



Published in final edited form as:

JAMA. 2025 March 25; 333(12): 1074–1079. doi:10.1001/jama.2025.0068.

A Unified Approach to Health Data Exchange:

A Report From the US DHHS

Ali B. Abbasi, MD,
Jennifer Layden, MD, PhD,
William Gordon, MD,
Susan Gregurick, PhD,
Nancy DeLew, MPA,
Jordan Grossman, JD,
Arlene S. Bierman, MD, MS,
Susan Monarez, PhD,
Lesley H. Curtis, PhD,
Abigail H. Viall, ScD, MA,
Mitra Rocca, Dipl Inform Med,
Donna R. Rivera, PharmD, MSc,
Hilary Marston, MD, MPH,
Alexandra Mugge, MPH,
Scott R. Smith, PhD,
Katherine Bent, RN, PhD,
James Macrae, MA, MPP,
Ann Sheehy, MD, MS,
Renee D. Wegrzyn, PhD,
R. Burciaga Valdez, PhD, MHSA,
Carole Johnson,
Laina Bush, MBA,
Jonathan Blum, MPP,
Mandy K. Cohen, MD, MPH,
Monica M. Bertagnolli, MD,
Robert M. Califf, MD,
Micky Tripathi, PhD, MPP

US Food and Drug Administration, Silver Spring, Maryland (Abbasi, Curtis, Rocca, Rivera, Marston, Califf); Centers for Disease Control and Prevention, Atlanta, Georgia (Layden, Viall, Cohen); Centers for Medicare & Medicaid Services, Baltimore, Maryland (Gordon, Mugge, Blum); National Institutes of Health, Bethesda, Maryland (Gregurick, Bertagnolli); Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services,

Corresponding Author: Robert M. Califf, MD, US Food and Drug Administration, White Oak Campus, 10903 New Hampshire Ave, Silver Spring, MD 20993, (commissioner@fda.hhs.gov).

Washington, DC (DeLew, Smith, Bent, Bush); Health Resources and Services Administration, Rockville, Maryland (Grossman, Macrae, Sheehy, Johnson); Agency for Healthcare Research and Quality, Rockville, Maryland (Bierman, Valdez); Advanced Research Projects Agency for Health, Washington, DC (Monarez, Wegrzyn); Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT, Washington, DC (Tripathi).

Abstract

IMPORTANCE—Health information technology, such as electronic health records (EHRs), has been widely adopted, yet accessing and exchanging data in the fragmented US health care system remains challenging. To unlock the potential of EHR data to improve patient health, public health, and health care, it is essential to streamline the exchange of health data. As leaders across the US Department of Health and Human Services (DHHS), we describe how DHHS has implemented fundamental building blocks to achieve this vision.

OBSERVATIONS—Across DHHS, we have implemented 3 foundational building blocks called for by the 2016 21st Century Cures Act to create a unified approach for secure, high-quality, and timely exchange of health data across the health care system. The United States Core Data for Interoperability provides a minimum baseline for data elements that must be available in federally regulated health information technology systems such as certified EHRs. These data elements now must be accessible using Fast Healthcare Interoperability Resources—a secure, flexible, and open-industry standard for health data exchange. The Trusted Exchange Framework and Common Agreement provides a network to securely exchange health data across the country. The 3 building blocks of United States Core Data for Interoperability, Fast Healthcare Interoperability Resources, and Trusted Exchange Framework and Common Agreement are now in place thanks to diligent public and private sector work over 2 administrations. Across DHHS, we are working to refine these building blocks and increase their adoption through regulatory authorities, grants, and public-private partnerships.

CONCLUSIONS AND RELEVANCE—The technological building blocks described in this article are creating a unified approach to health data exchange for patient access, clinical care, quality improvement, scientific research, public health, and other uses of health data. Collaborations between the public, nonprofit, and private sectors are needed to maximize their potential. By unlocking the potential of health data, these building blocks are the foundation of a 21st-century digital health care system that will improve the experience of patients and clinicians and result in better health outcomes.

Electronic health data have become a transformative force in health care. Over the past decade, federally certified electronic health records (EHRs) have been adopted in many parts of the US health care system, including 97% of hospitals and 78% of physician offices, thanks in part to \$35 billion in incentives through the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009.^{1,2} While these investments represent a critical first step to enable digital health care, it is now up to all in the public and private sectors to enable the full transformative potential of these data to improve care and outcomes.

