Emerging Issues and Opportunities of the Genomic Data Revolution: Is Your Organization Ready?

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Now is the time to get your organization ready for the genomic data revolution. From government agencies to the private sector, from healthcare to technology, and everything in between, all organizations need to be prepared for upcoming challenges and opportunities.

Data analytics and the healthcare industry are both changing dramatically due to three scientific and technological leaps:

1. Scientists mapped the human genome and are now correlating genetic biomarkers with diseases.
2. Most hospitals have at least a basic system for digitizing patient health data.
3. Our ability to process massive amounts of data keeps growing exponentially.

The synergy across these industries is changing the whole model of modern healthcare.

Until now, healthcare has been about evaluating symptoms and providing treatments based on an understanding of an “average person.” However, we know that everyone is unique, and each treatment has a different efficacy based on the patient.

Personalized or precision medicine starts with the belief that you are unique, and thus your predisposition to a disease is based on your genetics, combined with your lifestyle and environment. A personalized or precision medicine approach would allow your healthcare provider to arrive at a diagnosis and design a treatment plan based on your genetic data within the context of your symptoms and family history.

After a 13-year-long, publicly funded project, the possibilities became real in 2003, when scientists announced the successful mapping of the human genome.1 Studying how one genome is different from another can give us clues about the causes and cures for diseases. Scientists are making huge strides in this area. They keep discovering how components of the genome impact human health. More than 1,800 disease-related genes have been identified.2

The future of healthcare depends on finding patterns across many people’s genomic data and putting that data in the context of yet more health data. A genome is a reflection of how a person’s body behaves and responds to the environment. If scientists look only at the genome and not the patient history, they may not be able to properly evaluate what they see. In order to leverage genomic data to help patients, it must be combined with their other health records.

How Are Most People Experiencing Personalized or Precision Medicine Now?

We are only at the beginning of these changes. Most patients have not seen the impact yet in their regular clinic visits, but it is starting to happen.

Let’s start with medications. With many illnesses, people do not respond well to the first medication they are prescribed.3 This happens more with some health conditions and diseases, such as depression, asthma, and diabetes, than others. Why do some medications work better for some people? Could doctors customize medication based on an individual’s genes?

This area of study is called pharmacogenomics. Until now, doctors would prescribe a drug based on a patient’s symptoms, avoiding known drug allergies. When a drug worked well for one person and not another, the reason was unclear. Now, with pharmacogenomics, we are approaching a point where we can get more clues about why.

Dr. Yuan Ji is the medical director for Molecular Genetics and Genomics at the ARUP Laboratories, a national reference laboratory owned by the University of Utah, and she is also an assistant professor in the Department of Pathology at the University of Utah, School of Medicine.

“If we are thinking this is the moment when pharmacogenomics or pharmacogenomics will go prime time, there are a lot of barriers that we must overcome first,” says Dr. Ji. “Evaluating which drug to give a patient is not only about one thing. It’s about a combination of multiple factors including genetic variants. Predicting how a drug will interact with a patient is evaluating such combinations.”

You need to have the knowledge in both molecular genetics and clinical pharmacology to synthesize all factors together.4

Dr. Ji notes that while genomic data is becoming more easily accessed, it is challenging to analyze all the variants because every lab follows its own standards, and every digital health record has its own format as well. A new wave of genomic-focused startups provide genetic test results directly to the public, not ordered through their doctors. In some cases, this allows patients to have a more active role in their health management. However, the value of this data is limited without the context of the patient’s other health information and the expertise of a doctor or genetic counselor.

“The price of retrieving data on the whole genome is dropping, but we don’t have the practical knowledge to use all that data yet. Maybe only a handful of the variants are well documented in the database with the drug relationship. Only those variants have clinic utility or application,” says Dr. Ji.

One area seeing great leaps is oncology. While people have genomic data, so do tumors and viruses. Each tumor or virus is unique, and oncologists increasingly have data about a tumor’s vulnerabilities.5 Oncologists can target a tumor with specific medications based on its genomic data.

Finding the best medications for an illness is only one benefit of connecting genomic data with health data. It could result in new cures, better preventative treatments, or even removing a health risk by editing a gene.6

10 Dawn McMullen, Ibid.

How Could Genomic Data Improve Healthcare over Time?

With the analysis of genomic data becoming increasingly accurate, predictive, and accessible, healthcare experts are discussing a model called a knowledge-generating or learning healthcare system. In this system, there would be a constant flow of data from patient to data analysts and back again. This expedites scientific research about diseases or drugs while providing doctors information they need to improve patient care. Here’s how the data would flow between the individual and a larger data ecosystem:

1. The more data available, the more scientists can do to solve common or rare diseases across diverse populations, and customize treatments to help patients avoid while reducing adverse side effects.

2. Meanwhile, the system sends recommendations back to the patient’s healthcare provider about how to customize treatment—whether that is an alternate drug or a preventative intervention.

