Laboratory Results Release to Patients under the 21st Century Cures Act: The Eight Stakeholders Who Should Care

Simone Arvisais-Anhalt[1] Neda Ratanawongsa[2] Shobha Sadasivaiah[3]

[1] Department of Laboratory Medicine, University of California San Francisco, San Francisco, California
[2] Department of Medicine, Center for Vulnerable Populations, University of California San Francisco, San Francisco, California
[3] Department of Medicine, University of California San Francisco, San Francisco, California

Address for correspondence Shobha Sadasivaiah, MD, Department of Medicine, University of California San Francisco, 1001 Potrero Avenue, San Francisco, CA 94110 (e-mail: Shobha.Sadasivaiah@ucsf.edu).

Appl Clin Inform 2023;14:45–53.

Abstract

A major aim of the 21st Century Cures Act is to support patients' access to their electronic health data and to prevent information blocking practices by health care organizations and health information technology developers. Prior to the Cures Act, significant variation existed in patient access to laboratory test results, key pieces of health data which enable timely self-management and engagement in care. Although many health care systems began releasing test results immediately through patient portals because of the Cures Act, implementation remains challenging due to variations in state regulations around electronic results release, local interpretations of allowable exceptions to Cures information blocking, concerns about privacy of sensitive laboratory results, and technological limitations. This paper outlines the eight stakeholder groups involved in implementation of electronic laboratory result release to patients and describes recommendations for these groups to consider in achieving the Cures Act goals to support a patient's access to their health information and control of their health care.

Keywords

- patient portals
- electronic health record
- health information technology
- clinical informatics
- decision-making
- laboratory

Background and Significance

Patients have not always had direct and immediate access to their laboratory test results, but this has changed rapidly with the United States (U.S.) implementation of the 21st Century Cures Act Final Rule. The U.S. 21st Century Cures Act was signed into law in 2016, to "accelerate the discovery, development, and delivery of 21st century cures, and for other purposes."[1] The Office of the National Coordinator for Health Information Technology (ONC), through its Health IT Certification Program, is responsible for implementing the interoperability and information blocking portions of the Cures Act Final Rule.[2] Starting April 5, 2021, the Information Blocking Provision of the Cures Act Final Rule mandated that patients have unencumbered, free access to their electronic health information (EHI) as defined by the U.S. Core Data for Interoperability version 1, including all laboratory test results. On October 6, 2022, the Final Rule expands to all EHI.

Of note, the Cures Act final rule does not increase the type of health information that patients can access, which was codified under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. Instead, the Cures Act final rule ensures that health care providers, health information exchanges, and electronic health record (EHR) vendors do not participate in practices that could interfere with access, use, or exchange of information. However, because of continued variability in state regulations and stakeholder

received
August 22, 2022
accepted after revision
November 28, 2022
accepted manuscript online
November 30, 2022

DOI https://doi.org/10.1055/a-1990-5157.
ISSN 1869-0327.

perspectives, the implementation of laboratory result release to patients remains complex.

Based on a review of available literature and the authors' consensus from implementation experience, this paper outlines the history of regulations related to laboratory release to patients, details the variability in implementation of the Cures Act Final Rule, and describes the differing views and evidence surrounding the effect of laboratory result release on patient care. Then, this paper synthesizes the literature review into recommendations for the eight stakeholder perspectives that should be considered in designing the process of laboratory release to patients and provides a set of recommendations for more effectively achieving the Cures Act's stated goals.

Before Cures Act: Variability and Poor Compliance with Meeting Patients' Rights to Access Information under HIPAA

Before the implementation of the Information Blocking provision of the Cures Act, clinical laboratory sharing of results varied geographically and was largely governed by state-specific laws and Centers for Medicare & Medicaid Services regulations through the Clinical Laboratory Improvement Amendments (CLIA).[3] Before the Cures Act, state laws varied widely with several states authorizing clinical laboratories to release laboratory results directly to patients, while others only authorized direct release to ordering clinicians.[3] CLIA, which governs U.S. laboratory practices, only allows clinical laboratories to release laboratory results to authorized persons and to individuals responsible for using test results.[3] CLIA does not explicitly permit clinical laboratories to release results directly to patients and instead defers to state laws. In the absence of state guidance, CLIA specifies that clinical laboratories may only release test results to individuals who ordered the test.

