

Addressing Sustainability and Informatics Challenges for Clinical Data Registries: A Qualitative Study

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Topics for Discussion

Clinical Data Registries (CDR)

- Powerful tools for collecting, storing, and analyzing electronic health data
- Means to generate clinical research knowledge using electronic health data and translating into clinical practice
- Instrumental in conducting patient-centered outcomes research, improving quality of care, and providing public health surveillance.

Problem Statement

Despite the potential of clinical data registries and the hefty investment into health information technology, there are still some clear challenges to using EMR-based clinical data registries for CER.

Research Questions & Objectives

Research Questions:

- RQ1: What are the primary facilitators and barriers for constructing a CDR?
- RQ2: How can program administrators address these barriers?

Objectives:

- To understand the similarities and differences in strategies, operations, and technology;
- To examine what interventions have been put in place; and
- To build a model that can be followed.

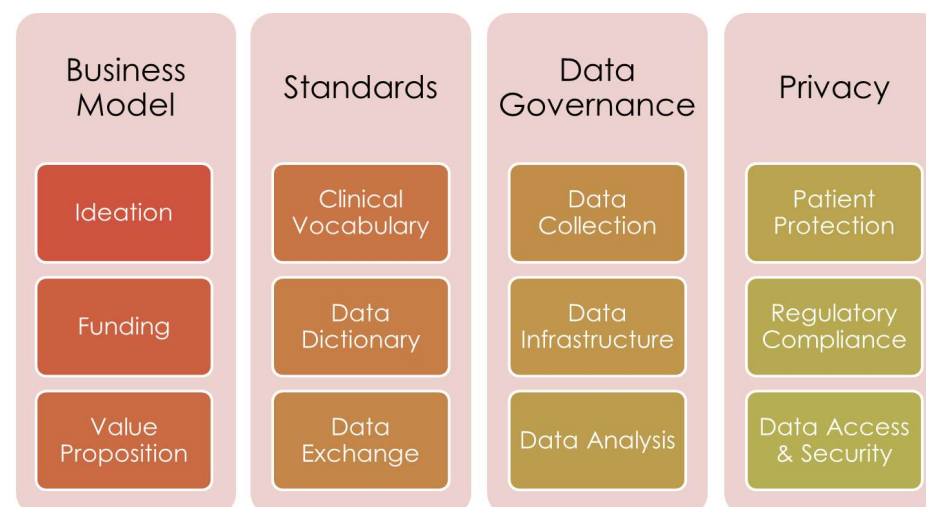
Conceptual Framework

The framework highlights and categorizes key challenges associated with the development and management of clinical data registries.

Primary domains include:

- **Business Model:** sustainable business practices that support rapid expansion of the program
- **Standards:** necessary to facilitate electronic data sharing and aggregation
- **Data Governance:** data management processes
- **Privacy:** complying to regulations that are designed to protect patient privacy

Clinical Data Registry Challenges Framework



Research Methods

- **Method:** study utilizes qualitative comparative analysis to identify major barriers and lessons learned
- **Study Sample:** highlights four not-for-profit U.S.-based clinical data registry programs that accept electronic data
- **Data Collection:** more than 20 semi-structured interviews were conducted with program representatives, physicians, policy makers, technology experts, and industry personnel
- **Data Analysis:** themes, challenges, and innovations were identified using both primary and secondary data.

Findings: Lessons Learned

- **Ideation:** Quality improvement is the primary driver for establishing.
- **Funding:** Establishing a viable funding model is the greatest challenge.
- **Value Proposition:** All CDRs target specific professional constituencies.
- **Clinical Vocabulary:** All have developed standard clinical terminology.
- **Data Dictionary:** Have adopted a technical standard as a means to appropriately map data.
- **Data Exchange:** Each is actively establishing data sharing network with other CDRs.
- **Data Collection:** Each has an automated process for collecting and validating data.
- **Patient Protection:** All believe they own or have exclusive rights to de-identified data.

Findings: Strategies Facilitating Program Success

1. Clearly defines the mission, vision, and primary/secondary purpose during Ideation.
2. Things globally with strategic planning to remain innovative and increase revenue opportunities.
3. Develops innovative funding models that create multiple revenue streams.
4. Highly prescriptive with clinical vocabularies and data field definitions.
5. Adopt XML as technical standard.
6. Establish a Data Use Committee.
7. Leverage advanced technologies.

Contact

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