As leaders from across the US Department of Health and Human Services (DHHS), we believe that it is critical to build on this progress by improving the ability to capture, access, exchange, and use health data while continuing to protect patient privacy and data security, as envisioned in the 21st Century Cures Act of 2016.³ Over 2 administrations, we have worked to promote a set of foundational building blocks that create a common baseline for health data exchange across the US health care system spanning health care delivery, human services, and public health. The goal of this unified approach to health data is to create a vibrant, competitive ecosystem for innovation, so that all patients, regardless of where they receive care, can benefit from improved care quality and better health outcomes. Here, we describe the technological building blocks to enable this vision, the actions DHHS has taken to implement and promote their use, and the challenges and opportunities ahead.

The Potential of Electronic Health Data

Electronic health data can unlock clinical insights to support better patient care when captured and aggregated in EHR systems. For example, software for clinical decision support, increasingly enabled by artificial intelligence, assists physicians to provide safer and higher-quality care. When implemented responsibly, these tools improve care outcomes and empower patients. However, given the relationship between clinician burnout and documentation burden, these tools must provide value for health care professionals to justify their use (eg, enabling them to spend more time listening to patients and less time on documentation). Electronic health data can also be aggregated for research, powering studies that identify and test new treatments, enable rapid detection of novel threats, guide response to bioincidents, and support health services research that improves care delivery. To ensure the algorithms developed and insights gained from health data apply to all patients, it is essential to improve the ability to capture data from diverse populations in terms of geography, income, sex, age, race, and ethnicity.^{4,5}

Accessing and exchanging health data in this highly fragmented health care system is very challenging. Health care data are not consistently standardized and require manual curation and transformation. Data exchange frequently relies on custom tools for sending and receiving data that are inflexible beyond the intended use case. We are now poised for a more unified and standardized approach to health data that will enhance the utility and representativeness of clinical data not only to improve care, but also to better support research, human services, and public health activities on issues that affect the health and well-being of the public.

The Building Blocks

Through collaborations across the department, DHHS has supported the development of foundational technological building blocks that streamline data exchange while respecting patient privacy and improve data security (Figure). The building blocks include a common baseline for data elements (United States Core Data for Interoperability [USCDI]), a standard for exchange (Health Level 7 Fast Healthcare Interoperability Resources [FHIR]), and a connected trust network to enable broad exchange across health care entities (Trusted Exchange Framework and Common Agreement [TEFCA]). With these building blocks,

health care data exchange is shifting away from inefficient customized approaches to a more streamlined and unified data flow.

USCDI: Capture Minimum Common Data Elements

Different health care professionals commonly capture and code data using different terminologies. During the early years of EHRs, a primary data element—such as a blood pressure measurement or hemoglobin level—could not be accessed by sending the same electronic request to 2 different health systems, even if both used the same EHR vendor. To bridge this gap, DHHS has developed the USCDI,⁶ which establishes a standardized set of data elements and classes that must be available for exchange in most certified health information technology (IT) using standard mechanisms such as structured documents (eg, using the Consolidated Clinical Document Architecture format), data-level application programming interfaces (APIs), and patient portals. Defined and updated annually through collaboration with industry and agency partners by the DHHS Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology, the USCDI allows for the consistent capture and coding of many data elements and standardized exchange across different EHR and health IT platforms.

FHIR: Common Standards for Data Transfer

Transferring health data between different health IT systems requires formats that both the receiving and sending systems can decipher. Historically, this has been accomplished by permitting multiple different data standards and formats. While this approach offers flexibility, it also introduces inefficiencies because it requires separate data pipelines for each use case, which generates redundant systems and information loss with data transformation. Fortunately, health care now has a common format for exchanging health information, known as FHIR.⁷ FHIR is becoming the consensus-based standard for sharing health data across various domains and purposes because it is a flexible open-industry approach, supports a wide range of data types, and features a modular design where data are categorized into resources that can be combined and extended to fit various types of health data through use-case-specific profiles. Most important, FHIR enables app-based exchange that allows health IT systems to operate more like interactive platforms akin to smartphones rather than closed systems.

