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Cite this article as:

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*Health Affairs*, 33, no.7 (2014):1187-1194

doi: 10.1377/hlthaff.2014.0038

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# Optum Labs: Building A Novel Node In The Learning Health Care System

DOI: 10.1377/hlthaff.2014.0038  
HEALTH AFFAIRS 33,  
NO. 7 (2014): 1187-1194  
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**ABSTRACT** Unprecedented change in the US health care system is being driven by the rapid uptake of health information technology and national investments in multi-institution research networks comprising academic centers, health care delivery systems, and other health system components. An example of this changing landscape is Optum Labs, a novel network “node” that is bringing together new partners, data, and analytic techniques to implement research findings in health care practice. Optum Labs was founded in early 2013 by Mayo Clinic and Optum, a commercial data, infrastructure services, and care organization that is part of UnitedHealth Group. Optum Labs now has eleven collaborators and a database of deidentified information on more than 150 million people that is compliant with the Health Insurance Portability and Accountability Act (HIPAA) of 1996. This article describes the early progress of Optum Labs. The combination of the diverse collaborator perspectives with rich data, including deep patient and provider information, is intended to reveal new insights about diseases, treatments, and patients’ behavior to guide changes in practice. Practitioners’ involvement in agenda setting and translation of findings into practical care innovations accelerates the implementation of research results. Furthermore, feedback loops from the clinic help Optum Labs expand on successes and give quick attention to challenges as they emerge.

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**I**n the United States there is mounting pressure to improve the value of health care services and meet the Triple Aim of improving health care quality and health outcomes while lowering health care costs.<sup>1</sup> Concurrently, the rapid uptake of health information technology is fostering unprecedented and irrevocable change in the health care industry.

Hospitals and physician practices are implementing electronic health records (EHRs), payers and providers are using ever more sophisticated analytical software, and mobile health innovations are engaging participants across

the care continuum. Abundant new data thus are being generated that contain previously inaccessible insights about health needs and care delivery. Examples include documented divergence between physician-prescribed regimens recorded in clinical records and patients’ actual behavior as captured by administrative and consumer data, and patients’ use of social networks and their possible role in reinforcing compliance.

Policy makers, eager to convert these data into new knowledge to better address unmet needs across the spectrum of acute and chronic illness, are supporting the development of new multi-

institution networks of data and researchers. Relevant examples include PCORI's National Patient-Powered and Clinical Data Research Networks,<sup>2</sup> NIH's Big Data to Knowledge (BD2K) initiative,<sup>3</sup> NIH's Health Care Systems Research Collaboratory,<sup>4</sup> the FDA's Sentinel and Mini-Sentinel program,<sup>5</sup> and the Electronic Data Methods Forum sponsored by the Agency for Healthcare Research and Quality.<sup>6</sup> Singly and together, government and private entities are racing to make further significant investments in transforming the research and learning infrastructure and funding new initiatives to bring about a learning health care system.<sup>7-9</sup> The goal is to drive change in clinical practice by supporting research-based frameworks to integrate research into practice.<sup>10,11</sup>

The concept of a learning health care system envisions interacting national and regional research networks that consist of multiple contributing nodes, or collaborations of providers and consumers of data or research. Each node may include several organizational participants that are not exclusive to it. The impact of these learning networks ultimately depends on how well participants can align and integrate their efforts, especially through collaboration at the nodal level.

Most nodes develop by building on past associations with one or two constituencies—typical academic institutions and integrated health care delivery systems. Such collaborations have made and will continue to make important contributions. However, as efforts to create a learning health care system move ahead, policy makers do not want to be limited to traditional learning models; traditional participants; or smaller, incremental changes.

The emerging environment of big data and advanced analytics and the overall need for accelerated learning is also fostering innovative alliances. Catalyzed by the availability of massive data resources, new partnerships that seek to integrate the continuum of inquiry, research, and translation of research findings into health care practice are emerging in pursuit of important and actionable findings to improve health care.

### Optum Labs

Optum Labs was established in early 2013 as a novel approach in this evolving constellation of learning health care systems. It was novel in the composition and breadth of its participant groups, the data and analytic resources it used, and its approach to collaborative discovery and the integration of new knowledge into health care.

