioral Sciences Team (SBST), should the next administration decide to reinstate it, or from a similar office. The SBST was historically chaired by the White House Office of Science and Technology Policy (OSTP) and included representatives from a dozen federal agencies as well as offices within the Executive Office of the President. The SBST therefore would be perfectly poised to help steer a large-scale awareness campaign dependent on social-behavior drivers across multiple public-health agencies.

Part 2: Clinician Engagement and Education

Patients face a variety of barriers to exercising their health-data and tissue rights. These barriers are compounded by clinician and/or organizational resistance, as well as poor provider understanding of patient rights. There is not yet clear consensus among medical professionals that patients should have unfettered access to their data or tissue. Clinicians may fear that granting such access could impose additional workloads on providers or disrupt healthcare workflows. In addition, clinicians may not fully understand existing legal requirements that already mandate a large amount of access.²² Education and awareness at the healthcare-provider level will position providers as catalytic advocates for patient rights. As such we recommend that the next administration pursue the steps outlined below.

²⁰ National Academy of Medicine (2020). Health Data Sharing to Support Better Outcomes. Whicher, D.; et al. [Eds]. https://nam.edu/wp-content/uploads/2020/11/Health-Data-Sharing-to-Support-Better-Outcomes_prepub-final.pdf.

²¹ U.S. Centers for Disease Control and Prevention (2018). Prevention and Public Health Fund. <https://www.cdc.gov/funding/pphf/index.html>.

²² Donovan, F. (2018). Patient Privacy Rights Education Requires Provider Input. Health IT Security—xtelligent Healthcare Media, September 14. <https://healthitsecurity.com/features/patient-privacy-rights-education-requires-provider-input>.

Execute a pilot education program surrounding patient health-data and tissue rights

Patients deserve proper education regarding their core health-data and tissue rights. Much education will need to come from providers. The next administration should launch a pilot program to train providers on how to be effective educators, through the Office of Civil Rights, Department of Health and Human Services (HHS). This program could be structured as an extension of requirements in Title III of the Cures 2.0 Act: Patient Engagement in Health Care Decision-Making.²³ The program should be developed and implemented in collaboration with stakeholders including healthcare organizations, social-impact organizations that focus on health data and/or patient empowerment, and nonprofits focused on health and social behavior. Specifically, the pilot should train providers to:

- Help patients understand (i) their rights to access their health data, and (ii) what is included as part of their full “designated record set”.²⁴
- Help patients understand their rights (or lack thereof) with respect to tissue samples.
- Disseminate foundational informational resources like the patient data and tissue bill of rights proposed above and suggest additional online resources that patients can access any time.
- Ensure that patients have sufficient time to digest information before being asked to make decisions.
- Educate patients on how to effectively use their health data or share their tissue samples (e.g., guidance on how to access their records for review, or seek a second opinion). Education should also include informing patients about the potential unintended consequences of having access to their designated record set.

The pilot should include clear metrics to evaluate effectiveness and outcomes. The pilot should also include a requirement and plan for scaling up implementation of findings and lessons learned from the pilot.

Issue a compliance notice to reiterate providers’ legal obligations with respect to patient health-data rights

The Centers for Medicare & Medicaid Services (CMS) should issue this notice annually to hospitals and provider groups, with special attention to those responsible for records management. The goal of this low-barrier intervention is to remind providers of their legal obligations with respect to patient health-data rights under HIPAA, the HITECH Act, and the CMS Interoperability and Patient Access Final Rule, as well as of the legal ramifications of noncompliance.

Develop a brief mandatory Continuing Medical Education course focused on patient health-data and tissue rights

²³ (2020). 21st Century Cures 2.0. Office of U.S. Congresswoman Diana DeGette.

https://degette.house.gov/sites/degette.house.gov/files/Cures%202.0%20Concept%20Paper_0.pdf.

²⁴ Bricker & Eckler Attorneys at Law (2020). HIPAA Privacy Regulations: Definitions - Designated Record Set - § 164.501.