Key to enabling FHIR-based exchange across health care systems is the Health Level 7 US Core Implementation Guide, which specifies how to represent USCDI-defined data elements in FHIR profiles.⁸ The US Core Implementation Guide is like a cookbook, putting together “recipes” (ie, profiles) for how to use the USCDI data (“ingredients”) to perform health care functions using FHIR. For example, the USCDI specifies that laboratory results should be encoded in Logical Observation Identifiers Names and Codes (LOINC) terminology, and the US Core Laboratory Result Observation Profile shows how to represent these laboratory results as FHIR resources. Through ongoing public-private collaboration, FHIR is supporting a growing range of use cases, including quality measures, adverse event reporting, and public health outbreak monitoring.

TEFCA: Enabling Secure Data Exchange Across Health Care Systems

Sharing data among clinicians is essential to coordinating and improving care. Over the past decade, health systems have joined interoperability networks to facilitate health information exchange. While providing value for network participants, this approach has not scaled to seamless nationwide exchange because different networks are not connected to each other, use different technical approaches, require unique legal contracts, have spotty participation, and do not support exchange for purposes other than clinical care.

In 2023, DHHS completed a goal specified in the 21st Century Cures Act by facilitating the launch of TEFCA,⁹ which designates Qualified Health Information Networks to voluntarily connect through a common agreement, enabling secure, nationwide sharing of health information for various authorized purposes. Seven Qualified Health Information Networks are live (with 3 more to come), connecting more than 400 hospitals, 5000 physician offices, 200 long-term postacute care and behavioral health facilities, and more than 100 000 individual clinicians. Sixty public health agencies are already receiving electronic case reports through TEFCA, some of which can also securely query clinicians for missing data using TEFCA, eliminating the requirement for additional collection through telephone or fax and reducing the reporting burden on resource-strapped clinicians and public health agencies while improving the secure availability and timeliness of data for public health response. As of July 2024, TEFCA participants (including patients) can securely exchange data using Consolidated Clinical Document Architecture (an older data format) or via FHIR-based exchange.

The Road Map to Unified Health Data Exchange

To ensure that health data used for care delivery, public health, human services, and scientific research represent and serve all of the public, investments in health IT adoption and these building blocks must be leveraged to enable a common baseline for health data exchange based on competition-enhancing principles and nonproprietary standards for all patients and care environments. The building blocks are the foundation for achieving this vision, but more work remains to be done.

Ongoing Development of the Building Blocks

DHHS agencies are working together on opportunities to continue developing these building blocks. For example, TEFCA does not currently allow data exchange for clinical research because there is not yet nationwide digital standards for informed consent or de-identification. This use case is currently under active development, led by the Assistant Secretary for Technology Policy in collaboration with federal partners, academic researchers, industry, and health systems.

In addition, USCDI lacks many data elements that are needed for secondary health data uses such as scientific research, quality measurement, or public health response. To close these gaps, the Assistant Secretary for Technology Policy is actively developing USCDI plus (USCDI+) standards with agency partners and industry for specific use cases.¹⁰ For example, the USCDI+ cancer domain is developing implementation guides to facilitate

exchange of essential oncologic data such as staging information that could streamline clinical trials, cancer registry reporting, adverse event detection, and clinical care for patients with cancer. These implementation guides will serve as expansion packs to the US Core Implementation Guide. Developer communities support these initiatives through FHIR accelerators that bring together government, private sector, and nonprofit partners to develop, test, and implement FHIR implementation guides and help facilitate public feedback to the USCDI+ process and domains. Other USCDI+ initiatives include quality measurement, public health, behavioral health, research, and health center reporting.

Increasing Adoption of the Building Blocks

DHHS is working to accelerate nationwide adoption of the building blocks, as outlined by the DHHS Data Strategy¹¹ and the 2024–2030 Federal Health IT Strategic Plan.¹² To accelerate adoption, DHHS agencies are deploying the building blocks in their programs: the DHHS Health IT Alignment Policy requires all DHHS agencies to ensure that grants, contracts, cooperative agreements, and rulemaking activities that involve the adoption or use of health IT align with standards such as FHIR and USCDI where applicable and to the extent permitted by law.¹³ Illustrative examples of how these building blocks are being deployed in programs across DHHS agencies are listed in the Table.^{14–19} Of course, the building blocks will not replace all other health care data exchange standards. In some cases, other data standards may be more appropriate or required by law or regulation, but the goal is to create a common minimum baseline for health data exchange across the entire health care system that will remove barriers to competition and catalyze innovation.

