

Data Consortia: Answering Tomorrow's Questions Today

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Data Consortia: Answering Tomorrow's Questions Today

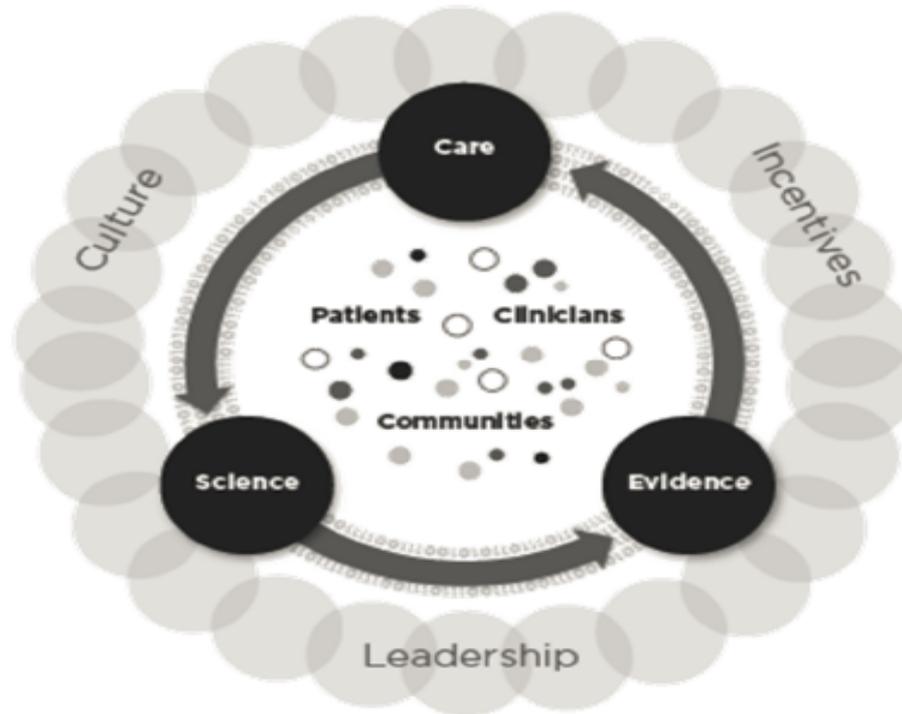
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Data Consortiums Promise