Once a clinician has received laboratory results from a clinical laboratory, patients have the right to access those results through that clinician under the HIPAA Privacy Rule. However, prior to the Cures Act, hospitals showed poor compliance and burdensome processes for patients' requests for their records. One study which included 86 U.S. hospitals across 29 states illustrated noncompliance across several areas including hospitals refusing to provide records in the format requested by the patient, surpassing state requirements for processing times, and charging above the federal recommendation of $6.50 for electronically maintained records.[4] Prior to the Cures Act, variation occurred in: what laboratory results health care systems shared or withheld (e.g., genetic testing, drugs of abuse testing, sexually transmitted infection testing, etc.); when health care systems shared laboratory results (e.g., immediate release, delayed, or even released at all); and how health care systems shared laboratory results (e.g., electronic, physical mailings, and fax).

Implementing the Information Blocking Provision of the Cures Act Final Rule: Continued Variability and Complexity

The Information Blocking Provision of the Cures Act Final Rule aims to help patients access their test results in a timely manner, unless state laws govern otherwise or an exception to the information blocking provision applies. To avoid practices that could be deemed information blocking, many health systems have released most (if not all) laboratory results to patients as soon as they are finalized by the clinical laboratory through patient portals, which are secure websites where patients can access their EHR information.

The Cures Act has not standardized practices in laboratory result release to patients for several reasons. First, state laws governing electronic laboratory release to patients continue to differ. For example, in California, HIV antibody tests, hepatitis antigen tests, drugs of abuse tests, and tissue tests revealing a malignancy must be disclosed to a patient by means of oral communication, such as in person or by telephone, unless the patient requests a different means of disclosure.[5] In Kentucky, state law requires a clinician deliver the results of a positive HIV test to the patient in combination with appropriate counseling and referrals.[6] As a result, health care systems must balance Cures compliance with state regulation compliance in implementing laboratory release to patients, and organizations within the same state may differ in interpreting this balance. Furthermore, large health care systems with facilities spanning multiple states must be aware of state-specific differences in these laws.

Second, institutions may differ in their interpretation of allowable exceptions to the Information Blocking Provision. Among eight exceptions to the Information Blocking Provision, the two exceptions for the ordering clinician include the preventing harm exception and the privacy exception.[7] The preventing harm exception states that, provided certain conditions are met, a clinician can prevent a patient's access to their EHI if it is "reasonable and necessary to prevent harm to a patient or another person."[8] A clinician must reasonably believe that preventing a patient's access to their EHI will significantly reduce a risk of substantial harm, and that the interference is no broader than necessary, thus excluding "blanket" applications for a given type of care situation or a specific patient. The privacy exception exempts clinicians from information blocking risk when the intent is to protect the patient's privacy. This can be applied when more stringent state privacy regulations exist compared with U.S. regulations or when patients request information to be kept confidential. It is up to the health care system to interpret these exceptions in the context of state privacy regulations and guide their clinicians on when to invoke them in practice. Confusion remains over compliant interpretation and implementation of the Information Blocking Provision and its exceptions.[7,9,10]

Third, state laws vary in how they govern minors' ability to consent to specific services such as reproductive or mental health services and in minors' confidentiality rights. When both minors and guardians may have electronic access to a minor's health information, health systems may opt to block electronic laboratory release to avoid risk of inadvertent disclosure to guardians. For example, in California, minors may consent to services such as birth control, pregnancy, and sexually transmitted infection services, but parents cannot be notified unless the minor agrees.[11] Thus, health care

systems must consider how to protect minors' confidentiality rights under California law (protecting pregnancy test results) while avoiding information blocking practices preventing guardians access of non-confidential health information (allowing guardian access to allergy tests). The technical and workflow mechanisms for accomplishing this balance remain very complex for many health care organizations, and clinicians in many health systems are left to weigh whether blocking a laboratory release is appropriate to respect adolescent privacy laws for example or is considered information blocking.[12,13]

Finally, the penalties for information blocking have yet to be fully implemented, which may result in different interpretations in the importance of complying with the Cures Act Information Blocking provision. ONC encourages individuals who have experienced information blocking to file complaints for the Health and Human Services Office of Inspector General to investigate. From April 5, 2021 to June 30, 2022 ONC received 441 complaints of information blocking through their online portal and deemed 407 to be possible claims of information blocking.[14]

The Effect of Laboratory Results Release on Patient Care: Differing Views and Evidence

Before and since the implementation of the Information Blocking provisions of Cures Act, many groups have expressed concerns over potential patient harm in laboratory result release of certain results before outreach by the clinical team.[15] One study surveying 82 oncologists revealed that 87% of the oncologists agreed that patient online access to abnormal radiology/pathology results before consultation has negative consequences.[16] Another study surveying 315 physicians in the United States and Australia revealed that physicians were generally in favor of direct notification of normal results (i.e., without physician review) but had substantial concerns about direction notification of abnormal results.[17] Other studies cite potential benefits to patients of having immediate, direct access to their information, such as clinical notes. One study investigating the experience and perceptions of patients who read ambulatory visit notes revealed that patients find note reading very important for their health management and share their notes frequently with others; patients are rarely troubled by what they read; and patients traditionally underserved in the United States report particular benefit to note access.[18] It remains to be seen how the immediate release of laboratory results affects patient outcomes.