Optum Labs is a wholly owned subsidiary of Optum—a commercial data, infrastructure services, and care organization that in turn is a subsidiary of UnitedHealth Group, a diversified health and well-being company. A collaboration between Optum and Mayo Clinic, an academically oriented integrated health care delivery system, led to the creation of Optum Labs. Optum Labs is being developed as a sustainable organization within Optum. Participants in the collaboration will contribute data, expertise, tools, and financial support over time to Optum Labs.

Leaders of Optum and Mayo Clinic collectively recognized the convergence of three key factors with substantial potential to improve the value of care: opportunities for accelerated innovation and translation, using emerging infrastructure, analytic tools, and relationships; an unprecedented database with sophisticated analytics to support the discovery of new knowledge about treatment efficacy, effectiveness, and patient outcomes; and the potential power of tapping insights from diverse industry participants on critical and emerging questions about research and innovation in the health care system.

The founders of Optum Labs also recognized that the need for new approaches to knowledge generation and use transcends traditional organizational silos and business models and that taking full advantage of the emerging opportunity would require engagement with a diverse group of like-minded partners from across the entire health care ecosystem. Consequently, Optum Labs is engaged with a broad range of collaborators, including academics, payers, policy makers, health care delivery systems, care providers, and life sciences companies. The goal is to use divergent perspectives to guide the application of new research collaborations and methods—combined with the largest, most comprehensive database of health experience available—to affect care delivery.

The primary outcome of the Optum Labs collaboration is to improve patient care and value in the health care system by connecting the generation of evidence with its accelerated translation into practice and its widespread adoption into care delivery. The collaboration also aims to provide a platform for innovating policy on ensuring robust privacy protection and the development of strategic approaches to sustainability and governance of multi-institution knowledge-development collaboratives.

This article describes the progress of the Optum Labs collaboration in forming a learning organization and contributing to health system knowledge. It also describes the implications of that experience for the changing policy environment of health care research and learning.

## Forming Partnerships Across The Health Care Ecosystem

The Optum Labs collaboration has expanded from the initial commitment of Mayo Clinic and Optum. The additional participants—AARP, the American Medical Group Association, Boston Scientific Corporation, the Boston University School of Public Health, Lehigh Valley Health Network, Pfizer, Rensselaer Polytechnic Institute, Tufts Medical Center, and the University of Minnesota School of Nursing—include academic institutions, health care systems, provider organizations, life sciences companies, and membership and advocacy organizations.

Reflecting the full diversity of the health care ecosystem, these collaborators bring various perspectives and competencies in research, the translation of evidence into practice, technology, and health care delivery. The Optum Lab collaborators collectively care and advocate for over a hundred million Americans. They are committed to extending the collaboration to include other researchers from the public and private sectors, policy makers, technology leaders, and patient or consumer organizations.

## The Data

A key asset of Optum Labs is a rich, high-quality, integrated, up-to-date, research-ready health care database, also referred to as a data warehouse, which contains deidentified claims and clinical data from multiple health plans and health care providers for over 150 million people, covering ten years or more of patient experience. The database includes plan enrollment information, medical and pharmacy claims, and lab results from multiple payers, all integrated across care settings and longitudinally linked at the patient level.

Claims data provide a useful backbone for data linkage and research. This is because the generation of individual-level claims data follows the patient through all of the health care services covered by the contributing health plans. The large scale of the database enables the generation of robust data on important subgroups and the identification of rare health occurrences. The claims data are supplemented for selected cohorts by information such as consumer data; mortality status; and data from health risk self-appraisals, including weight and tobacco use. The warehouse also contains detailed, anonymized data on characteristics of providers.

Housed in a secure data warehouse constructed with a mechanism that securely protects privacy, the claims data are linked to other large research databases. The most notable of these is an EHR database containing deidentified infor-

mation on over thirty million patients, which is operated by Humedica,<sup>12</sup> a leading vendor of EHR-related analytics to health care providers. Hundreds of clinical data elements (Exhibit 1) are extracted from EHRs through natural language processing; curated (that is, screened and edited to ensure data quality); normalized; and then linked to claims at the individual level to add great clinical depth to the breadth of the claims population.