Vision: High-Value Care
Driven by Rapidly Improving Science



Source: IOM, 2012

Trends Driving Consortia

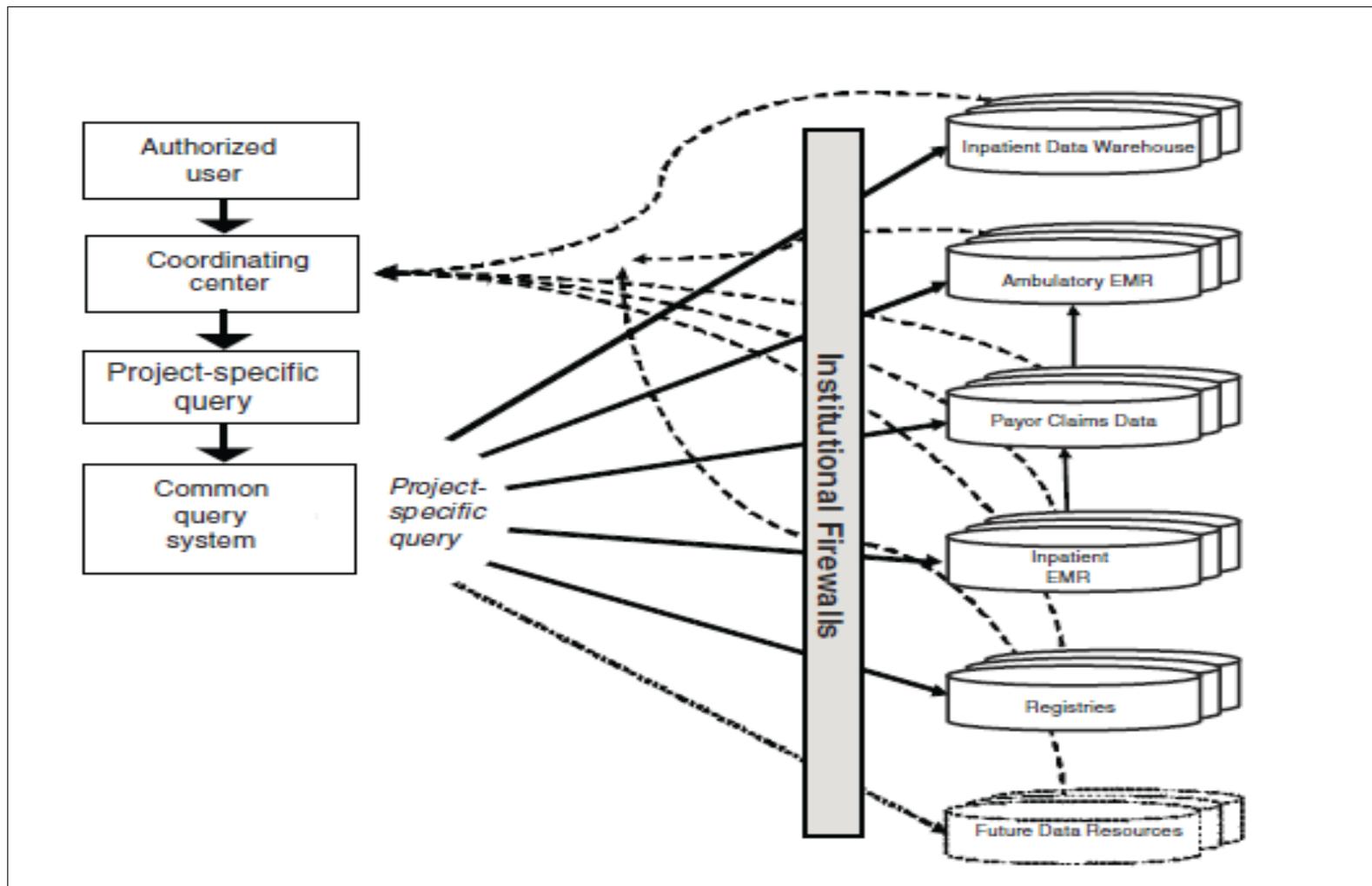
- American Recovery & Reinvestment Act, and Meaningful Use goals, especially monitoring population health measures
- ACA mandate to cover conditions of shared concern by HC and PHS systems and national strategy for quality improvement in health care
- Prevalence of chronic diseases
- Successes of public–private partnerships
 - Interagency Registry for Mechanically Assisted Circulatory Support—INTERMACS
 - Simulations carried out by the HMO Research Network demonstrating how their “virtual database” would have detected Vioxx ADE within months

Consortiums Versus Databases

Consortiums avoid the creation of large, static data bases susceptible to leaks or tampering

- “Virtual Data Networks” or “ Distributed Data Networks”
- NHDSE—AHRQ proposed National Health Data Stewardship Entity which would
 - act as a data repository and manager
 - possess policy making, data governance and stewardship functions
 - advising public agencies in standard-setting
 - regarding the acquisition, management, and use of health information, as well as on priority matters
 - Public comment on NHDSE proposal:
 - Concerns around role being given to public versus existing private vendors
 - Few comment on structure and governance (e.g., advisory committee) and public records

Data Consortia: AHRQ Prototype



Types of Data Consortia-Terms

- Data stewardship
 - denotes an approach to the management of data, particularly data that can identify individuals.
 - management methods covering acquisition, storage, aggregation, and de-identification, and procedures for data release and use
 - conveys a fiduciary (or trust) level of responsibility toward the data.
- Data governance
 - process by which responsibilities of stewardship are conceptualized and carried out.
 - Policies and approaches that allow stewardship
 - Establishes qualifications of users
- Health services research-twin assumptions
 - good evidence can be created from health care data on patients, providers, and health care systems
 - The data will be available

Types of Data Consortiums-Owners

- Types of owners:
 - Individual investigators
 - Health care providers (e.g., MCO)
 - Government sponsored
 - Public–private partnerships
- Data ownership versus data access. Owners can give access to multiple research organizations
- Government role: monetizing vs. stewardship:
 - Stewardship chosen with ACA: supports goals set by advocates of evidence-driven care (although subject to important limitations on the use of data.)
- Issues beyond ownership
 - We have the mechanisms to manage research in safe and secure environments—now the social and legal frameworks need to catch

Data Consortium Components

Data consortium components:

- System design to transmit aggregate data to a central repository
- Data-processing software
- Selection of statistical techniques and parameters
- Automated alerting.