<https://www.bricker.com/industries-practices/hipaa-health-information-technology/insights-resources/resource/hipaa-privacy-regulations-definitions-designated-record-set-%c2%a7-164501-318>.

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Continuing Medical Education (CME) courses are comprehensive events designed to expand or reinforce pertinent knowledge for providers, particularly as it relates to services provided for patients and the public. This course should be developed by HHS in collaboration with the American Medical Association and similar partners and could integrate existing resources (such as those developed by the HHS Office for Civil Rights). Course topics should cover the importance of health information sharing, ways in which patients can contribute their data or tissue specimens and maintaining regulatory compliance as set out by HIPAA, the HITECH Act, and the CMS Interoperability and Patient Access Final Rule, and the Federal Trade Commission (FTC) Act.²⁵

Issue a guideline and subsequent mandate for hospitals to document all tissue samples in a standardized report

This report should include information on the types and amounts of tissue collected from a patient, how much tissue is needed for clinical use (i.e., diagnostic tests), how much has been shared with research organizations, how much remains, and how long the tissue will be held before being disposed of. Standardizing reporting in this way will improve knowledge about tissue availability in the United States. Reports should be made available to patients so that patients are aware of the tissue that was extracted and when the extracted tissue will be disposed of, giving patients time to share remaining samples for research purposes. Ideally, reports will ultimately include unique codes to support tissue tracking and organization of tissue data.

²⁵ HHS (2016). Sharing Consumer Health Information? Look to HIPAA and the FTC Act. Office for Civil Rights. https://www.ftc.gov/system/files/documents/plain-language/pdf-0219_sharing-health-info-hipaa-ftcact.pdf.

Frequently Asked Questions

Why is HIPAA inadequate for ensuring patient access to their health data?

Although HIPAA establishes the right for patients to access their health data, no broad effort has been made to ensure that all patients are aware of these rights. Many individuals do not know they can access their health data. Those that do know may not know that they are entitled to *timely* access and that if they are denied access, they are entitled to a written letter explaining why.

For more information on HIPAA, please refer to the U.S. Department of Health and Human Services.²⁶

What is the HITECH Act?

In 2009, the HITECH Act, enacted as part of the American Recovery and Reinvestment Act, instructed HHS to strengthen individuals' data-access rights in a number of important ways. First, it expressly required healthcare providers that had adopted electronic health-record technology to give individuals electronic access to their health data. The HITECH Act also specified that individuals have the right to direct their provider to transmit a copy of their health records to a designated person or entity, including web-based applications.

For more information on the HITECH Act, please refer to the U.S. Department of Health and Human Services.²⁷

What is the CMS Interoperability and Patient Access final rule (CMS-9115-F)?

The CMS Interoperability and Patient Access final rule (CMS-9115-F) gives patients access to their health information when they need it most and in a way they can best use it. Part of the Trump Administration's MyHealthEData initiative, this final rule improves data interoperability and patient access to health information by using CMS authority to regulate Medicare Advantage, Medicaid, CHIP, and Qualified Health Plan issuers on the federally facilitated exchanges (FfEs).

For more information on this rule, please refer to the U.S. Centers for Medicare & Medicaid Services.²⁸

²⁶ HHS (2020). Your Rights Under HIPAA. Office for Civil Rights. <https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html>.

²⁷ HHS (2017). HITECH Act Enforcement Interim Final Rule. Office for Civil Rights. <https://www.hhs.gov/hipaa/for-professionals/special-topics/hitech-act-enforcement-interim-final-rule/index.html>.

²⁸ U.S. Centers for Medicare & Medicaid Services (2020). Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information. Health Informatics and Interoperability Group. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>.

How does the Federal Trade Commission (FTC) Act play a role in sharing patient health data?

The FTC Act prohibits companies from engaging in deceptive or unfair acts or practices in or affecting commerce. Among other things, this means that companies must not mislead consumers about what is happening with their health information. Therefore, businesses need to do more than just meet minimum requirements for HIPAA compliance. R must consider all statements to consumers to make sure that, taken together, they don't create a deceptive or misleading impression.