Once cleaned and linked, Optum Labs data are held in a separate, secure central location to facilitate fast feasibility testing of proposed research, quickly yield potential sample counts, and enable rapid turnaround on analyses. Researchers' access to data is distributed via secure enclaves—that is, distinct research environments with firewalls—guarded by robust security controls. For each study, a research enclave is prepared that contains the specific deidentified data required for the study.

Protecting patients' identities is of the highest importance for the Optum Labs participants. Linkage of claims data, information from EHRs, and other patient-level data is accomplished using sophisticated encryption methods with a second level of deidentification that is applied to further reduce the likelihood that any specific patient will be reidentified. Only data that have been deidentified in compliance with the Health Insurance Portability and Accountability Act

### EXHIBIT 1

#### Types Of Data In The Database Of Optum Labs

##### SAMPLE CLAIMS DATA FOR ALL PLAN-COVERED SERVICES ACCESSED BY PATIENTS

- Unique patient identifier
- Patient sociodemographic characteristics
- Patient family claims data
- Diagnoses from all claims, both outpatient and inpatient (ICD)
- Treatments from all claims, both outpatient and inpatient (CPT, ICD, or both)
- Pharmacy prescriptions filled (NDC numbers, dates, and quantities), including switches from brand-name to generic
- Blood-based lab results
- Attributes of providers

##### SAMPLE DATA FOR ENCOUNTERS CAPTURED IN PROVIDERS' ELECTRONIC RECORDS

- Unique patient identifier
- Patient vital signs (such as body mass index and blood pressure)
- Diagnoses from EHR (including cancer stage)
- Treatments from EHR (including treatments not billed for)
- Pharmacy prescriptions written
- Over-the-counter drug use
- Physician text notes (abstracted)
- Pathology reports (such as cancer histology)
- Operative reports (abstracted)
- Imaging notes (abstracted)

**SOURCE** Authors' compilation of information from the Optum Labs Warehouse data dictionary. **NOTES** ICD is *International Classification of Diseases, Ninth Revision, Clinical Modification*. CPT is *Current Procedural Terminology, Fourth Edition*. NDC is National Drug Code. EHR is electronic health record.

(HIPAA) of 1996 are held by Optum Labs and used for research.

In addition, researchers are not allowed to download any patient-level data from the enclave. This prevents linkage between Optum Labs data and external databases, further reducing the risk of reidentification.

### Creating Sustainable Learning

The Optum Labs collaboration is designed to integrate problem identification, research and generation of findings, design and development of interventions, and implementation of interventions into health care processes. Collaborator representatives oversee the development of the research agenda and the selection of studies, which include both care research and methodological studies. The methodological studies are aimed at improving the quality of research and developing new scientific approaches to analysis.

The involvement of health care practitioners from participating organizations ensures that practical experience is applied to research oversight. Furthermore, staff from collaborating organizations and Optum Labs work with care delivery participants to convert important findings into prototypes for implementation. Several collaborators have experience and expertise in translating research results and guidelines into change in health care practice at the practitioner and patient levels.

Feedback from the providers on the front lines of health care—whether through structured data collection or systematically collected anecdotal inputs—flows to Optum Labs. The feedback may lead to the jettisoning or refining of innovations that are not achieving their objectives or to the proliferation and acceleration of initiatives that generate demonstrable improved care delivery and patient outcomes. The research formulation, oversight, and publication work of Optum Labs operates with editorial independence and provides the collaborators with an impartial health care and policy research environment.

### Expanding Through Research, Translation, And Innovation

The Optum Labs collaboration focuses on research that can directly benefit individual patients and population health. This includes comparative effectiveness, methodological, and behavioral and policy research and studies on variations in care and the management of multiple chronic conditions. These themes are not mutually exclusive; many research topics include multiple themes.