Considering the current state of releasing test results across the United States, in the section below, we identify and describe eight key stakeholders' viewpoints and provide a set of recommendations for more effectively achieving the Cures Act's stated goals (►Table 1).

Eight Key Stakeholders

Patients, Families, and Caregivers

Although patients are central to the Cures Act, additional support is needed to ensure the preferences of patients, families, and caregivers are reflected in the ways laboratory results are released electronically. Although many health systems are now releasing most laboratory test results immediately to patient portals upon finalization, patients may differ in their preferences for when and how they want to receive test results, preferences that could change depending on the specific result or clinical scenario. Thus, patients should be informed when options exist to set personal communication preferences. For example, some patients may not want to be notified that they have new test results available for viewing on the patient portal and prefer to discuss with their clinician during an appointment. However, if their preferences for a specific test result differ, patients may need to ask their clinicians to block a particular test result from release when ordered or may need to be counseled to avoid viewing a result even when it is technically available to them. Conversely, patients may be surprised when some results are not released or have delayed release due to interpretations of state regulations. An additional dimension worth considering is a patient's health literacy and numeracy, and how they influence the patient's ability to both access and understand the meaning of a laboratory result.[19,20] Clinicians should encourage their patients to discuss any concerns about how they receive test results ahead of time with their care team and encourage patients to discuss any concerns surrounding their understanding of laboratory tests being ordered in the context of their care. Settings in which the patient and/or families/caregivers are present with the care team when the result is received, such as emergency departments[21] or inpatient areas, may present unique opportunities and challenges that warrant further consideration.

Finally, patients may have proxies, such as families or caregivers, accessing their EHI on their behalf, but patients may not want certain laboratory results shared with proxies.[22] The strategies to address these nuances depend on state laws, feasibility of data segmentation, and institutional practices. Before granting proxy access to a proxy, health care systems should provide clear, jargon-free information to help patients understand health system practices for what will get released to proxies through their patient portals. Adolescent patients, other patients with proxies, and proxies should be educated about what the proxy access entails, how results are restricted, and how these restrictions change over time.

Clinicians and Care Teams

Clinician communication with patients about test results is critical to quality patient care and engagement. With electronic laboratory result release through patient portals, clinicians must balance what is set by their health systems to comply with regulatory mandates while simultaneously respecting the needs of individual patients. Clinicians should counsel patients ahead of time that a test result may be available to them immediately and that patients may see the result before the clinician. If the test is particularly critical to a diagnosis or change in treatment plan, clinicians must make a plan with the patient for when and how they will discuss the results. For sensitive laboratory tests, such as

Table 1 Recommendations for eight key stakeholders involved in the implementation of electronic laboratory results release based on the review of available literature and the authors' consensus from implementation experience

