

# Optimizing Health Information Technology's Role in Enabling Comparative Effectiveness Research

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Health information technology (IT) is a key enabler of comparative effectiveness research (CER). Health IT standards for data sharing are essential to advancing the research data infrastructure, and health IT is critical to the next step of incorporating clinical data into data sources. Four key principles for advancement of CER are (1) utilization of data as a strategic asset, (2) leveraging public-private partnerships, (3) building robust, scalable technology platforms, and (4) coordination of activities across government agencies. To maximize the value of the resources, payers and providers must contribute data to initiatives, engage with government agencies on lessons learned, continue to develop new technologies that address key challenges, and utilize the data to improve patient outcomes and conduct research.

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In the past several years the federal government allocated substantial funds to 2 initiatives often perceived as independent: health information technology (IT) and comparative effectiveness research (CER).<sup>1,2</sup> Although health IT and CER have many separate domains, each enables the other to have an optimal impact on health. For example, there is a critical need for an improved data infrastructure to support CER. Conversely, the comparative effectiveness of different health IT interventions on patient outcomes and system efficiency will inform important adoption decisions. Investment in CER data sources also helps build the health IT infrastructure.

In this commentary, we outline how health IT is a key enabler of CER. First, seminal work on health IT standards has laid the foundation for data sharing and the potential for distributed networks. Second, the health IT focus on linking and networking data is essential to enable research. Distributed networks hold tremendous promise for expanding the secondary use of health data and addressing the myriad challenges associated with doing so. In particular, they provide a way to address concerns about upholding patient privacy and protecting proprietary business interests. Third, health IT initiatives will increasingly augment the current research data infrastructure with clinical data.

It is important to note that provider adoption of electronic health records (EHRs) is necessary but not sufficient for the CER enterprise. For CER to be conducted, these EHRs must be connected to data networks enabling access to at least portions of their captured data. It will be challenging to implement EHRs on a large scale and to develop electronic networks substantial enough to produce observational data that alter clinician, patient, and other decisions. However, the importance of this data infrastructure is rapidly growing, particularly as the role of observational research grows through an increasing emphasis on effectiveness research.

Recognizing the need for CER data infrastructure to build on existing health IT infrastructure, the federal government allocated \$268 million (24%) of the \$1.1 billion American Recovery and Reinvestment Act of 2009 (ARRA) CER funds to the development of data infrastructure.<sup>3</sup> These investments complement other initiatives that push for the public release and utilization of existing resources, and several that focus on advancement toward distributed data networks.<sup>4,5</sup> Four principles will enable maximum value to be obtained from these investments:

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1. Utilize healthcare data as a strategic asset for improving health.
2. Leverage public–private partnerships. Without the participation of payers and providers, the program will suffer from a lack of feasibility, subpar generalizability, and an unrefined value proposition.
3. Build a robust, scalable platform of technology that enables new research as it is deployed, but is sufficiently advanced to incorporate the next wave of innovation supporting integration of clinical data.
4. Coordinate activities across government agencies.

### Utilize Healthcare Data as a Strategic Asset to Improve Health

The current health system enterprise generates huge amounts of administrative and clinical data in the routine delivery of care. These data must be viewed as a strategic asset to be utilized in evaluating and improving the health outcomes and efficiency of the system. Tangible examples include maximizing the release of administrative data for research purposes from the Centers for Medicare & Medicaid Services (CMS) and other payers using vehicles such as tiered user access schemes, limited data sets for public use, and linked data across data sets and time. Initiatives developing distributed data networks may be ideal outlets. In addition, clinical data collected via EHRs and health information exchanges should be made available whenever possible (within privacy and security constraints) to researchers analyzing data at a local level to guide care and improvement.

There is substantial value in health data that can be used to support and extend the current observational research enterprise. Actionable research that informs public policy and healthcare delivery decisions often is limited by access to and quality of the data. Enabling greater access to data and improving the data's breadth, depth, and longitudinality will help overcome several obstacles (eg, poor access to data from certain delivery models such as HMOs, inability to adequately risk-adjust, and difficulty in studying persons across settings and policy types). Although use of these data may not remove all barriers to quality research, it is crucial for a learning healthcare system that improves over time.<sup>6</sup>

### Leverage Public–Private Partnerships

Public–private partnerships are essential for health IT to enable CER that has maximal value. The federal government is embarking on ambitious large-scale initiatives to bring large volumes of data from multiple sources together into common resources, often distributed, for the purpose of research. The private sector (eg, Blue Cross and Blue Shield with its Blue Health Intelligence initiative, Kaiser Permanente's National Research Database) has undertaken efforts of similar magni-

tude.<sup>7,8</sup> Key players traverse a landscape rife with challenging issues such as ensuring privacy of beneficiaries and numerous technological barriers. By collaborating with the federal government in synergistic partnerships, the private sector will be able to share key lessons learned and best practices with leaders in the federal government.