## The involvement of health care practitioners ensures that practical experience is applied to research oversight.

**BEHAVIORAL AND POLICY RESEARCH** Behavioral and policy research focuses on understanding the underlying factors that drive patients' and providers' behaviors and on the evaluation of alternative policy initiatives. One major challenge in using observational data from claims and EHRs is that these data reflect the combined behaviors of patients and providers. To draw reliable statistical inferences about the behaviors of either group, the behaviors must be disentangled. The solution involves adding information to the database and applying statistical techniques that separate the underlying behaviors of the two groups and enable better targeting of interventions for patients and providers.

Another aspect of behavioral research is the application of techniques such as graph analytics, which are used by web-based businesses<sup>13</sup> in analyses of acute and chronic illness.<sup>14,15</sup> Such analyses may enhance understanding of non-medical factors that influence patients' engagement with and adherence to care, thus revealing new ways to improve care outcomes.<sup>16</sup>

**HEALTH DISPARITIES** Geographic variations in treatment patterns have been well documented.<sup>17,18</sup> A large literature also demonstrates substantial variability in access to care by race or ethnicity.<sup>19</sup> However, much remains to be done to examine the impact of these disparities on health outcomes. Robust and diverse data such as those contained in the Optum Labs data warehouse can support research on geographic and racial or ethnic variations in health outcomes that was not previously possible.

**PATIENTS' RESPONSES TO TREATMENT** The heterogeneity of patients' responses to treatment is a significant challenge to understanding the foundations of better health outcomes and pursuing improved efficiencies in care. Researchers in Optum Labs are studying the applicability of statistical decomposition methods for addressing this challenge.

As genomic and other molecular data become

available, they will play a key role in understanding and, ultimately, predicting response to treatment. This is already happening in many areas—most notably cancer care—but the potential is much broader.<sup>20</sup> The aim is to expedite the discovery of relationships between successful treatment outcomes and individual patient characteristics that support the personalization of care.

**MANAGING CHRONIC CARE** Research on the management of care for multiple chronic conditions is another of health care's biggest challenges. Treatment guidelines designed specifically for patients with complex conditions are almost completely absent, which contributes to large variations in treatment patterns, costs, and outcomes. The ability to link patients' clinical information with health care interventions across treatment sites enables researchers at Optum Labs to control for the complexity of patients' conditions and, therefore, better measure and model response to treatment.

**METHODOLOGICAL RESEARCH** Methodological research is focused on improving the quality of evidence from observational studies, including understanding the sources of potential bias. One area of focus is examining how bias can be minimized through improved data quality and completeness and the use of new statistical methodologies.

The goal of this research is to develop methods for performing observational studies that achieve results as close as possible to the estimate that one would get from a randomized trial designed to answer the same question. Clinical trials are costly and take years to perform. Observational data cannot replace trial results. However, improving the ability to draw robust conclusions from observational analyses can reduce costs, speed the testing of hypotheses, and allow more effective study of rare conditions.<sup>21</sup>

**OPTUM LABS' RESEARCH FINDINGS** Since Optum Labs was formed, multiple studies have been pursued, with findings affecting care and research methods and resulting in peer-reviewed publications. Examples of studies that have been completed and are under way are presented below and in Exhibit 2.

►**RESEARCH ON MEDICINES FOR DIABETES:** Metformin is consistently recommended as the initial intervention for patients newly diagnosed with uncomplicated type 2 diabetes. However, there are a number of choices for second-line medication treatment, including older sulfonylurea drugs and newer oral agents plus insulin.

An observational study using the Optum Labs database that compared alternative medication management strategies across 37,501 patients showed similar effects for all drugs in achieving glucose control, longevity, and overall quality of

## EXHIBIT 2

### Topics Of Research Studies Under Way At Optum Labs

#### Topic

Patterns of use and safety of new anticoagulants in the treatment of atrial fibrillation  
National trends in the screening, diagnosis, and treatment of localized prostate cancer  
Unplanned hospital readmission and ED care for complications of acute diabetes

Use of hemoglobin A1c testing in patients with well-controlled type 2 diabetes  
Analysis of screening mammography rates in women with diabetes  
Variations in use of proton beam therapy

Linkage methodologies for EHR and claims data  
Step-down protocols in asthma medication management  
Diagnosis, treatment, and service use for spine-related problems

Replication of the ACCORD lipid trial using observational data  
Use of machine learning to identify medication adherence phenotypes  
Use of machine learning to characterize reference populations for the management of comorbidities

**SOURCE** Author's compilation from Research Oversight Committee notes. **NOTES** ED is emergency department. EHR is electronic health record. ACCORD is Action to Control Cardiovascular Risk in Diabetes.

life. However, the cost of this benefit was less in patients who were treated with sulfonylureas.<sup>22</sup> These drugs were also associated with a longer interval until insulin was required than was the case when other oral agents were used. These findings are being translated into potential revisions of guidelines used by care providers.

