

# **Challenges and Solutions for Globally Establishing and Standardizing Population Healthcare Databases**

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### BACKGROUND Limitations in sharing de-identified structured healthcare (HC) data is a g

Limitations in sharing de-identified structured healthcare (HC) data is a global public health issue.

Wide variations exist currently in data collection methods, availability, database (DB) format, and standards, thereby posing a major challenge.

There is a need for <u>standardization</u> of critical data elements in all DBs.

Conformance of DB elements will support global sharing of HC data [e.g., electronic health records (EHRs), insurance claims, and registries], and will allow valuable comparisons worldwide.

### OBJECTIVE

Explore opportunities for collecting, standardizing, and sharing HC data worldwide.

### METHODS

A Panel of pharmacoepidemiology, pharmacovigilance and drug policy experts with HC DB experience in multiple regions (Africa, EU, Middle East, USA) was convened in February 2017 to identify gaps in DB research and potential approaches for harmonizing HC DBs.

RESULTS

The international Panel of experts identified several challenges in developing and maintaining standardized DBs, as well as proposed potential solutions (Table 1).

#### Table 1. Challenges and Potential Solutions for Establishing and Globally Standardizing Population Healthcare Databases

Issue	Major Questions	Potential Solutions	Examples of Successes
Implementing policy	<ul> <li>Are government regulations setting basic requirements for establishing DBs?</li> <li>Do governments provide a framework for performance standards for HC DBs?</li> </ul>	<ul> <li>✓ Governments can take the <b>lead</b> in establishing DBs</li> </ul>	★ FDA's Sentinel System FDAAA requirement that FDA develop a system to obtain information from multiple existing EHRs to assess the safety of approved medical products
Financial obstacles	<ul> <li>Who will fund the DB?</li> <li>Is there skepticism for commercial funding?</li> <li>Is there adequate funding to allow development of high quality DBs?</li> </ul>	<ul> <li>✓ Governments can incentivize institutions to create and share data</li> <li>✓ Data access fees can help offset the cost of DB development and maintenance</li> </ul>	★ Commercial data vendors (e.g., QuintilesIMS) Companies found value in sharing data and charging for the use of data
Lack of Infrastructure	<ul> <li>Are data linkable and comparable?</li> <li>Is it a paper-based or electronic DB?</li> </ul>	✓ Repurpose existing DBs	<ul> <li>* Nationally linked electronic HC DBs</li> <li>Nordic countries use civil registration numbers to link administrative, vital statistics, clinical, disease / drug registries, etc.</li> <li>* openMedicine (www.open-medicine.edu)</li> <li>EU eHealth Action Plan to deliver medical products across borders efficiently through a Common Data Model (CDM) and Standardized Vocabulary (SV) for identifying and describing medicines unambiguously</li> </ul>
Insufficient Human Resources	<ul> <li>Who understands the data to design the right DB?</li> <li>Are there qualified epidemiologists and statisticians to analyze the data?</li> <li>Are doctor offices willing to spend time entering medical information?</li> </ul>	<ul> <li>✓ Establish and promote schools of public health, and incorporate DB design into training programs</li> <li>✓ Improve education in public health, epidemiology, and DB design</li> <li>✓ Increase publications on DBs</li> </ul>	★ B.R.I.D.G.E. TO DATA® (www.bridgetodata.org) An online compendium of population HC DBs that standardizes DB descriptions, serves as a template for DB design, is an educational tool, increases awareness of data collection efforts around the world, and promotes collaboration of existing data sources ( <u>Figure 1</u> )
Technical Considerations	<ul> <li>Are data fields standardized?</li> <li>Are the data longitudinal?</li> <li>Are the data validated?</li> <li>Is there a way to track patients across their multiple HC providers?</li> </ul>	<ul> <li>✓ Pull existing technology from other sectors (banking, commercial transportation)</li> <li>✓ Use high-level standards (e.g., HL7) as a basis for HC data exchange</li> </ul>	<ul> <li><b>* WHO CIOMS SMQ Working Group</b></li> <li>A project to harmonize &amp; standardize adverse drug reaction terminology and DB search queries to allow comparisons of drug safety findings across different DBs.</li> <li><b>* OMOP</b></li> <li>A public-private partnership to identify validated methods for analyzing multiple data through a CDM and SV in order to produce meaningful, comparable and reproducible results</li> </ul>
Ownership of data	<ul> <li>Are data owners willing to share data?</li> <li>Are there multiple public health</li> </ul>	✓ Establish mechanisms for data sharing, DB standardization and development	★ FDA Open (https://open.fda.gov) A government-sponsored project providing each access to and education on the row data and documentation for

applications for data?

development

Can collaborations reduce redundancies?

to and education on the raw data and documentation for FDA's public datasets

#### Figure 1. Commercialized Research Tool that Globally Addresses HC DB Solutions



### CONCLUSIONS

- The Panel recommended establishment of standards for creating HC DBs in various settings worldwide, identified challenges in developing and maintaining HC DBs, and recognized the importance of data sharing.
- The standardization of data fields would permit a common data language and increase the effectiveness of global public health research.
- Data sharing will reduce effort, time, and cost of research.
- Stakeholders can draw upon successful examples to achieve these goals; e.g., B.R.I.D.G.E. TO DATA® may facilitate collaboration between data centers, serve as a template for developing new DBs, and be a useful tool in HC DB education.
- Real-time data can have a huge impact on guiding international public health actions and decisions.

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