Stakeholders	Considerations	Recommendations
Patients, families, and caregivers	Patients have individual preferences as to when and how they would like to receive test results	When multiple options available for receiving test results, set communication preferences for your personal preferences
	Patients' preferences for receiving test results may vary with test and clinical scenario	Prepare to not view a test result online when you feel that you would prefer to hear the result from your clinician or view at a more convenient time electronically
	Certain test results deemed sensitive by state or federal policy may not be deemed sensitive by patients. Test results deemed sensitive by patients may not be covered under current state/federal policy	Discuss ahead of time with the care team concerns about receiving test results
	Proxy access is determined by the health care organization and limits patients' ability to choose what is shared/restricted with families and caregivers	Understand what is shared in the health system where you are getting care before giving someone proxy access to your health information
Clinicians and staff	Clinicians must both abide by federal/state regulations and also engage patients in their preferences for receiving health information and desires for privacy	Discuss with patients ahead of time what the test results could show and the possibility that a patient could view the result before the clinician
	Thorough evaluation of a specific health issue may require ordering multiple sensitive laboratory studies	Use language with patients that reduces stigma and be clear with what is being ordered and why to prevent surprises to patients when viewing results electronically
	Clinicians want to get patients into timely treatment and care, especially urgent when public health is at stake	Release results immediately, if not automatically released at your organization at the time resulted by the laboratory
Health information technology/ informatics	Health information systems are often asked to build complex systems of sharing and restricting data for patients and their proxies	Work with EHR vendor support to understand options and limits of technical configurations within current systems
	Health information systems can be configured in different ways to respect state and federal regulation, each with different pros and cons	Work with multidisciplinary stakeholder groups including clinicians, legal and compliance, health information management, risk management, and patient experience to determine optimal approach
	Regulations and EHR capabilities change over time	Plan to review technical configuration in EHR with regular cadence to ensure best practices are being deployed
Health care organizations	Health organizations must interpret state and federal data sharing policies in context of internal policies	Design policy that is equitable, reflects excellence in clinical practice, and can be met with currently available technical tools
	Health systems cater to different patient populations with diversity of needs and concerns	Engage with clinical leaders and vulnerable patient populations at your health care organization
	Health care systems are obliged to share laboratory data with patients and proxies, though certain patient populations may have difficulties accessing their data due to systemic inequities in digital literacy and access	Provide support to patients and families who need extra help to find and understand test results
	Clinicians within a health care system may face varying challenges around communicating test results and have different workflows	Develop policies that take clinician workflow into consideration and provide ample education and support while implementing and maintaining change
Laboratories	Patients may ask laboratories for release of or explanations about test results	Develop standard processes for answering questions from patients and guiding them to the correct resources to address their needs
	State laboratory release laws may pose challenges for laboratories that work across multiple state lines	Work with laboratory compliance managers to understand and advocate for reconciliation (or alignment) of state and federal policies
	State adolescent privacy laws may pose challenges for laboratories that work across multiple state lines	Work with laboratory compliance managers to understand and advocate for reconciliation (or alignment) of state and federal policies

Table 1 (*Continued*)

Stakeholders	Considerations	Recommendations
EHR developers and vendors	EHR developers face challenges designing systems that can customize to individual health care organizations and their interpretation of state and federal regulation	Work with compliance managers to understand and advocate for reconciliation (or alignment) of state and federal policies
	Patients will vary in how they wish to receive test results electronically	Allow options for delayed result release at the time of ordering by the provider and options for patients to delay result receipt after the time of ordering
	Patients desire to control their individual data and who can access individual elements and for how long	Allow options for patients to control what information is released to patients and proxies beyond what is standardly configured by a health system
	Many patients are not easily able to take advantage of existing EHR capabilities to view test results due to risk factors for digital inequity (e.g., language or digital literacy)	Invest in research and development to provide systems that allow for multilingual support and include patients in system design to ensure interfaces are easy to navigate and provide health care systems tools, such as data dashboards, to determine if inequities in access to test results within a health care system exist by race, ethnicity, language, age, or other predictor of digital inequity
	Clinicians want to meet patients' needs in ways that are optimized for efficient workflows	Confer with end users on how to make innovation that fits patient needs and enhances clinician workflows
Healthcare technology innovation	Applications offer ability to consolidate data across disparate EHRs and health systems	Design applications that allow for increased patient choice for data sharing, segmentation, and restriction while maintaining patient safety and privacy concerns and following an approach grounded in health equity to ensure that historically underserved patients have the best possible access to innovative technologies
State and Federal policymakers	Policymakers are tasked with achieving maximum interoperability to improve patient outcomes, care coordination, and reduce costs while also respecting patients' rights to their data and for privacy	Standardize policies across state lines and in alignment with federal regulations, where possible
	Policymakers asked to support policy around electronic laboratory release must evaluate which test results warrant special protections prior to electronic release	Approach policymaking with grounding in health equity to make determinations if certain groups may be disproportionately impacted by restrictions in this access
	Policymakers asked to support policy around restricting results release to patients before they are communicated by their clinician should evaluate which tests warrant special protections due to harm to patients who see results before discussion with their clinician	Approach policy making with grounding in health equity to make determinations if certain groups may be disproportionately impacted by restrictions in this access. Consider both the potential risks and benefits of patients having immediate access to a specific type of test result
	Policymakers must balance public health needs with concerns surrounding patients receiving a sensitive result	Where public health or safety is at stake, consider whether restrictions on electronic release would be beneficial or harmful to patients and communities for disease control efforts
	Policymakers receive concerns from clinicians, EHR vendors, patients, and families around overly/underly prescriptive legislation surrounding results release	Engage all stakeholders in depth to evaluate concerns and collect data to support changes in policies over time

Abbreviation: EHR, electronic health record.

genetic testing, certain infectious disease testing, and testing that could reveal a malignant diagnosis, clinicians should discuss what is being ordered using non-stigmatizing language to prevent patients feeling surprised by the results.