Data linkage requires

- expertise in several areas, including knowledge of the datasets to be linked— their limitations and idiosyncrasies
- skills in the use of linkage programs
- skills in statistical analysis and interpretation that comes from a multidisciplinary team including database managers and programmers
- statisticians work collaboratively with health services researchers to resolve technical problems while keeping eye on the research question.
- iterative cycles of assessment within and between sites
- constant communication between site-level data providers, data coordinating centers, and principal investigators.

Data Consortium Components-Data

Data must yield reliable and consistent results

- This requires careful definition of data elements and hypothesis statement before the research begins
- More data is better? Always able to simplify later?
- Data consistency is needed across the consortium, to allow independent researchers to validate the results
- Complete and accurate records on data collection are required
- Data complexity and inconsistency/non-comparability
- Need for markers/predictors of outcomes
- Investigate types and degree of missing data (e.g., attrition, nonresponse, non-coverage)
- Investigate miscoding

Data Consortium Data: Outcome Assessment

Outcomes Assessments That Data Consortia Need To Access

ISPOR defines outcome assessments:

- All-cause mortality/survival
- Patient reported outcomes
- Clinician reported outcomes
 - Performance measures –six minute walk test, FEV1
 - Readings – liver/spleen size, swollen joints
 - Ratings – positive and negative signs and symptoms (PANSS) scale; switching interventions
- Observer reported outcomes
- Biomarkers

Outcomes measurement supports CER and HTA objectives

Data Consortia: ADE Surveillance

- Data consortia are well-positioned for adverse drug event surveillance
 - FDA risk evaluation and management ETASU documentation
 - HHS National Action Plan for Adverse Drug Event (ADE) Prevention for opioids, diabetic drugs, anticoagulants
 - Potential for real-time surveillance that provides comprehensive patient information to share among health care providers, health plans, MCOs, and PBMs
- For ADE surveillance, data consortia need to include
 - Standardized signs and symptom measures (e.g., the critical path PRO consortium (<http://www.C-path.Org/>))
 - Laboratory Results and Biomarkers

Data Consortium Issues

Data consortium issues

- Selecting of appropriate data partners and developing trust between data partners and users
- Developing and refining statistical analyses and methods (e.g., Ensuring consistency across the data sources)
- Patient privacy
- Valid statistical approaches, for example:
 - Space-time scan statistic (to account for naturally occurring temporal and geographic trends)
 - Risk adjustments, selection bias, over-adjustment bias versus unnecessary adjustment
 - Propensity scores/adjustment for observables, longitudinal analysis/individual effects, instrumental variables
 - Cluster randomization, policy comparisons (instrumental variables)

Data Consortium Issues

- Concerns about potential liability under a host of civil and criminal laws, as well as on their competitive market position.
- Concerns about shielding information that may carry business, legal, or social costs.

Are these concerns valid?

- Most common legal cases are for providers who resisted releasing health data to their own patients out of liability concerns
- Shielding information from patients or failing to make use of information carries liability risks of its own (Institute of Medicine 2001)
- Under ACA, government has the power to establish a data steward (Federal Coordinating Council for Comparative Effectiveness Research)