Federal investments are also ensuring that actors across the health ecosystem have the support necessary to implement technologies and processes that align with these building blocks. For example, through its Public Health Infrastructure Grant, the Centers for Disease Control and Prevention awarded funding to national partners to stand up and expand the capacity of 4 implementation centers. These centers will provide technical assistance to state, tribal, local, and territorial health departments to improve public health data exchange between public health jurisdictions and health care professionals using these building blocks.¹⁴

HHS agencies have also collaborated on rulemaking to require or encourage using USCDI, FHIR, and TEFCA. The 21st Century Cures Act final rule (Cures Act Rule)²⁰ adopts USCDI and FHIR APIs as required standards for certified health IT. It prohibits information blocking, defined as interfering with, preventing, or discouraging access, exchange, or use of health information. The Centers for Medicare & Medicaid Services' Interoperability and Patient Access Final Rule, released in January 2024, identified FHIR as the chosen standard for interoperability and required payers to establish Patient Access APIs using FHIR.²¹ The Centers for Medicare & Medicaid Services' Interoperability and Prior Authorization Final Rule requires that impacted payers give clinicians and health systems access to claims information and automate prior authorization via standard FHIR APIs.^{22,23} The Assistant Secretary for Technology Policy's Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) proposed rule released in June 2024 proposes to add voluntary certification programs for health IT

used by payer and public health IT systems, which would support greater efficiency and effectiveness of Centers for Disease Control and Prevention and Centers for Medicare & Medicaid Services programs, and create greater transparency and innovation across the health care delivery, payment, and public health domains.²⁴

As DHHS agencies continue to maximize the use of USCDI, FHIR, and TEFCA, actors across the health care systems can increase efficiency and avoid redundancy by using these technologies wherever possible. For example, health systems are now able to channel more activities through standardized FHIR APIs and TEFCA access instead of using custom data portals and bespoke point-to-point interfaces. Research sponsors and investigators can use FHIR and USCDI to extract standardized data from the EHR, using custom case report forms only to fill in the gaps. Private payers and clinicians can leverage FHIR APIs to streamline administrative functions for patients and clinicians, such as more efficiently facilitating prior authorization.

Challenges and Opportunities Ahead

While the foundational technological and regulatory building blocks are in place, additional opportunities exist to enable and encourage using these blocks across the care continuum. HITECH Act incentives to adopt certified health IT did not extend to public health jurisdictions, nor to nearly 60 000 clinicians and facilities, including skilled nursing facilities, long-term acute care hospitals, inpatient rehabilitation facilities, and home health agencies, as well as inpatient, outpatient, and residential psychiatric facilities. As a result, most of these entities have not adopted certified health IT, which can impact their ability to participate in health information exchange essential for ensuring coordinated care transitions and protecting the country from public health threats.^{25–27} Modernizing health IT requires resources—both financial and workforce—that many facilities and jurisdictions lack. As a first step toward closing these gaps, President Biden’s fiscal year 2025 budget proposal included more than \$1 billion in incentives to advance health IT adoption and engagement in interoperability for certain behavioral health providers.²⁸

Although the building blocks described here are foundational for data exchange, they do not directly address the continuing challenges of data quality, completeness, and complexity. Most health systems capture data in terminology and structures that are rarely consistent with other health systems: for example, health systems may select different LOINC codes for the same test or variations of a similar test.²⁹ As a result, even when the building blocks function as intended, data may not have the same meaning in the receiving system as it did in the sending one, reducing the accuracy of interpretation or analysis. Public and private partnerships will continue to be essential to improve data standardization at the source.

The building blocks on their own also fail to address the documentation burden experienced by clinicians, which EHRs can even exacerbate due to “note bloat” (notes containing excessive or irrelevant information) and workflow challenges. As the EHR increasingly becomes the primary source of truth for clinical care and secondary data uses, it is essential to reimagine the role of the EHR as a platform to enable person-centered care—a platform where the goals of care are captured and care processes are aligned to achieve these goals across the entire spectrum of care using a variety of native and integrated tools. By adopting

this approach, EHR platforms will more easily adapt to clinical workflow instead of the infrastructural data flow and return value to clinicians through more personalized user experience and enhanced decision support and care coordination.

