

**Comments of
The Health Record Banking Alliance
In response to
Office of Science and Technology Policy (OSTP)
Request for Information (RFI) on Clinical Research Infrastructure and
Emergency Clinical Trials
87 FR 64821 (Oct. 26, 2022)**
Submitted on January 25, 2023 via emergencyclinicaltrials@ostp.eop.gov

The Health Record Banking Alliance (HRBA)¹ offers comments in response to OSTP's Request for Information on clinical research infrastructure for purposes of conducting emergency clinical trials. *Please note: these comments complement, and should be read in conjunction with, HRBA's comments, also filed this date, in response to OSTP's Request for Information on data collection for emergency clinical trials.*

Summary of Recommendations

OSTP should implement the National Biodefense Strategy by building a clinical trial infrastructure on a foundation of Health Data Banks (HDBs) as the principal source of patient-level data. HDBs, enabled by the Interoperability Rule, will emerge as a technology-based industrial sector. HDBs will securely house patients' longitudinal health records and facilitate their use for care and for consented research. *(Please refer to the Appendix for a schematic of Health Data Banks.)*

A Health Data Bank is a secure, private- or public-sector institution. HDBs will offer secure, encrypted repository accounts that patients and other consumers own and control, and where they can aggregate, store, and analyze their health data. Health data includes (and is not limited to) encounter reports – institutional medical records – at clinician offices and hospitals, pharmaceutical data, and payment information related to health care. This information can be integrated using software at the HDB to create a longitudinal, problem-oriented Personal Health Records (PHRs), which consumers own and access to which they control.

Consumers can use their PHRs to help manage interactions with the health care system and to help understand and manage their health care. HDBs will offer analytical and advisory services to help PHR account holders interpret what is in their lifetime records. Third parties may also offer complementary analytical services. HDB PHRs will also offer patients the ability to integrate new data from various providers as time goes by in order to keep their lifetime records updated, accurate, and instantly available.

¹ The Health Record Banking Alliance, P.O. Box 6580, Falls Church, Virginia 22040, is recognized as a business league by the Internal Revenue Service under Section 501(c)(6) of the Internal Revenue Code.

Used routinely for diagnostic and other medical decisions, HDB account data can potentially improve care for all Americans, especially in underserved populations. HDBs will become part of standard care and research infrastructure in the U.S.

HDBs can be infrastructure resources for decentralized clinical trial networks. They can be useful with points of care across the nation where, increasingly today, *both* clinical care and clinical research are being performed.² OSTP can expect HDBs, enabled by Fast Healthcare Interoperability Resources (FHIR), to provide two-way channels for communications with patients during public health emergencies at the grass roots level of U.S. health care. HDB functionality will, for example, aid rapid collection of data, including novel digital endpoints, as needed for new outbreaks. HDBs, created initially as a care resource to benefit patients and their providers, will thus also offer a permanent, standing resource for “warm-base” clinical research.

HDBs as a component of infrastructure for clinical trials are an alternative to ONC’s implementation of the Trusted Exchange Framework and Common Agreement (TEFCA). This TEFCA implementation is an inherently insecure systems design. The federal government, including the Food and Drug Administration and other regulatory authorities, and the clinical trial industry cannot rely on TEFCA as a component of the National Biodefense Strategy.

Beyond its unsuitability in a secure biodefense environment, ONC’s TEFCA implementation is too fragmented to be trusted for clinical trial recruitment. It is a congeries of disparate network-connecting designs assembled to preserve inefficient and soon-to-be-obsolete HIEs (Health Information Exchanges). TEFCA’s standard operating procedures (SOPs) and network-centric (rather than patient-centric) architectures are not, and not required to be, uniform. Functional inefficiency is written into TEFCA’s structure.

HRBA is filing a companion response to OSTP’s RFI seeking input on data capture for clinical trials. There we will explain further why the current TEFCA architecture is inherently insecure, not a sufficiently reliable resource for ongoing patient care management, and all the more unfit for trial data management, where trustworthiness is paramount and flexibility to effect rapid modification of nationwide master trial protocols is likely to be a functional necessity.

We will show, in contrast, how HDBs can be expected to contribute operationally in the world of clinical research as part of a robust clinical trials infrastructure.

Transformative Impact of the Cures Act and Interoperability Rule on Health Data Exchange

Under the Interoperability Rule, health data expressed in FHIRs (“FHIR-based health data”) will be the standard for nationwide health data exchange. *Standardized* FHIR, expanded continuously under the Interoperability Rule’s Standards Version Advancement Process (SVAP)³, will enable moving patients’ data from previously siloed, proprietary EHR (Electronic Health Record) systems into PHRs housed in Health Data Banks.