Health Information Technology/Informaticians

Health information technology (IT) experts and informaticians are primarily responsible for building and testing systems for sharing EHI. In this role, they are often asked

to build complex systems capable of both sharing and restricting data for patients and their proxies, taking into account challenging issues such as user-friendly interfaces, clinical workflows, and data segmentation (the capability of an EHR to suppress certain PHI within the context of other PHI, such as the capability to suppress certain paragraphs of a clinical note, some laboratory results, some medications, etc.). This group must work closely with the EHR vendors to understand fully the options and limitations of their systems and advocate for patient empowerment and equitable care that does not come at the expense of efficiency in clinician workflow. Despite our ability to leverage modern EHRs to deliver test results to patients electronically through patient portals, the variance in local regulatory interpretation of state and federal laws prohibits a one size fits all approach for a compliant EHR. Thus, IT analysts and informaticians must work with multidisciplinary groups in their institution including clinicians, legal and compliance, risk management, and patient experience to determine the optimal approach for configuration in a given health system. They need to craft education to help individual patients and clinicians understand how individual preferences may or may not be met under their system settings. Lastly, despite efforts to implement suitable configurations, regulations and EHR capabilities are constantly evolving; therefore, IT analysts and informaticians should plan to review their technical configuration regularly to ensure that the best practices regarding results release are deployed.

Health Care Organizations

Health care organizations play an important role in the design of how test results are released to patients and have their own unique considerations. When designing internal policies and practices, organizations must interpret local, state, and federal data sharing policies in addition to understanding the needs and concerns of their patient population and clinicians, developing policies that reflects best practices for clinical care, patient experience, and equity. Each health system caters to different patient populations with diverse needs and concerns. For example, a pediatric hospital may have different concerns regarding results sharing than an adult oncology hospital. Patients also differ in their ability to access their laboratory data due to systemic inequalities and digital literacy.[23] As part of a comprehensive plan for health equity, health care organizations should provide support to patients and families, such as elderly and uninsured patients, who have been shown to be less likely to use patient portals[24] and may need extra help to gain access to and use patient portals to access their data.[23]

When it comes to implementation, organizations should support clinicians and their care teams, who may be variably equipped to implement the workflow processes related to laboratory results release. For example, if systems expect or experience that on demand access to EHI leads to increased calls and messages to the clinical teams,[25] health care organizations should ensure sufficient resources to support clinicians, their care teams, and patients in facilitating communication and discussion of laboratory results. Additionally, consideration should be given to designing EHR result routing and communication workflows to leverage team-based care and population health management.[26] Leadership should always engage with clinicians when designing and implementing new policies to ensure that care teams have ample education and support to provide the best possible care. Lastly, organizations may benefit from consulting their local ethics committees when reconciling stakeholder tensions in the ethical and legal considerations in the design of policies around laboratory result release.

Laboratories

Laboratories have variable considerations and responsibilities in complying with reporting requirements depending on their structure and the geography they serve. Hospital-based laboratories across the United States will likely be folded into broader institutional decision making, using the same laboratory release procedures and policies as other EHI captured in the EHR is reported. Standalone laboratories, such as commercial laboratories and reference laboratories, must develop strategies to comply with federal and state regulations to report these results to patients. Laboratories that work across multiple state lines must be aware of and comply with geographic differences in reporting requirements and adolescent privacy laws. Additionally, laboratories must be prepared to receive calls or messages from patients asking for explanation of test results. Considering this current landscape, laboratories should work with state and federal policy makers to understand constraints and develop standard processes for answering questions from patients to guide them to the correct resources to address their needs.