Data Consortia: MCO

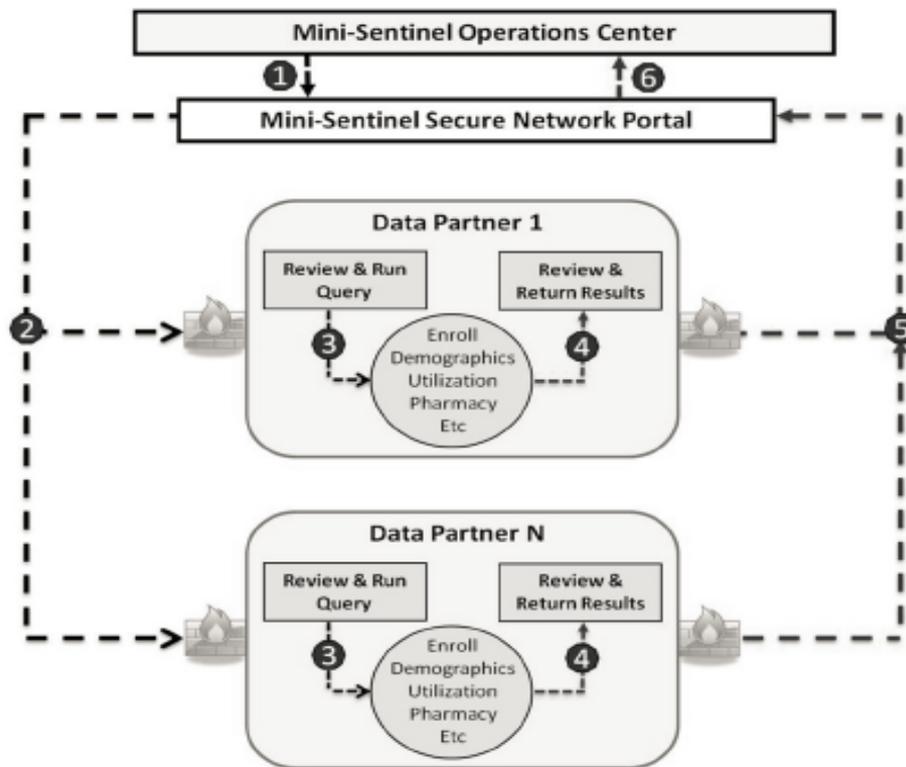
- Research characteristics that may discourage MCO engagement in a consortium
 - Benefits (premiums, deductibles, copays)
 - Payments and service agreements
 - Networks

Data Consortia: Mini-Sentinel Example

- Mini-Sentinel
- data partners to maintain physical and operational control over the electronic data within their existing environments
- Common Data Model for Surveillance Activities
 - allows MCO to protect patient privacy
 - MCOs run queries within their unique data system
 - Sample output
 - calculating incidence rates
 - protocol based assessments of medical products
 - How many patients taking olmesartan had developed celiac disease compared to those taking other similar drugs for high blood pressure?
- The methods and infrastructure established to support Sentinel present a valuable platform for developing a shared national resource

Data Consortia: Sentinel Example

FDA Sentinel Initiative: Mini-Sentinel's Distributed Database



1- User creates and submits query (a computer program)