While the building blocks alone are not sufficient to solve these challenges, they are a necessary prerequisite. A health care system in which high-quality health data serve as the criterion standard source of truth cannot be realized if data remain trapped in individual EHR systems. Seamless health data exchange is of fundamental importance to ensure that health data can power both care and secondary data uses, such as business operations, research (with appropriate consent), and public health reporting, without imposing additional burdens on the health care workforce. A unified approach to health data exchange through the building blocks will create fertile ground for innovations such as artificial intelligence–powered technologies that can begin to address the challenges of patient experience, clinician workload, and data quality.

Conclusions

Building on the progress that has been made with the adoption of EHRs, DHHS is creating a unified approach for secure data capture, access, and exchange to enhance the innovative potential of health data. Through the 21st Century Cures Act, DHHS has played a key role putting in place foundational building blocks, which open opportunities for public and private sector innovation to directly enhance patients' lives. With these building blocks in place, we are poised to harness the transformative power of artificial intelligence–based technologies and build a 21st-century digital health care system that works for patients and clinicians seeking better care, learning health systems working toward continuous improvement, researchers developing the next generation of therapies, and public health agencies protecting from outbreaks. The health and well-being of all the public is at stake.

Conflict of Interest Disclosures:

Dr Abbasi reported receiving personal fees from MIS Technologies and travel expenses from Johnson & Johnson. Dr Curtis reported receiving personal fees from Regeneron Pharmaceuticals, NFL Players Association, and Boehringer Ingelheim and grants from GlaxoSmithKline and Novartis. Dr Califf reported being previously employed by Alphabet and previously serving on the boards of Cytokinetics and Centessa. No other disclosures were reported.

REFERENCES

1. American Recovery and Reinvestment Act of 2009. Accessed November 27, 2024. <https://www.congress.gov/bill/111th-congress/house-bill/1/titles>
2. Assistant Secretary for Technology Policy. National trends in hospital and physician adoption of electronic health records. Accessed November 27, 2024. <https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records>
3. Pub L 114–255: 21st Century Cures Act. 2016 Accessed May 8, 2022. <https://www.govinfo.gov/app/details/PLAW-114publ255>
4. Baquet CR, Commiskey P, Daniel Mullins C, Mishra SI. Recruitment and participation in clinical trials: socio-demographic, rural/urban, and health care access predictors. *Cancer Detect Prev*. 2006; 30(1):24–33. doi:10.1016/j.cdp.2005.12.001 [PubMed: 16495020]

