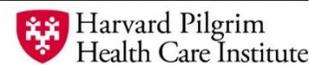


International Comparison of Approaches to Common Data Models for Comparative Effectiveness Research

International Population Data Linkage Network Conference 2018
Banff Centre, Banff, Alberta, Canada
September 12, 2018

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Disclosures

- I am an employee of Harvard Pilgrim Health Care Institute.
- I have research funding from FDA, NIH, PCORI, BBCIC, IMEDS, and Pfizer.
- I am the inventor of PopMedNet, an open source software application used to support distributed health data networks.
- I consult for IBM, Roche, and Bayer on issues related to the use of observational data for real-world evidence generation.

Data holders, lives covered, data access model, and network governance



- 18 data partners: 17 health insurers and 1 national hospital system
 - 9 integrated delivery systems with EHRs
 - All can request access to full medical charts
- ~300m member identifiers; ~67m current members
- >14 billion dispensings and > 13 billion medical visits
- Data access: Distributed data model - send questions to the data, securely return *information* via PopMedNet
- Governance: FDA directs all querying, data model changes, and tool development; Sentinel Operations Center distributes all network queries

Process for transforming a repository's data into the common data model

- Common data model created based on guiding principles developed in partnership with collaborators and based on FDA's specific needs
- Partners transform local data to the common data model based on the data dictionary, documentation, and ongoing guidance
- Initially, weekly calls to share knowledge and lessons learned; now monthly
- Rigorous data checking and characterization process after every data refresh; data must be approved by operations center before use
- Data model changes implemented using standard progress that includes distinct Discovery, Planning, Testing, and Implementation phases

www.sentinelinitiative.org/sentinel/data/distributed-database-common-data-model/sentinel-common-data-model

www.sentinelinitiative.org/sentinel/data/distributed-database-common-data-model/data-quality-review-and-characterization

www.sentinelinitiative.org/rss/sentinel-data-quality-assurance-practices

Target audience(s), process of identifying queries and knowledge dissemination plan

- Sentinel resources used at FDA's direction and managed by the Sentinel Operations Center (SOC)
- All queries are initiated by FDA
- Data model and tools publicly available
- Query results posted on public website, with complete details
 - Query specifications, dates, code sets, and analytic tools used (version number)
- By policy and guiding principles, the Sentinel Distributed Dataset held by partners can be used for other purposes at their discretion
 - Designed for FDA with other uses considered
 - IMEDS, BBCIC, NIH Collaboratory, multiple industry sponsored studies

Two key challenges faced by the network and the lessons learned

Data Standardization and Change Management

- Data curation requires substantial ongoing resources and trust
- Data model changes have important change management ramifications for partners, data curation, and tools
- Small change can be complicated

Managing Expectations for Speed and Data Completeness

- Highly curated data and standard tools enable rapid response
- But all queries are subject to validation processes and verification of appropriateness
- Programming “tweaks” are risky in a distributed network