EHR Developers and Vendors

Heath care systems and laboratories invest millions of dollars in their EHRs and Laboratory Information Systems and their workflows are tied to the capabilities offered to them through these technologies. EHR developers face challenges meeting the adaptability and customizability requirements needed by end users to comply with state and federal regulation. EHR vendors should stay abreast of policy development at the state and federal level and listen to the dilemmas raised by informaticists and health care organizations in defining and troubleshooting the technical challenges of proposed policy. EHR developers must also make greater efforts to elicit the preferences of diverse patients, a stakeholder group not always at the table for technology companies. Patients vary in how they wish to receive test results electronically and desire to control their individual data, including who can access individual elements and for how long. Thus, developers should work toward building systems that give additional control to patients on how to receive and share their EHI. Many patients are not able to easily take advantage of existing EHR capabilities to view test results due to communication barriers such as language or digital literacy, and thus it is imperative that investments are made in systems that can provide and maintain multilingual support and are easy to navigate interfaces. Vendors should provide health care systems tools, such as data dashboards,

to determine if inequities in access to test results within a health care system exist by race, ethnicity, language, age, or other predictors of digital inequity. Lastly, EHR vendors need to consider how to optimize clinical care team workflows for ordering, reviewing, and communicating laboratory results, collaborating with end users on how to make innovation that fits patient needs and enhances clinical workflows.

Health Care Technology Innovation

One of the major motivations for the Cures Act Final Rule is to create an environment that is fertile for digital health innovation. ONC wants to empower patients to interact "with their health record in a modern health IT economy."[27] Third-party health care innovators are uniquely positioned and encouraged to offer applications (apps) that consolidate data across disparate EHRs and health systems, giving patients more options and autonomy over their EHI. There is much enthusiasm and support from the health care community for a digital health transformation and optimism for how mobile health (mHealth), remote patient monitoring, and enhanced access to conventional health records can improve patient experience and outcomes.[28,29] Innovators should design apps that allow for increased patient choice for data sharing, segmentation, and restriction while maintaining patient safety and privacy concerns and following an approach grounded in and focused on achieving health equity[30,31] to ensure that historically underserved patients have the best possible access to innovative technologies.[23]

State and Federal Policymakers

Regulations, policies, and laws are key drivers in how laboratory results are released to patients and proxies and should be informed by the needs of the diverse stakeholder groups discussed above. Policymakers are driving toward maximum interoperability to improve patient outcomes, care coordination, and reduce costs while also respecting patients' rights to their data and privacy. In the era of interoperability where clinical care and data can cross state lines, policy standardization across state lines and in coordination with federal regulations would simplify implementation for the stakeholders above. However, since the Cures Act does not consider practices that comply with state law to be information blocking and thus do not require invoking a specific information blocking exception, several states have finalized or proposed legislation to delay results reporting. For example, Kentucky legislation mandated a 72-hour waiting period for automatic release of finalized pathology or radiology reports with a reasonable likelihood of showing or finding a malignancy and tests that could reveal genetic markers, requiring provider intervention to direct earlier manual release.[32] Similarly, to address certain aspects of Information Blocking, the California Senate reviewed a bill to expand regulations which delay the release of certain laboratories and imaging results that has been signed by the Governor.[33]

For states which have regulations governing laboratory results release to patients, policymakers should work closely with patient, clinical, and health system stakeholders and approach these issues grounded in health equity to determine if certain groups may be disproportionately impacted by restrictions in this access. In addition to determining when results are available to patients, policymakers should consider best practices around how results are delivered to patients to promote maximal understanding and engagement in their health. It must also be understood what infrastructure limitations, such as broadband access, impact patients' ability to participate in their care.[34] Lawmakers need to reconcile the discrepancies between state regulations and Cures Act and inform their perspectives using a data driven approach. In addition, when a patient's awareness of testing positive for a communicable disease[35] with impact to public health or safety, lawmakers should consider whether restrictions on electronic release would be beneficial or harmful to patients and communities for disease control efforts. With any regulatory change, lawmakers should engage all stakeholders above in depth to evaluate their concerns and evaluate specific data to support iterative changes in policies over time.

Conclusion

Health care delivery will continue to be shaped by technological advances that allow patients to have greater access to their own health information, as well as the legislation, policy, and cultural expectations that inform the development and implementation of those advances. All eight stakeholders detailed above and in ►Table 1 have interests in the ongoing iteration in how laboratory results are released to patients. The authors' recommendations, summarized in ►Table 1, serve as a guide to illustrate how all parties are important and interconnected. Among these groups, clinical informaticists are in the best position to bring together these disparate groups to facilitate the necessary collaboration to achieve solutions that are simultaneously patient-centered, compliant, and technically feasible. The implementation of the Cures Act and its interplay with state-specific legislation are still in their infancy, and clinical informaticists need to be active participants in shaping legislative evolution. Informaticists can lead the ongoing research and program evaluation to determine key outcome metrics on the impact (positive and negative) of immediate laboratory result release on diverse patient populations and inform future evidence-based legislative efforts. In doing so, the goal to empower patients at the center of their health and health care can be more easily, effectively, and equitably achieved.