5. Xiao H, Vaidya R, Liu F, Chang X, Xia X, Unger JM. Sex, racial, and ethnic representation in COVID-19 clinical trials: a systematic review and meta-analysis. *JAMA Intern Med.* 2023;183(1):50–60. doi:10.1001/jamainternmed.2022.5600 [PubMed: 36469312]
6. United States Core Data for Interoperability (USCDI). Interoperability Standards Platform. Accessed November 27, 2024. <https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi>
7. HL7 FHIR release 5. FHIR overview. Accessed November 27, 2024. <https://www.hl7.org/fhir/overview.html>
8. Health Level Seven. US Core Implementation Guide. Accessed January 2, 2025. <https://build.fhir.org/ig/HL7/US-Core/>
9. The Sequoia Project, Office of the National Coordinator for Health Information Technology. What is the Trusted Exchange Framework and Common Agreement? Accessed November 27, 2024. <https://rce.sequoiaproject.org/tefca/>
10. Assistant Secretary for Technology Policy. USCDI+. Accessed February 23, 2023. <https://www.healthit.gov/topic/interoperability/uscdi-plus>
11. US Department of Health and Human Services Office of the Chief Data Officer. HHS Data Strategy. Accessed November 27, 2024. <https://cdo.hhs.gov/s/hhs-data-strategy>
12. US Department of Health and Human Services. HHS finalizes federal health IT strategy to drive systemic improvements in health and care. September 30, 2024. Accessed November 27, 2024. <https://www.hhs.gov/about/news/2024/09/30/hhs-finalizes-federal-health-it-strategy-drive-systemic-improvements-health-care.html>
13. Assistant Secretary for Technology Policy. HHS Health IT Alignment Policy. Accessed November 27, 2024. <https://www.healthit.gov/topic/hhs-health-it-alignment-policy>
14. Layden JE, Swain MJ, Brennan N, Tripathi M. Plugging public health data into the health IT ecosystem to protect national health. *NEJM Catal Innov Care Deliv.* 2024;5(8). doi:10.1056/CAT.24.0129
15. Association of Public Health Laboratories. eCR—electronic case reporting. Accessed November 27, 2024. <https://ecr.aimsplatform.org/>
16. Agency for Healthcare Research and Quality. eCare plan. Accessed November 27, 2024. <https://www.ahrq.gov/ecareplan/index.html>
17. US Food and Drug Administration. Source data capture from electronic health records (EHRs): using standardized clinical research data (OneSource phase I). January 26, 2021. Accessed November 28, 2024. <https://www.fda.gov/science-research/advancing-regulatory-science-source-data-capture-electronic-health-records-ehrs-using-standardized-clinical-research-data>
18. US Food and Drug Administration. FDA grant awards for projects supporting the use of real-world data to generate real-world evidence in regulatory decision making. November 14, 2023. Accessed January 2, 2025. <https://www.fda.gov/drugs/science-and-research-drugs/fda-grant-awards-projects-supporting-use-real-world-data-generate-real-world-evidence-regulatory>
19. Advanced Research Projects Agency for Health. PRECISE-AI. August 29, 2024. Accessed November 28, 2024. <https://arpa-h.gov/research-and-funding/programs/precise-ai>
20. US Department of Health and Human Services. 21st Century Cures Act: interoperability, information blocking, and the ONC health IT certification program. Federal Register. May 1, 2020. Accessed May 8, 2022. <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>
21. Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers. Federal Register. May 1, 2020. Accessed November 27, 2024. <https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicare-programs-patient-protection-and-affordable-care-act-interoperability-and>
22. Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior

- Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program. Federal Register. February 8, 2024. Accessed November 27, 2024. <https://www.federalregister.gov/documents/2024/02/08/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability>
23. Centers for Medicare & Medicaid Services. CMS finalizes rule to expand access to health information and improve the prior authorization process. January 17, 2024. Accessed November 28, 2024. <https://www.cms.gov/newsroom/press-releases/cms-finalizes-rule-expand-access-health-information-and-improve-prior-authorization-process>
24. US Department of Health and Human Services. Health data, technology, and interoperability: patient engagement, information sharing, and public health interoperability. Federal Register. August 8, 2024. Accessed November 27, 2024. <https://www.federalregister.gov/documents/2024/08/05/2024-14975/health-data-technology-and-interoperability-patient-engagement-information-sharing-and-public-health>
25. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Care Services; Committee on the Quality of Care in Nursing Homes. The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff. National Academies Press; 2022.
26. Busch AB, Bates DW, Rauch SL. Improving electronic health record adoption in psychiatric care: a cornerstone for healthcare transformation. *N Engl J Med*. 2018;378(18):1665–1667. doi:10.1056/NEJMp1800465 [PubMed: 29719176]
27. Devers K, Lallemand N, Napoles A, Spillman B, Blavin F, Ozanich G. Health information exchange in long-term and post-acute care settings: final report. US Department of Health and Human Services. November 2015. Accessed October 27, 2024. https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/151761/LTPACsetting.pdf
28. Budget of the US government: fiscal year 2025. Accessed January 7, 2025. https://www.whitehouse.gov/wp-content/uploads/2024/03/budget_fy2025.pdf
29. Parr SK, Shotwell MS, Jeffery AD, Lasko TA, Matheny ME. Automated mapping of laboratory tests to LOINC codes using noisy labels in a national electronic health record system database. *J Am Med Inform Assoc*. 2018;25(10):1292–1300. doi:10.1093/jamia/ocy110 [PubMed: 30137378]