Private sector involvement also is critical to gathering more complete administrative payer data. The federal government has committed to contributing its data (eg, CMS data) through various initiatives.<sup>4,5,9</sup> Although CMS is a necessary source of data, these data are not sufficient to support the comprehensive study of clinical or healthcare delivery CER. Furthermore, the imperative to contribute data is not limited to payers. Providers in the private sector retain access to clinical data with the potential to vastly enrich administrative resources. Although the federal government can play a critical role in contributing public data and providing funding to key initiatives, private sector entities across the health sector must increase participation to create resources that maximize the ability to improve patient care, an imperative made less costly by recent advances in distributed data networks.<sup>10</sup>

Private sector involvement can refine the value proposition of research data infrastructure. Analytic tools developed in the private sector also can allow for faster, more efficient performance of research, as well as other activities aimed at improving outcomes and efficiency. For example, benchmarking, which is a common application among payers and providers, is intrinsically linked to promoting efficiency of care. In addition, the measurements enabled by data infrastructure are key components of quality improvement efforts. In order to gain maximal participation, payers, providers, and clinicians must perceive data collection and infrastructure efforts as part of the care delivery and improvement enterprise. The role of government in this respect is largely to catalyze a new market that leads to additional research opportunities and promotes an evolving data infrastructure that can be used to both answer research questions and drive care improvement.

### Build a Robust, Scalable Platform of Technology

When it comes to managing health data for clinical effectiveness research, the million-dollar question is when large databases (eg, claims databases) will incorporate clinical-level data. Although inclusion of these data has been hailed as the holy grail of secondary research for CER, it is rife with challenges. The federal government faces the imperative of making investments that yield timely returns for stakeholders (eg, patients), yet myopic investments will lead to resources that fail to evolve with future advancements in technology. The vehicle for much of the recent data infrastructure investment is ARRA, which stipulated strict time lines to push money

into the economy. Balancing short-term and long-term goals in such a setting was challenging but essential.

In addition to the time line and bureaucratic challenges, protecting the privacy of patients is of utmost importance. The power of linking clinical information with administrative data also manifests in less desirable ways such as lowering the degree of difficulty in identifying individual patients. Thus, although there is value in integrating administrative and clinical data, implementing this integration on a large scale must be done cautiously. The public and private sectors must pursue technologies that maximize access to data while maintaining privacy and security and that also can be scaled over time to incorporate additional clinical data. Furthermore, these technologies must address other outstanding challenges that arise in the large-scale implementation of health IT systems. These issues include those that are the focus of government initiatives (eg, interoperability of systems), as well as those that face data providers more exclusively (eg, need for substantial resources to transform and standardize data).

### Coordinate Activities Across Government Agencies

The ARRA CER program provides the federal government with an opportunity for significant health data infrastructure investments to enable future research. The Federal Coordinating Council for CER played a fundamental role in coordination at the federal level that allowed for alignment of data infrastructure investments with those in complementary categories (eg, scientific and human capital, research, dissemination, translation).<sup>1</sup> Although within-program coordination is important and likely more easily accomplished, the investment in data infrastructure must be synchronized across programs. The Federal Coordinating Council and its subsequent operational groups worked across the US Department of Health and Human Services, including the Office of the National Coordinator, to try to coordinate investments across the department. Various initiatives may have differing goals, but without coordination, synergies in investments and activities may go undiscovered. There also are numerous other initiatives (eg, All-Payer Databases) at the state level. For example, Utah approved House Bill 133 on July 8, 2008, to fund “the creation of an All-Payer Database.”<sup>11</sup> Ideally, the state and federal investments will be coordinated and even connected to one another. A further step necessary will be for the private sector to participate in future planning of investments and in determining how to best leverage them.

The case for coordination is a strong one. Because of the common challenges and priorities (ie, data ownership and privacy), there has been a convergence toward distributed database models. These models favorably change the nature of data contribution and access. Fewer concerns about privacy

and ownership and more control of data contributions have resulted in increased enthusiasm for partnerships. Coordination has increased in importance because data infrastructures that were conceived separately and for different purposes are gravitating to a common distributed framework. An example is the case of the FDA Sentinel Initiative and the ARRA CER multipayer claims database initiatives.<sup>12,13</sup> Although each may have been created in response to different needs, their common operational approach, using distributed data as at least 1 component, may create unforeseen synergies and opportunities to learn what worked well (and not so well). If left uncaptured, these potential lessons would be a missed opportunity.

Thus, there is a call for more coordination in health data infrastructure investments that cut across applications, whether they are for health IT, research, or surveillance of device or drug safety. A coordinated effort could facilitate realization of the promises inherent in bringing clinical and administrative data together. While the Office of the National Coordinator is creating metrics of meaningful use of EHRs, linking EHRs to the research data infrastructure has yet to be incorporated into the criteria.<sup>14</sup> As the technology platforms evolve, it will be important for the Office of the National Coordinator, standard-setting organizations, health IT vendors, and the research enterprise to work collaboratively to capture all the potential value.

Payers and providers play an essential role in the success of a robust and effective research data infrastructure. They must be engaged throughout the life cycle of investments to make implementation feasible. Patients, clinicians, and the federal government alike depend on them for specific action. Payers and providers must contribute data to initiatives, engage with government agencies at the state and federal levels on lessons learned through their own efforts, and continue to develop new technologies that access nascent markets. As participation increases, it is likely that the private sector will see opportunities where its missions align with that of the government.

In summary, health IT and a robust data infrastructure play a large role in enabling CER. Four main principles should be considered: utilization of data as a strategic asset; leveraging of public-private partnerships; building robust, scalable technology platforms; and coordination of activities across government agencies.

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## Health IT in Comparative Effectiveness Research

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