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Prescriptions for Excellence in HEALTH CARE

A COLLABORATION BETWEEN JEFFERSON SCHOOL OF POPULATION HEALTH AND LILLY USA, LLC

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Rethinking Health Information Technology on the Journey to Personalized Medicine

By *Brett J. Davis*

Health care and life sciences organizations have long recognized the potential for a convergence of their 2 disciplines, envisioning a bidirectional information pipeline between bench and bedside that would facilitate the development of more personalized and effective treatments. For several years, the health care community has struggled to make progress on this front in the face of multiple challenges that range from institutional objections to change, to security/privacy concerns, to inadequate funding, to technology limitations.

With global health systems under unprecedented strain, the realization of personalized medicine has never been more imperative – and, in the wake of breakthroughs in our understanding of biology at the molecular level, it has never been more possible.

Although the health care industry is poised for progress, a significant hurdle remains: Building the right information technology (IT) infrastructure to support the new data management challenges of this paradigm. Many IT systems being adopted across research and care domains today were not designed to permit the secondary data uses that are necessary for research and personalized care. To a great extent, these existing transactional systems

support individual silos across the health science ecosystem that impede

– and in many cases prevent – the integrated view of data that is essential for collaborative research activities including management of genotypic and phenotypic data, analytical secondary uses of health data, and the ultimate realization of personalized medicine.

To move forward, health sciences organizations must take a different approach to their health care IT infrastructures – an approach that enables large-scale reuse of the vast volume of health care information that is locked in today’s transactional systems. New platforms will be required to enable health care information exchange among organizations. New analytic solutions will be necessary to answer the most difficult questions in health care: What works, for whom, why, in what context, and at what cost? The next generation of health care IT systems has the potential to be truly transformational and usher in a new era of health care delivery but a critical first step is recognizing that today’s systems were not designed to get us there.

Industry at a Crossroad

Over the past 25 years, the world has seen an unprecedented expansion of scientific knowledge as a result of breakthroughs in imaging, genomics, proteomics, diagnostics, and other disciplines. These breakthroughs promise to deliver precision medicine for some of the most complex and

debilitating diseases (eg, cancer, Alzheimer’s disease, Parkinson’s disease) as well as prevalent chronic conditions such as diabetes.

At the same time, global health systems are nearing their breaking points. Like other developed nations, the United States is struggling with skyrocketing costs associated with aging populations and the management of increasingly expensive chronic conditions. The United States also must address the serious issues of inconsistent quality and outcomes that are not commensurate with the dollars expended.

Even after accounting for variations in wealth, the Organization for Economic Cooperation and Development estimates that approximately 31% of total US health care expenditures are “excess” in comparison with other member nations.¹ In the United States alone, estimates of the tab for unwarranted care range from \$250 billion to \$325 billion annually.² Another example of “wasted” care is that many major classes of drugs do not work for a large percent of the population who take them each year. For example, 38% of patients with depression, 50% of patients with arthritis, 40% of patients with asthma, and 43% of patients with diabetes will not respond to initial treatment.³

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Personalized medicine represents a potential way forward. It can help address cost and quality challenges by promoting targeted therapies and interventions for the patient populations most likely to benefit from them. If built using a data driven approach, it can sustain and accelerate new discoveries and innovations that advance prevention or improve outcomes.

A Perfect Climate for Change

At a time when it is most needed, the health care industry is experiencing a convergence of developments that present an opportunity to achieve substantial progress on the path to personalized medicine. Each of these developments requires new information management platforms beyond today's clinical systems.

First, scientific advances in the last decade are providing valuable insight into the reasons why some patients may be more susceptible to particular conditions and/or respond differently to specific treatments. With the completion of the Human Genome Project, we have entered an exciting new era that is yielding a broader understanding of health and disease at a molecular level. We are realizing important benefits, such as the ability to assess genetic risk for certain types of cancer or to predict which individuals may react positively or negatively to a particular treatment. Most experts expect the rapid pace of advancement in scientific understanding to continue for many years to come.

The second important trend is a fundamental shift in the approach to health care reimbursement. For example, the United States has begun a transition from its traditional fee-for-service model to a pay-for-value approach that rewards outcomes. The Patient Protection and Affordable Care Act of 2010 (ACA) will expand a number of programs that were piloted by the Centers for Medicare and Medicaid Services in the last decade. Specifically, Medicare's launch of the Hospital Value-based Purchasing Program in October 2012 will mark the

beginning of a fundamental shift in how Medicare pays health care providers and facilities. Under the new program, US hospitals will be paid for inpatient acute care services based on care *quality* - not just the *quantity* of the services they provide. Many private insurers are also experimenting with new reimbursement strategies that reward value and outcomes.

Finally, comparative effectiveness research (CER) initiatives also factor into the mix of activities that are likely to reshape how health care organizations treat patients. The ACA authorizes the creation of a nonprofit corporation known as the Patient-Centered Outcomes Research Institute, the purpose of which is to assist patients, clinicians, purchasers, and policy makers to make informed health decisions through CER. The Institute supplants the Federal Coordinating Council for Comparative Effectiveness Research, established under the American Recovery and Reinvestment Act of 2009, which allocated \$1.1 billion for CER.

A Fractured Frame

With the necessary scientific and policy components in place to advance personalized medicine, the industry now must address the technological barriers. To be effective, health care organizations must reconfigure their information infrastructures to enable large-scale secondary use of the health care data that is locked in their existing transactional systems (Figure 1).

Secondary use of data captured in transactional systems across the health care ecosystem (eg, electronic health records, claims/billing systems, clinical trial management systems, research databases, clinical and laboratory systems) is essential to enable and accelerate the new paradigm of personalized health care. The information-based transformation of health care to a more personalized health care paradigm is conceptualized in the "learning health care framework" first introduced in a 2007 Institute of Medicine Study.