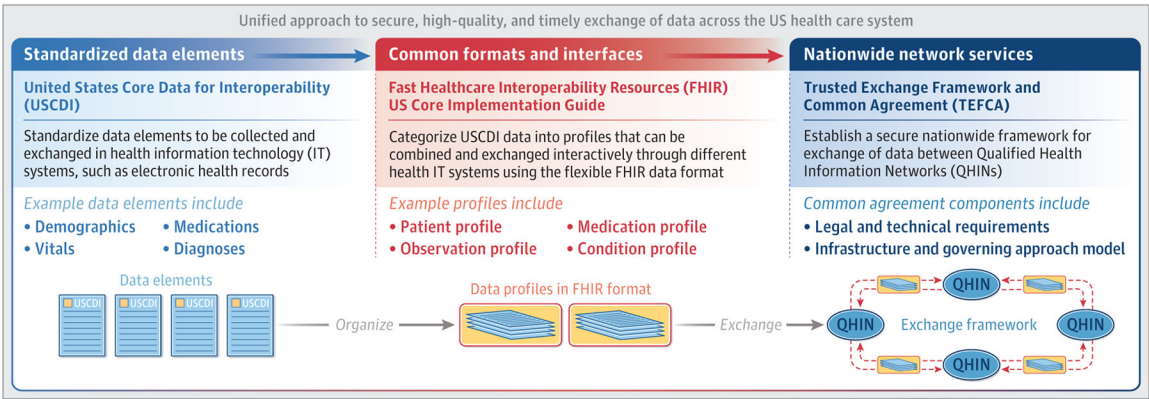


Figure.
The Building Blocks for a Unified Approach to Health Data
The building blocks create common baseline capabilities for health data exchange across the health care system. USCDI provides the minimum data elements that have to be accessible through standardized electronic requests in the electronic health record. The US Core Implementation Guide describes how the data elements in USCDI can be represented in using FHIR resources, which provide a flexible, open-industry data format for transfer and exchange. TEFCA has created a nationwide system of interconnected networks for health data interoperability, which supports exchange in Consolidated Clinical Document Architecture (a structured document format) or FHIR.

Illustrative Examples of How DHHS Agencies Are Using the Building Blocks of USCDI, FHIR, and TEFCa to Standardize the Capture, Transfer, and Exchange of Health Data

Table.

Agency	Example use case
National Institutes of Health (NIH)	NIH is leading a coalition of federal partners to develop technology capabilities for USCDI+ implementation guides for cancer research, which could be used in NIH-funded research.
Health Resources & Services Administration (HRSA)	HRSA is transitioning the federal Health Center Program's Uniform Data System from manual data entry to automated FHIR-based reporting, leveraging a USCDI+ program that includes deidentified patient-level data. All 1400 HRSA health centers will be expected to report at least in part using FHIR in 2025.
Centers for Disease Control and Prevention (CDC)	CDC is working with state, territorial, local, and tribal public health agencies to improve the timeliness and efficiency of public health data exchange using FHIR, USCDI, and TEFCa. ¹⁴ For example, 60 jurisdictions have already received electronic case reports through TEFCa. ¹⁵
Agency for Healthcare Research and Quality (AHRQ)	AHRQ in partnership with NIDDK, building on USCDI, has developed a set of FHIR-based open-source applications and an HL7 Implementation Guide to facilitate collection, aggregation, and sharing of EHR data to support shared care planning and care coordination. ¹⁶
Centers for Medicare & Medicaid Services (CMS)	CMS is working across its quality programs to move to digital quality measures and is pursuing quality measure data submission on FHIR, including through a new USCDI+ quality measurement domain.
US Food and Drug Administration (FDA)	FDA is supporting collaborative regulatory science projects to evaluate the use of FHIR and USCDI to capture data from routine practice to support various clinical study designs. ^{17,18}
Advanced Research Projects Agency for Health (ARPA-H)	ARPA-H programs require the use of FHIR, USCDI, and TEFCa where applicable. For example, the PRECISE-AI program, which is developing capabilities to detect and mitigate AI model degradation, requires solutions to adhere to standards established or endorsed by DHHS including FHIR. ¹⁹

Abbreviations: AI, artificial intelligence; DHHS, Department of Health and Human Services; EHR, electronic health record; FHIR, Fast Healthcare Interoperability Resources; HL7, Health Level 7; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; PRECISE-AI, Performance and Reliability Evaluation for Continuous Modifications and Useability of Artificial Intelligence; TEFCa, Trusted Exchange Framework and Common Agreement; USCDI, United States Core Data for Interoperability; USCDI+, United States Core Data for Interoperability plus.