►**RESEARCH ON TOTAL KNEE REPLACEMENT SURGERY:** Earlier studies with Medicare data revealed that the number of total knee replacement surgeries has increased steadily in elderly patients.<sup>23</sup> An Optum Labs study examined 116,319 primary knee arthroplasty and 9,798 revision surgeries performed on people who were too young to be eligible for Medicare.<sup>24</sup> The study showed a steady increase in these surgeries for all age groups, with people ages 45–54 having the largest rate of change during the ten-year study period (an 84 percent increase).

The prevalence of diabetes and obesity among patients undergoing these surgeries increased substantially during this time. These findings are prompting the development of additional Optum Labs studies about differential outcomes for patients with comorbidities, as well as a re-assessment of care protocols at delivery system participants.

►**RESEARCH ON METHODS:** A methodology-focused study of 2,031 patients with hepatitis C found that the statistical linkage of clinical information from laboratory test results—the aspartate aminotransferase (AST) to platelet ratio index, also known as the APRI score—to claims data reduced bias in treatment effect estimates by 24 percent for all ambulatory visits and by 79 percent for visits related to hepatitis C, relative to the use of claims data alone.<sup>25</sup>

## Translation From Research Into Practice

As noted above, findings from studies are being rapidly used to drive health care reassessment and inform further research. Translating new evidence into routine clinical practice remains an important challenge in medicine. Successful translation requires the dissemination and uptake of evidence coupled with local adaptation, as needed, to best align an intervention with the priorities and capabilities of health care delivery settings without vitiating the validated research finding. This needs to occur expeditiously and iteratively and is challenging to accomplish in practice. The process works best if both researcher and practitioner are made aware of and understand the nuances and challenges of care delivery processes.

The facilitation of translation is multifaceted and often unique to a location of care. Factors influencing local uptake include validation of the research finding through peer-reviewed publication, reframing the innovation to fit specifics at a particular care setting, development of clinical champions, implementation of decision support tools to sustain the innovation, intervention-specific technical assistance, and training.

Optum Labs is designed to promote researchers' and practitioners' awareness of shared opportunity and to promote active collaboration between the groups. The intent is to create and sustain a research environment that explicitly includes end users' perspectives from the development of a research idea through its implementation and refinement in the clinical setting.

Effective translation of research findings is actively supported in two key ways. The first is that explicit planning for the dissemination of research findings is required as a part of each project's overall design. The second is the required involvement of diverse collaborators, including those who would use findings in practice, as active members of the investigative team.

As a further component of translation activities, Optum Labs works with collaborators to build data collection into the testing and implementation process. This ensures that participants have feedback to identify and expand upon successes, and to refine initiatives that are faltering.

## The Patient As An N Of 1

One priority at Optum Labs is to address a cross-cutting translation challenge: how to enable clinicians to connect findings from big-data analyses directly to the care of an individual patient. This is expected to be particularly important when care needs are complex and require

## Translating new evidence into routine clinical practice remains an important challenge in medicine.

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careful prioritization for the patient, as in the care of people with multiple comorbid chronic conditions.

For generations, clinicians have referred to such patients as an "N of 1" and have sought to fit the patient, often imprecisely, to the clinician's own medical experience and the knowledge base as reflected by the medical literature. All too often, the literature has incompletely addressed such patients' full previous experience and immediate concerns. Thus, the clinician has little directly applicable knowledge beyond his or her personal clinical judgment and experience.