Clinical Relevance Statement

Since the implementation of the 21st Century Cures Act, institutions and clinicians have grappled with reconciling federal and state regulations, with pending changes related to laboratory release to patients. This paper outlines the eight stakeholder groups involved in the implementation of electronic laboratory result release to patients and describes recommendations for these groups to consider to best

achieve the 21st Cures Act goals to support a patient's access to their health information and control of their health care.

Multiple-Choice Questions

1. What is one of the main goals of the Information Blocking Provision of the Cures Act Final Rule?
   a. Providing patients access to their protected health information.
   b. Mandating hospitals publish their chargemasters to increase price transparency.
   c. Providing subsidies to health care systems that implement electronic health records.
   d. Establishing the standards surrounding the protection of health information.

   Correct Answer: The correct answer is option a. Providing patients access to their protected health information. Starting April 5, 2021, the Information Blocking Provision of the Cures Act Final Rule mandated that patients have unencumbered, free access to their electronic health information (EHI) as defined by the U.S. Core Data for Interoperability version 1 (USCDI V1), including all laboratory test results. After October 6, 2022, patient access to their data expands beyond USCDI V1 to include all EHI.

2. What is one major challenge health care systems face when implementing laboratory result release to patients?
   a. Reconciling interstate regulations.
   b. There are no challenges.
   c. Identifying patient samples.
   d. Handling patient complaints.

   Correct Answer: The correct answer is option a. Reconciling varying interstate regulations. State laws surrounding laboratory result release preempt federal law and vary across the United States. Laboratories and health care systems providing care to patients across state lines must be familiar with varying interstate regulations to maintain proper compliance.

Protection of Human and Animal Subjects

The authors declare this manuscript is not based on any human subject research.

Conflict of Interest

None declared.

References

1 P.L. 114–255 Approved December 13, 2016 (130 Stat. 1033) 21st Century Cures Act. Compilation Of The Social Security Laws. Accessed July 12, 2022 at: https://www.ssa.gov/OP_Home/comp2/F114-255.html
2 Federal Register: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. Accessed July 13, 2022 at: https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification
3 Purington K, Alfreds ST, Pritts J, Buxbaum J. Electronic Release of Clinical Laboratory Results: A Review of State and Federal Policy. The California HealthCare Foundation; 2010. Accessed August 05, 2022 at: https://www.chcf.org/wp-content/uploads/2017/12/PDF-ElectronicLabResultsExchangePolicy.pdf
4 Lye CT, Forman HP, Gao R, et al. Assessment of US hospital compliance with regulations for patients' requests for medical records. JAMA Netw Open 2018;1(06):e183014
5 California Assembly Bill. AB-2253 Regular Session 2011-2012. Clinical laboratory test results: electronic conveyance. Accessed December 23, 22 at: https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201120120AB2253
6 214.181 Legislative findings–General consent to testing for HIV–Emergency procedures–Disclosures of test results–Voluntary testing programs in each county. Accessed August 08, 2022 at: https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=49028
7 HIMSS. Confused about information blocking? Turn to the experts | Healthcare IT News. Accessed July 13, 2022 at: https://www.healthcareitnews.com/news/confused-about-information-blocking-turn-experts
8 HealthIT.gov. Information Blocking. Accessed July 13, 2022 at: https://www.healthit.gov/curesrule/final-rule-policy/information-blocking
9 HIMSS. Confusion remains about ONC information blocking rules, even after start date | Healthcare IT News. Accessed July 13, 2022 at: https://www.healthcareitnews.com/news/confusion-remains-about-onc-information-blocking-rules-even-after-start-date
10 TechTarget. Status, Challenges of Information Blocking Rule Compliance. Accessed July 13, 2022 at: https://healthitsecurity.com/features/status-challenges-of-information-blocking-rule-compliance
11 Public Health Institute. Understanding Confidentiality and Minor Consent in California: an adolescent provider toolkit. Accessed August 05, 2022 at: https://www.phi.org/thought-leadership/understanding-confidentiality-and-minor-consent-in-california-an-adolescent-provider-toolkit/
12 Health Affairs. The Promise Of Health Information Technology In 2022 | Health Affairs. Accessed August 03, 2022 at: https://www.healthaffairs.org/do/10.1377/forefront.20220217.71427/#:~:text=In%20short%2C%20the%20Cures%20Act,170.404
13 Health Affairs. Provider Obligations For Patient Portals Under The 21st Century Cures Act | Health Affairs. Accessed August 03, 2022 at: https://www.healthaffairs.org/do/10.1377/forefront.20220513.923426/
14 Information Blocking Claims. By the Numbers | HealthIT.gov. Accessed July 13, 2022 at: https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers
15 Gerber DE. 21st century cures act: implementation without understanding implication? JCO Oncol Pract 2022;18(02):85–87
16 Winget M, Haji-Sheikhi F, Brown-Johnson C, et al. Electronic release of pathology and radiology results to patients: opinions and experiences of oncologists. J Oncol Pract 2016;12(08):e792–e799
17 Giardina TD, Callen J, Georgiou A, et al. Releasing test results directly to patients: a multisite survey of physician perspectives. Patient Educ Couns 2015;98(06):788–796
18 Walker J, Leveille S, Bell S, et al. Opennotes after 7 years: patient experiences with ongoing access to their clinicians' outpatient visit notes. J Med Internet Res 2019;21(05):e13876
19 Nouri SS, Adler-Milstein J, Thao C, et al. Patient characteristics associated with objective measures of digital health tool use in the United States: a literature review. J Am Med Inform Assoc 2020;27(05):834–841
20 Giardina TD, Baldwin J, Nystrom DT, Sittig DF, Singh H. Patient perceptions of receiving test results via online portals: a mixed-methods study. J Am Med Inform Assoc 2018;25(04):440–446
21 Turer RW, Martin KR, Courtney DM, et al. Real-time patient portal use among emergency department patients since implementation