² See: [Point-of-Care Clinical Trials: Integrating Research and Care Delivery](#), Duke-Margolis White Paper, May 11, 2021. See also: [The Coalition for Advancing Clinical Trials at Point of Care \(ACT@POC\)](#).

³ For explanation of SVAP, see Department of Health and Human Services, 21st Century Cures Act: Interoperability and Information Blocking, 85 Fed. Reg. 25642, 25644 (May 1, 2020).

As this de-siloing occurs, HDBs will replace the current health-data fax messaging system, today's de facto standard for point-to-point, health-data sharing, with *a national capability for routine, secure, convenient, point-to-point health data exchange*. This set of two-way functions includes patient-mediated digital communications and much more: point-to-point data flows between consumers and providers, providers and other providers, consumers and payors, providers and payors, payors and other payors, patients and researchers, clinical trial administrators and patients, clinical trial administrators and clinicians, clinical trial administrators and government agencies – all are benefits of standardized FHIR-based interoperability.

Parenthetically, this point-to-point functionality wholly undermines the need for a network architecture such as TEFCA to move health data for network-centric purposes.

Patient-centered health-data sharing will be bolstered by efforts such as the Centers for Medicare and Medicaid Services' proposal to establish a National Directory of Healthcare Providers & Services (NDH). The NDH would serve as a “centralized data hub” for secure healthcare provider, facility, and entity FHIR-endpoint directory information nationwide.⁴ For consumers, a CMS-maintained, vetted directory of FHIR endpoints for providers and provider-related services will offer a new, essential level of trust in identifying and contacting providers reliably, securely, and directly.

The impact of such trusted functionality will produce systems benefits for enhanced health data exchange flows far beyond the directory domain itself. In form, these records will be normalized and hence “computable” to a significant degree. Patient data normalized to the degree enabled by FHIR-based standards – even at early stages of FHIR standardization – offers immediate benefits for research and clinical trials, whether or not conducted in emergency settings.

The initial scope of exchangeable EHR data will be limited to the current version of the USCDI (United States Core for Data Interoperability). Consumers will nevertheless have the capacity to combine basic data from copies of their EHR medical records from diverse providers into normalized, problem-oriented, longitudinal PHR health records stored in HDB accounts that they own, maintain, and control. And the scope of exchangeable data and extent of data normalization will expand each year via the Standards Version Advancement Process.

HDBs will offer analytical and advisory services to help PHR account holders interpret what is in their longitudinal records. HDB PHRs will allow patients to integrate new data from diverse providers as time goes by in order to keep their lifetime records updated, accurate, and instantly available. Third parties also will offer complementary analytical services and services to help patients involve themselves in particular research projects.

Clinician and researcher burdens due to data system complexities and lack of data normalization will be ameliorated when HDB PHR account information is readily available as a *reference* “single source of truth” for compartmentalized import into hospital and medical office EHR systems. Reliable patient data with provenance, aggregated from diverse providers,

⁴ See Centers for Medicare and Medicaid Services, Request for Information on Establishing a National Directory of Healthcare Providers & Services (NDH), Agency/Docket Number CMS-0058-NC, 87 Fed. Reg. 61018 (Oct. 7, 2022).

supplemented with contemporaneous patient observations and with data from wearables and other personal devices, will be readily searchable in problem-oriented PHRs or other enhanced formats that HDBs may adopt. This is all consistent with 45 CFR 170.215, and will support faster and safer care while reducing clinician burden.

For research purposes, patients with HDB PHR accounts will be enabled to participate voluntarily in public health initiatives such as emergency clinical trials. Consumers will have convenient means to report voluntarily to clinicians and, as appropriate, public health authorities, to seek evaluation of symptoms, advice on potential treatments or vaccinations, and research projects related to public health emergencies. These HDB PHR capabilities will complement mandatory public health reporting requirements by clinicians and other provider institutions.

These are key health care priorities for a nationwide health IT infrastructure as contemplated in section 3001(b) of the Public Health Service Act (PHSA). They illustrate *the inherently efficient, superior systems design of integrating health data around the patient*, which bestows enormous improvement in the efficiency and utility of health information exchange. That is the core systems advance that HDBs will contribute as an industrial sector to U.S. health care, the health industry, and the health research enterprise.

For all these reasons, Congress and state legislatures are likely, eventually, to consider how to encourage the private sector to invest in HDBs, and otherwise to make possible consumers' rapid, pervasive adoption of HDB PHR accounts. Tax incentives and direct subsidies for HDB accounts are among provisions to be explored.

To summarize with regard to OSTP's emergency research scenarios: PHRs housed in HDB accounts enable a patient-centered information infrastructure for medical practice and medical research. Owing to the Interoperability Rule's mandated implementation of design specifications in the Cures Act, there is no turning back from patient-centeredness.