3. The learning healthcare system automatically cross-references real-time, relevant data with the patient’s genomic data. Alerts may go off if intervention is needed for that patient such as a new finding on potentially harmful drug or food interactions with currently prescribed medications.

4. Patient data would frequently or constantly go into an individual’s electronic health record—either at a clinic visit or via devices similar to a FitBit® that gather and wirelessly transmit the data securely to the patient’s electronic health record.

5. With strict data-sharing policies and de-identification practices in place to protect the confidentiality of patients, a patient’s genomic data then gets combined with data from millions of other patients. Scientists can then constantly search and analyze patient data repositories for revealing patterns, helping scientists confirm or deny hypotheses about what causes a disease or what treatments work best for which types of patients.

Genomic Data-Based Learning Healthcare System

Data Analysis and Visualization

Never before has data analytics had a bigger impact on healthcare.

In only a few short years, there has been a major cultural shift in hospitals. More than half have digitized their health records. Medical personnel now dictate and type data into these systems every day.

For many, it was a huge cultural shift. Hopefully, it set the stage for the next big shift, which is that medical professionals will leverage data analytics for diagnoses and treatment ideas based on the patterns of many patients. Ideally, this will position hospitals and medical professionals to take advantage of knowledge-generating or learning healthcare systems.

It also prepares these practitioners for the wealth of data that could come from genomic science. This is only possible because of the visionaries within the scientific community and corporations building a baseline of genomic data. This is done through biobanks that collect and process this data in large quantities. One of the largest collections in the U.S. is the Million Veterans Project, which had genomic data for 400,000 individuals as of July 2015. Storing and processing this data is a huge endeavor because the genomic data for just one person can add up to 200 gigabytes.

It will take time for physicians to harvest the benefits of this science. Most medical schools do not currently teach how to interpret genomic data. While increasing genomic literacy could become a goal of medical schools, it is likely that data will be made easier to understand when integrated at the “point of decision” with existing medical processes.

Imagine the team of top-notch brains it will take to make this happen:

• Medical doctors provide expertise in diagnosis and treatment.
• Social scientists, futurists, and entrepreneurs collaborate to further the impact on society.
• Data scientists build the computational algorithms, which can take advantage of the data and leverage the expertise of the genomic scientists, doctors, and other subject matter experts in order to derive insights from combined electronic health records and genomic data sets to support decision making.

Let’s focus for a moment on the data analysts. As health records have become digitized into electronic health records, there is an emerging common data model that has evolved—across all sorts of silos, including different healthcare providers and health insurance organizations. This model improves every year. So we know from experience that, with the leadership of organizations such as the National Institutes of Health, data models can evolve iteratively even amongst groups that may not have collaborated before.

A fascinating fact is that both genomic science and medical practitioners benefit from the flow of data back and forth across their worlds—or a “bidirectional feedback of data analysis.”

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Sarah H. Beachy, “Fitb”.

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How Could Your Organization Prepare for and Leverage the Trend of Precision Medicine?

While the potential of this trend seems huge, it opens a whole new world of challenges as well:

- **Technological**—storing huge amounts of data, ensuring systems can talk to each other, and having systems with sufficient processing power to support analysis in reasonable time frames
- **Legal**—privacy of individual data, security from hackers
- **Operational**—creating standards for how data is organized and gathered
- **Ethical**—handling situations where manipulating genes could put people at risk, ensuring that decisions made using genomic data do not adversely impact people (and comply with the Genetic Information Nondiscrimination Act [GINA]).

Whether your organization focuses on healthcare, technology, data analysis, or something else entirely, now is the time to think about how your teams should tackle these challenges.

- **Your Leadership Team**—Are there business opportunities that you could build related to this field? How could you show thought leadership in this area?
- **Your HR Benefits Team**—Have you talked with your insurance vendors to see what genomic testing will be covered as it becomes a more integral part of healthcare? Is it likely your employees or their physicians may start requesting more and more genomic tests? What training might your HR benefits team need in order to increase its genomic literacy so it can negotiate for the best healthcare coverage? What are the benefits to your staff pertaining to personalized or precision healthcare?
- **Your Information Technology (IT) Team**—How will you need to beef up your IT infrastructure to accommodate the additional data storage and processing needs of genomic data? What work needs to be done to integrate disparate databases? What security protocols need to be in place to protect genomic data privacy?
- **Your Legal Team**—Have you established internal policies related to the privacy of your employees’ genomic information that are consistent with federal laws, such as GINA?

Formulate Your Genetic Data Revolution Strategy

Now is the time to evaluate how this trend could impact your organization.

“Advances in clinical care have gone hand-in-hand with technology, whether it be gene sequencing or applying software and data analytics to the health of our community,” says Todd Stottlemyer, LMI board member and CEO of Inova Health System’s Center for Personalized Health.

If you have any questions on this topic, please contact Dan DuBravec (ddubravec@lmi.org) and Brent Auble (bauble@lmi.org).

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