of the 21st Century Cures Act: an open results study. Appl Clin Inform 2022;13(05):1123–1130
22 Arvisais-Anhalt S, Lau M, Lehmann CU, et al. The 21st century cures act and multiuser electronic health record access: potential pitfalls of information release. J Med Internet Res 2022;24(02): e34085
23 Lyles CR, Wachter RM, Sarkar U. Focusing on digital health equity. JAMA 2021;326(18):1795–1796
24 Tuan WJ, Mellott M, Arndt BG, Jones J, Simpson AN. Disparities in use of patient portals among adults in family medicine. J Am Board Fam Med 2022;35(03):559–569
25 Steitz BD, Sulieman L, Wright A, Rosenbloom ST. Association of immediate release of test results to patients with implications for clinical workflow. JAMA Netw Open 2021;4(10):e2129553
26 Implementing Team-Cased Care to Increase Practice Efficiency. Accessed Oct 24, 2022 at: https://www.pbgh.org/wp-content/uploads/2020/12/implementing-team_based_care_ama_2017.pdf
27 ONC's Cures Act Final Rule. Accessed July 13, 2022 at: https://www.healthit.gov/curesrule/overview/about-oncs-cures-act-final-rule
28 How Medical Devices Work with mHealth Apps | HealthTech. Accessed August 01, 2022 at: https://healthtechmagazine.net/article/2022/06/how-medical-devices-work-with-mhealth-apps-perfcon
29 HLTH 2021: Meet the Patients Where They Are in the Continuously Transforming Digital Health Sphere. HealthTech Magazine. Accessed August 01, 2022at: https://healthtechmagazine.net/article/2021/10/hlth-2021-meet-patients-where-they-are-continuously-transforming-digital-health-sphere
30 Pérez-Stable EJ, Jean-Francois B, Aklin CF. Leveraging advances in technology to promote health equity. Med Care 2019;57(suppl 6 suppl 2):S101–S103
31 HealthITbuzz. Key Themes from HITAC Hearing on Health Equity by Design - Health IT Buzz. Accessed October 24, 2022 at: https://www.healthit.gov/buzz-blog/health-information-technology-advisory-committee/key-themes-from-hitac-hearing-on-health-equity-by-design
32 Kentucky HB529 AN ACT relating to the disclosure of laboratory test results and declaring an emergency. Accessed August 04, 2022 at: https://trackbill.com/bill/kentucky-house-bill-529-an-act-relating-to-the-disclosure-of-laboratory-test-results-and-declaring-an-emergency/2229787/
33 Bill Analysis - SB-1419 Health information. Accessed October 27, 2022 at: https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=202120220SB1419#
34 Perzynski AT, Roach MJ, Shick S, et al. Patient portals and broadband internet inequality. J Am Med Inform Assoc 2017;24 (05):927–932
35 Turer RW, DesRoches CM, Salmi L, Helmer T, Rosenbloom ST. Patient perceptions of receiving COVID-19 test results via an online patient portal: an open results survey. Appl Clin Inform 2021;12(04):954–959