Figure 1. Multiple Applications of Secondary Use of Health Care Data

| |
|---|
| Health Care Providers |
| Clinical quality initiatives and reporting |
| Operational efficiencies |
| Financial performance management |
| Pay-for-performance initiatives |
| Pharmaceutical / Biotechs |
| Comparative effectiveness |
| Adaptive trials to support personalized medicine |
| Consumer and physician engagement and decision support |
| Academic Medical Centers |
| Translational, clinical, and comparative effectiveness research |
| Collaborative and extra-enterprise research |
| Public Health |
| Disease surveillance |
| Comparative effectiveness and clinical utility studies |

Adapted from *Transforming Healthcare Through Secondary Use of Health Data*. PricewaterhouseCoopers (PCW); 2009.

A majority of today's health care IT systems were created to automate specific workflows (eg, research, back office, direct care); hence, they are fragmented from a data perspective. The secondary use of data captured in core transactional systems is required for analysis that affords insight. In order to support a rapid-learning, value-based, personalized health care paradigm, data from these source systems must be "freed" and aggregated for secondary data usage.

For example, there are many financial, supply chain, claims, and billing systems that can determine costs within a health care organization; however, these systems cannot correlate these data with the actual cost of treating a patient for a specific condition or calculate the outcome of that treatment. The initial goal of capturing the data was to track a set of procedures in order to bill a payer and/or patient for the services rendered. In a value-based reimbursement system, organizations must be able to access, aggregate, and

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analyze these data to correlate costs and outcomes across patient populations.

The IT implications for this new paradigm are significant, particularly with respect to the need for secure exchange of data between systems and the analytics necessary to glean insights from the secondary use of the data in these systems.

Recognizing this need, the industry has begun to make the investments necessary to create interoperability between transactional systems and analytics platforms for the analysis of that data. As stated previously, most transactional IT systems adopted across the research and care domains today were purpose built (ie, not designed, developed, or implemented with the requirements of value-based personalized medicine in mind). These systems fall short on multiple fronts; most importantly, their failure to collect the necessary information in the right context and their inability to provide the necessary linkage between financial, operational, research, and clinical data and processes.

Building a New Foundation

Value-based personalized medicine requires the ability to manage, integrate, analyze, and leverage clinical, financial, claims, and other biomedical information from across the health care enterprise and from external sources.

Two fundamental technologies will drive the transformation. The first is an interoperable health information exchange that will aggregate and normalize data from core transactional systems and enable health care providers and researchers to act on it. In today's multi-vendor environments, integration standards and repeatable processes are critical to providing adequate data management capabilities. Building the right infrastructure to support data collection, integration, and transformation is essential to enabling new insights.

The second essential IT component, enterprise analytics, will drive more productive use of secondary health data on a wide scale. In the business bestseller, *Competing on Analytics*, authors Tom Davenport and Jeanne Harris make important distinctions between capabilities that enable access and reporting and those that provide true analytical insights. Much of the business intelligence industry has focused on capabilities that enable reporting, structured or ad hoc queries, and alerts that make delivery of surfacing information to decision makers more efficient. Davenport and Harris point out that the next level of value will be through more predictive and optimization-oriented solutions and practices.⁴ Their careful analysis of high-performing companies across multiple industries found a substantial correlation between the extensive use of analytics among high performers versus low performers.⁴

The same approach applies to the business and delivery of health care as well. Health care organizations require retrospective and predictive analytics that span enterprise data. Only then will they acquire the necessary insight to predict the likely outcome of a specific course of treatment for a specific patient in real time. With these tools, providers also may be able to gain a better understanding of the true cost of care and more accurately predict important outcomes such as the likelihood for readmission, the precise treatment for an individual's genotype and phenotype, or the risk of adverse events.

In the short term, the industry is deploying various stopgap measures. End users' need to glean some insights from existing transactional systems is driving investment in expensive, limited, one-off data marts and analytics environments. This, in turn, is generating more silos and complexity in health systems' IT environments. Without exaggeration, this is a very

complex and thus expensive way to approach analytics.

As health care organizations come to realize the importance of analytics systems, they are beginning to invest in enterprise-class, interoperable analytics platforms. This is true for biopharmaceutical companies, payers, and providers as well as academic medical centers. Health care organizations should think about these investments in the context of their trading partners. By investing in more robust information management architecture, organizations extend their ability to share data with other partners. In addition to leading to greater innovation, such investments can create new opportunities for collaboration.

A Platform Approach Accelerates Change

Historically, the process of creating and implementing a data model, building an enterprise data warehouse, and creating customized analytical applications has been a very expensive and lengthy undertaking - one that is beyond the resources of all but the largest of health care organizations. In essence, this approach requires health care organizations to be software development shops. An alternative to this expensive, complex approach is a platform-based approach to analytics solutions. The move toward a "productized" platform enables enterprise analytical applications and reduces costs and implementation timelines, thereby making the technology more accessible for health sciences organizations of all sizes.

Conclusion

Secondary use of electronic health care data can answer the hard questions in health care: What works for whom, why, in what context, and at what cost? To enable secondary use of health data and drive the advancement of personalized medicine, health sciences organizations require an integrated view across disparate transactional

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systems. This calls for a robust enterprise model that is optimized for analytics versus transactions. Once such a model is in place, the use of well-defined and well-integrated analytics throughout the health care value chain can be transformative. Given the immense size of the data challenge, the distinctness and geographic spread of many health care-related activities, and the fact that so many health care activities are conducted by different

companies and organizations that must interact with each other, there is really no other way to provide the tools necessary to enable and deliver personalized medicine and to control spiraling costs.

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