Historical Perspective on Why Health Data Banks Have Not Emerged Earlier

Longitudinal medical records, that is, personal health records or PHRs, have long been sought; but they have proven beyond entrepreneurs' and major corporations' repeated attempts to create them. Why are they now feasible and sustainable?

History is an important guide in assessing the preconditions for the feasibility of PHRs. Google (Google Health) and Microsoft (Health Vault) failed in early, richly funded efforts to create Health Record Banks to hold Personal Health Records. Major employers, seeking to improve the health of their workforces and lower total costs of corporate health plans, also failed in consortia (for example, Dossia, Haven) to develop Health Record Bank-like systems that would offer longitudinal PHRs to their employees and their families.

These failed projects share two common characteristics. *First* was corporate recognition that workforce health costs were out of control, and belief that employee and family health across the board could be improved – and workforce health costs reduced – if employees and their families had access to, and corporate motivation to use, longitudinal Personal Health Records.

Second, none of the corporations involved in these projects could overcome data processing barriers. They had no feasible means, at scale, to extract medical records from

disparate, incompatible institutional Electronic Health Record systems in hospitals and medical offices. Every one of these projects was doomed by that constraint.

(Many excuses, such as the incompatibility of corporate cultures, were offered to explain these failures. Those factors were at best peripheral. The core cause of failure in every case was an inability to extract and exchange digital data among incompatible institutional EHR systems.)

The motivation among major corporations to reduce workforce health insurance costs and improve workers' health is as compelling now as ever. As FHIR-based, standardized digital data exchange expands to become the norm, major corporations will once again seek Health Data Bank systems. Corporate adoption of HDBs is likely to be an initial impetus for consumers employed by large corporations to aggregate their records in PHRs that their corporate employers subsidize and encourage, but that the consumer/employees themselves own and control. The same trend is likely among governments at all levels.

The Requirement for HDB Industry Regulation and Self-Regulation is Apparent Today

A proponent of HDB PHRs since 2006, HRBA is an advocate both for industry self-regulation and standards of conduct, and for federal regulation of HDBs and other private-sector repositories of consumers' health data. Federal regulation must be structured to keep bad actors from offering predatory HDB services. Regulation must also be tailored so HDBs can innovate continually in the storage, analytical, and advisory services they make available to consumers and to employers who understand the advantages of encouraging (and in many cases subsidizing) PHR use by their employees.

Government, industry, and the public will inevitably draw conclusions about privacy and other ethical factors attending the collection of medical records and other health data, and the circumstances under which that data can be communicated to whom and by whom. HRBA expects to participate in helping organize private sector development of these policies, and in helping to coordinate them with federal and state regulatory initiatives in the delivery of care, public health services, health equity, and medical research.

Conclusion

HDBs are a patient-centric technology, really a bundle of technologies, that will emerge as a significant segment of infrastructure for health care and research in the U.S. The patient-centric, integrative function of HDBs in an evolving point-to-point nationwide health information network will facilitate patient engagement on a wide scale not seen before.