Big data provides an opportunity to complement the clinician's judgment and experience with dynamic access to the similar and relevant experiences of many other clinicians and patients. By drawing on the massive amount of information about population experience in the data warehouse, clinicians can find data on a focused subgroup with just the right specificity and granularity to apply directly to the presenting patient. As an extension of expressing research findings as statistical averages of an "N of many," it becomes possible to also reflect the results of a clinical trial or an observational study as being the aggregate of "many Ns of 1"—and thus more closely linked to the patient and problems at hand.

## Learning About Systematic Learning

Optum Labs was intentionally designed to bring together and engage the critical elements of a robust learning health care system from across health care constituencies. Collaborators, all of whom are committed active learners, include both producers and consumers of evidence and are drawn from researchers, care providers, advocates, and producers of drugs and devices. They have been attracted by the access to substantial data, technical support, and translation experience and resources that Optum Labs provides.

Within the Optum Labs collaboration, the

# Optum Labs was intentionally designed to bring together and engage the critical elements of a robust learning health care system.

scale and diversity of both the data resources available and the patients receiving care are substantial and possibly without precedent. The partners collectively have extensive experience across the full continuum of inquiry, discovery, validation, and implementation of effective interventions. By shaping the priorities and agenda for both discovery and translation of new findings, participants ensure that the priorities of the collaboration are aligned with those of their respective health care environments.

## Policy Considerations

As Optum Labs and others pursue the potential of big data to expand the national research and learning capacity, policy makers will need to examine and leverage successes and address new challenges that emerge. In addition to producing specific research results, Optum Labs can be among the centers for learning how to use evolving data and analytic capabilities robustly and responsibly.

Opportunities to inform policy discussions and developments concerning big data and a learning health care system could draw on experience from the Optum Labs structure and approach. Some areas that need further study are mentioned below.

**METHODS** Many new opportunities are arising from the emerging data, technology, and organizational entities, but results in terms of better patient outcomes are not yet clear. Optum Labs, in its use of conventional and alternative research approaches, presents an opportunity to review and potentially address key methodological questions, such as the role of expanding data sources, approaches to data linkage, imputation methods for missing data, and the use of machine learning as a complement to hypothesis-driven research.

**DATA WAREHOUSE GOVERNANCE** A recent review has revealed a sparse knowledge base in health care about the oversight and governance of large data warehousing efforts, including risk management.<sup>26</sup>

**RESEARCH AND PRIVACY OVERSIGHT** The historical legal foundations of research and patient privacy protection, such as HIPAA and the Common Rule, the federal policy for the protection of human subjects—as well as oversight groups such as Institutional Review Boards—must be scrutinized for their applicability to learning environments with very robust, diverse, and comprehensive routine data capture and availability.

**SUSTAINABILITY OF EMERGING RESEARCH NETWORKS** The wide promotion and use of multi-institution and multi-site data networks are relatively new phenomena, with emerging models reflecting multiple organizational and funding mechanisms and approaches to data access, governance, and longer-term sustainability.<sup>27</sup> It is not clear which of the models will be successful over the long run. In the case of Optum Labs, initial funding has been provided by Optum, with the intent that the collaboration will become self-supporting through direct contributions from collaborators, fees charged for access to data for specific projects, public and private research grants and contracts, and—over time—licensing of discoveries and innovations.

**RESEARCH, TRANSLATION, AND COMMERCIALIZATION** It will be important to understand the challenges involved in balancing the core research goal of generalizable knowledge with institutional needs for rapidly implementable knowledge and the associated time-related aspects of competitive advantage and market positioning. The diversity of the Optum Labs collaborators provides an excellent test case of what is possible given both converging and diverging objectives.

## Conclusion

Optum Labs is a new institution that was conceived as a novel node in the national learning health care system. It draws on the diverse perspectives and expertise of multiple health-related organizations. It also provides access to a unique, robust, and diverse data resource for the purposes of research, clinical translation, and innovation. In doing so, Optum Labs expands the capacity for knowledge generation and provides a unique environment for testing new ideas to inform decisions about the policies and operational requirements that will be needed to make the best use of emerging national big-data resources in an appropriate and sustainable way. ■

The authors gratefully acknowledge the input of Carol Simon and the contributions of Andrea O'Neill and Andrew Schwartz to the preparation of the article.

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