For more information on the FTC Act, please refer to the U.S. Department of Health and Human Services.²⁹

What constitutes health data?

HIPAA states that patients have access to their designated record set, which in most cases includes any clinical records, billing records and diagnostic records (including x-rays and images). In addition, it includes any other records used to make decisions about an individual.

We believe that biological material, such as tissue and blood, should be considered a component of health data. While patients may not be able (or want) to readily access these materials, we believe that patients have a right to know what samples are being stored, how they are being used for clinical or research purposes, how much remains, and when samples will be destroyed.

Who owns patient data?

Although by law patients have privacy, security, and accessibility rights when it comes to their own health data, New Hampshire is the only U.S. state that explicitly gives patients ownership of their health data. In other states, once health-care information is captured (either in written form or electronically), the provider gains possession of that information. The provider is then bound by specific legal rights and duties relating to possession and protection of the information.

How much would a national awareness campaign surrounding health-data and tissue rights cost? How would the campaign be funded?

The cost of such a campaign will depend on the campaign's length, the media used to raise awareness, and the agency that carries out the campaign. Using past public-health campaigns for reference, we estimate the cost of such a campaign at \$5–10 million per year for the duration

²⁹ HHS (2016). Sharing Consumer Health Information? Look to HIPAA and the FTC Act. Office for Civil Rights. https://www.ftc.gov/system/files/documents/plain-language/pdf-0219_sharing-health-info-hipaa-ftcact.pdf.

of the campaign. Costs may need to be slightly higher initially to launch the proposed pilot provider-education program. We recommend that funding for this campaign be directed by Congress through the CDC's Prevention and Public Health Fund. We further recommend that the CDC steward the campaign, given past success and experience conducting similar awareness campaigns related to heart disease, tobacco control, diabetes prevention and other public-health priorities.

What can be done at the grassroots level to complement federal involvement in health-data and tissue rights?

Much can be done at the grassroots level. Advocates and organizations can work together to educate physicians across rural and urban settings on patient's rights to access their health data and to standardize tissue sample documentation.

Should patients have the right to direct their tissue to the research organization of their choice?

We believe that patients should ultimately have the right to direct their tissue where they want it to go in order to advance research. But it may be premature to establish this right at this time. Before establishing this right, we as a nation need a better understanding of available tissue in order to ensure that sufficient quantities remain for clinical care, and to understand the supply of tissue relative to the supply of infrastructure available for distribution, storage, and oversight of tissue samples. This is why standardizing tissue reporting is an essential first step. Detailed tissue reporting will not only increase transparency for patients right now, but will also facilitate strategic investments in our nation's tissue-management systems that will pave the way for stronger patient rights over tissue samples in the future.

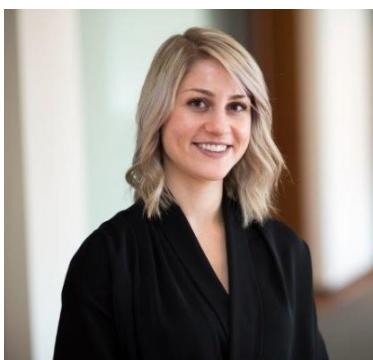
What infrastructure and oversight would be required for patients to donate their tissue to the organization of their choice?

First, an experienced organization would need to oversee preparation, distribution, tracking, storage, and distribution of tissue. The overseeing organization would need to establish standard specimen-preparation protocols and reliable specimen-transportation systems. Repositories would need to be established for secure physical storage of tissue and electronic storage of tissue data (including genomic and metadata associated with tissue samples). Protocols would need to be established for approved individuals and institutions to access samples and data for research purposes.

About the Authors



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About the Day One Project

The Day One Project is dedicated to democratizing the policymaking process by working with new and expert voices across the science and technology community, helping to develop actionable policies that can improve the lives of all Americans, and readying them for Day One of the next presidential term. For more about the Day One Project, visit dayoneproject.org.