2- Data partners retrieve query

3- Data partners review and run query against their local data

4- Data partners review results

5- Data partners return results via secure network

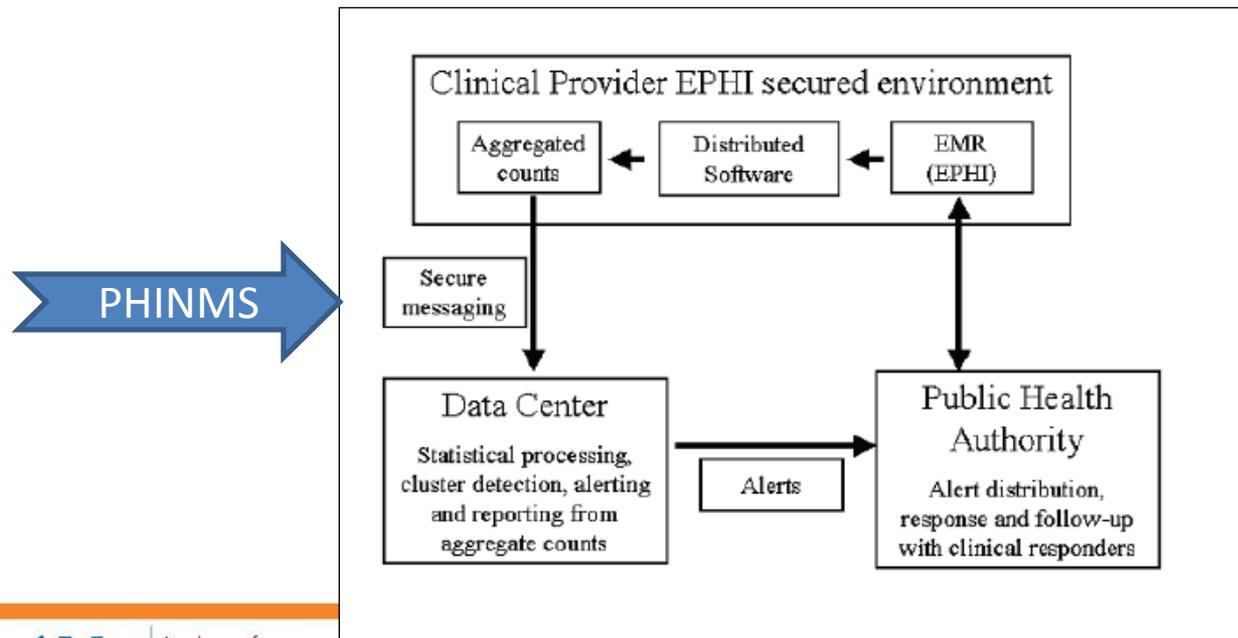
6- Results are aggregated

Data Consortia: HMORN Example

- HMO Research Network (HMORN) is a consortium of 16 dedicated research centers based in non-profit health care systems. Its purpose is to foster collaborative research and knowledge sharing to improve health and health care for people nationally and globally.
- “Virtual Data Warehouse” or distributed data network
- NIH-HMO Collaboratory to support large scale epidemiologic and pragmatic clinical
- Investigations across a range a diseases and health conditions. Source of investment is the NIH Common Fund
- CDC-supported surveillance projects : maternal morbidity, AMLS registry, vaccine surveillance, PID, TB and tuberculosis, and bioterrorism syndromes
- Structure: Governing Board and Asset Stewardship Committee.
 - Considering Executive Committee that could be more nimble and responsive, create strategy, and manage growth.

Data Consortiums: NDP Example

- The National Demonstration Bioterrorism Surveillance program (NDP) is Used for Detecting unusual clusters of disease and reducing alert levels
- A distributed data processing approach where highly aggregated count data is transferred for statistical processing using “first encounter” methodology
- “Syndromic surveillance system” monitors 13 syndromes – Respiratory, Lower and Upper GI, Neurological, Botulism-like, Fever, Hemorrhagic, Skin lesions, Lymphatic, Rash, Shock-death, Influenza-like illness and SARS-like illness



Data Consortia: OMOP Example

- Why: researchers were always hampered by a reliance on voluntary reporting for ADE
- 2007 Congress authorized FDA to initiate drug surveillance programs
- OMOP (Observational Medical Outcomes Partnership)
 - In partnership with PhRMA and the FDA, the Foundation for the National Institutes of Health launched a public-private partnership
 - Broad aim broader aims: identifying the most reliable methods for analyzing huge volumes of data drawn from heterogeneous sources
- OMOP Common Framework (Common Data Model and Vocabulary Specifications)
 - Continues to be used for building observational networks in CER and safety research
- OMOP Web Research Lab (Web RL) Cloud Provisioning Platform Software.
 - In public domain to build cloud-based data management and computationally rich computing environments
 - <http://omop.fnih.org/>

Announcing AMCP Task Force November 12

Biosimilar Collective Intelligence System: Utilizing Data Consortia to Prove the Safety and Effectiveness of Biosimilars

- Biosimilars represent an opportunity to bend the cost curve for specialty drugs.
- Will explore the feasibility of launching a Biosimilars Collective Intelligence System to document the safety and efficacy of biosimilars, with reference to the data available for the innovator specialty drug.
- Goal is to have a Biosimilars Collective Intelligence system up and running before the first biosimilars hits the market
- Data consortium and specialty drug experts from the leading US managed care organizations will lend their expertise to identifying the action steps
- Also engaging health services researchers including the Harvard Mini-sentinel group; governmental agencies including FDA, AHRQ, and PCORI; PBMs and specialty management organizations; the Brookings Institute; and pharmaceutical manufacturers.

Caveats for Data Consortia for CER

- EHRs may Contain Inaccurate (or Incorrect) Data
- EHRs Often do not Tell a Complete Patient Story
- Many of the Data Have Been Transformed/Coded for Purposes Other Than Research and Clinical Care
- Data Captured in Clinical Notes (Text) may not be Recoverable for CER
- EHRs may Present Multiple Sources of Data That Affect Data Provenance
- Data Granularity in EHRs may not Match the Needs of CER
- There are Differences Between Research Protocols and Clinical Care

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DRN and Laws Regs

- Scalable National Network for Effectiveness Research (SCANNER)—develop infrastructure consistent with privacy and security laws and best practices. (Along with EDM and PCORI)
- policies depend on
 - data type (aggregate counts, deidentified, limited, and fully identified datasets)
 - flow of data
- Possible requirements
 - Network agreement
 - Data use agreement
 - Authentication of users
 - Audit
 - IRB protocol
 - Identified data screening
 - Tagging data as sensitive

Med Care 2013;51: S66–S72