Respectfully submitted,

The Health Record Banking Alliance

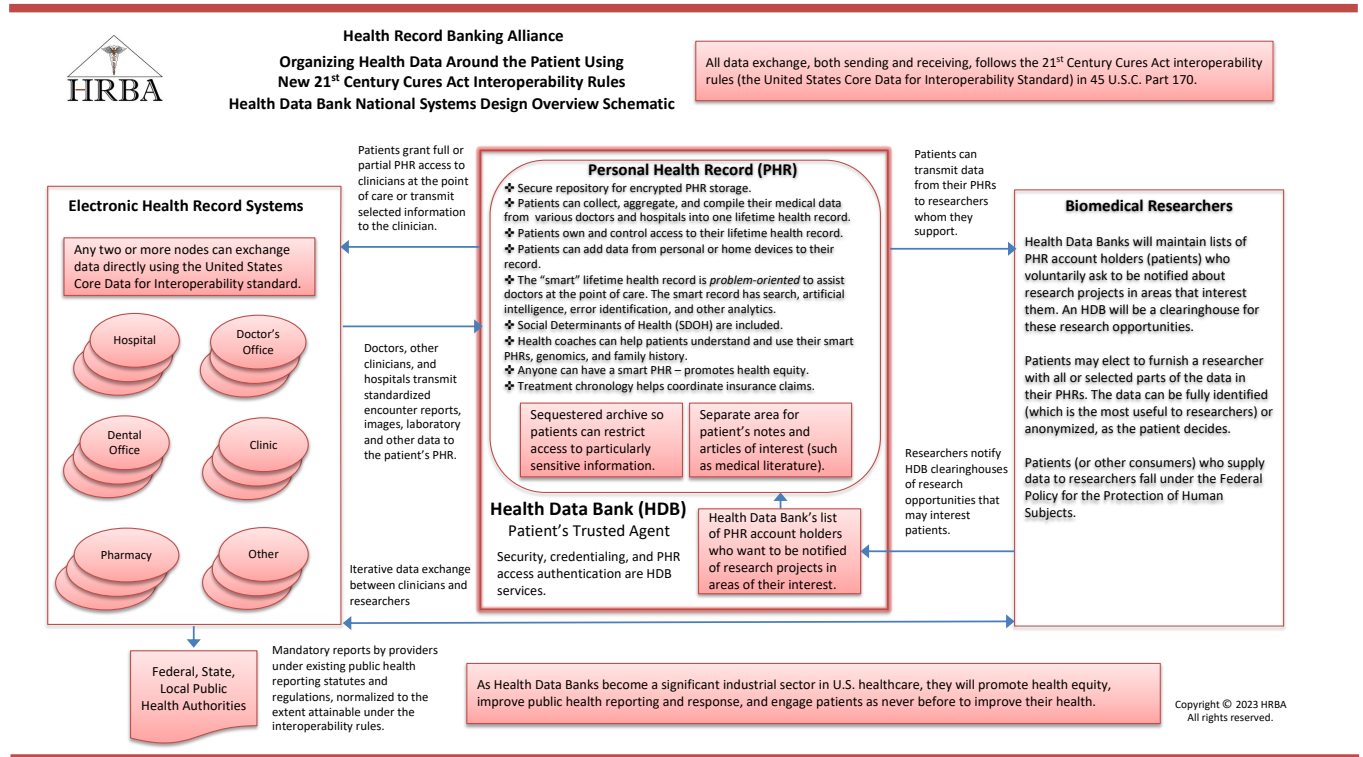
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Appendix

Health Data Bank (Health Record Bank) Schematic Overview And Descriptive Summary



Please see accompanying text on the following page.



Health Record Banking Alliance

Organizing Health Data Around the Patient Using New 21st Century Cures Act Interoperability Rules

Health Data Bank National Systems Design Overview

A **Health Data Bank (HDB)**, also called a **Health Record Bank** is an **integrated patient information services institution**. As a **trusted agent**, it offers a **secure repository** for each individual to collect and compile their “**interoperable**” digital health information in a **smart Personal Health Record (PHR)**. Individuals own and control their Personal Health Records, as in a bank checking account. With these **new information flows**, consumers will:

- exchange medical records and other health data in their Personal Health Records conveniently with doctors’ offices and hospitals for better, faster care; improve patient safety; and reduce information burden on physicians by supplying an aggregated, lifetime, searchable medical record for easy and immediate reference.
- control Personal Health Record access for doctors and hospitals; family, friends, and health coaches; medical researchers; members of the press; and others as they wish.
- use their Personal Health Records to help manage their health and healthcare, and to help shop for doctors, hospitals, and health insurance.
- view their Personal Health Records on smartphones, tablets, and other computers.

Health Data Banks and Efficiency: Integrating health information around each patient via HDBs is the most efficient way to aggregate and use “**interoperable**” health data under 21st Century Cures Act regulations. It is far more efficient and useful than a collection of “apps.”

HRBA’s Education and Policy Advocacy: HRBA advocates government policies promoting Health Data Banks as a **major new structural sector in U.S. health care**. This systems design includes a **national regulatory framework for Health Data Banks**.

Health Data Banks and Health Equity: Health Data Banks will promote **health equity** because **everyone** can have a Personal Health Record in a Health Data Bank.

Health Data Banks as Medical Research Clearinghouses: Medical researchers cannot get enough patient data to make fast or sufficient progress. HDBs can be clearinghouses between patients and researchers. Patients can **voluntarily** list themselves with their HDBs to be informed of research projects they are interested in, and to which they want to **contribute or sell their data**. This also is a path to developing **national federated diagnostic and research databases** while respecting **patients’ privacy rights** (because patients are in control). Better research will improve treatment for acute, chronic, and orphan diseases.

Health Data Banks, Security, and Patient Matching: Security, credentialing, and patient authentication and efficient matching are systems design features of HDBs.

Advanced Features of Smart Personal Health Records: Systems design features such as artificial intelligence (AI) and search capabilities, robust family history, and genomic analytics will deliver **problem-oriented data and analysis to mesh** with clinicians’ Electronic Health Record (EHR) systems **at the point of care**. Availability of this aggregated **reference record** will reduce burdens on clinicians while improving diagnosis, treatment, and patient outcomes.