

Market Trends in Genetic Services

Impacting Clinical Care through Better Prediction,
Detection, and Care Selection

by

Timathie Leslie
Vice President

Daniel Agar
Senior Associate

Sarah Fielding
Associate

Sophie Miller
Senior Consultant

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Market Trends in Genetic Services

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The genetic testing market is growing rapidly. In 2011, the US genetic and genomic clinical testing market size was estimated to be \$5.9 billion.¹ Given the potential role of genetics in guiding treatment and health behaviors, the economic impact of related care pathways is estimated to be substantially larger. The number of available tests has grown substantially, from 1,680 just 4 years ago, to 2,886 in 2012.² However, this 72-percent increase in the number of tests available has been slow to translate into clinical applications.³ Though the current clinical applications are still somewhat limited, demand from physicians and patients for testing is growing. A recent UnitedHealth survey found that three quarters of its network contracted physicians believe that some patients in their practice would benefit from genetic testing, but have not yet been tested.⁴

Methodology and Background

To gain insight into the genetic testing industry, Booz Allen Hamilton, a leading strategy and technology consulting firm, conducted interviews with industry experts and an in-depth literature review. The purpose of this market analysis was to identify market trends, major drivers of genetic testing adoption, and the roles of key players in the market.

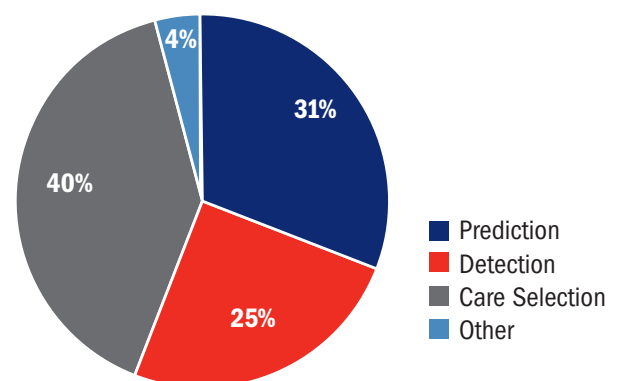
The interviews were conducted with experts representing different geographies, markets, and areas of expertise. Key senior leaders were interviewed, including representatives from direct provider organizations such as large health systems that deliver care to millions of patients nationwide; highly ranked academic medical centers specializing in personalized medicine; genetics laboratories serving thousands of hospitals and health systems; major national payors covering millions of lives; research institutions at the forefront of genetics and personalized medicine; and direct-to-consumer companies.

For the purposes of this study, genetic testing services include care delivery, genetic testing results interpretation, pre- and post-testing provider and patient awareness, education and counseling, information analytics, and the bioethical framework underlying the care delivery decisions.

Genetic Services: Market Context

While the evidence base is still growing, genetic services industry leaders strongly believe that emerging testing capabilities will have significant clinical impact in the future. Many expressed opinions that genetic services will make significant contributions to prediction, detection, and care selection, leading to better quality care and increased affordability. Available genetic tests and genomic applications, can be categorized according to their clinical method of use across prediction, detection, and care selection, as illustrated in Exhibit 1.

Exhibit 1 | Genetic Tests and Genomic Applications by Clinical Impact Area



Source: Genetic Tests and Genomic Applications in Practice and Prevention Database (N= 450), CDC Office of Public Health Genomics 2012

¹ Battelle Technology Partnership Practice, "The Economic and Functional Impacts of Genetic and Genomic Clinical Laboratory Testing in the United States", January 2012.

² GeneTests, <http://www.ncbi.nlm.nih.gov/sites/GeneTests/>, accessed November 2012.

³ United Health, "Personalized Medicine: Trends and prospects for the new science of genetic testing and molecular diagnostics." Working Paper, March 2012.

⁴ United Health, "Personalized Medicine: Trends and prospects for the new science of genetic testing and molecular diagnostics." Working Paper, March 2012.

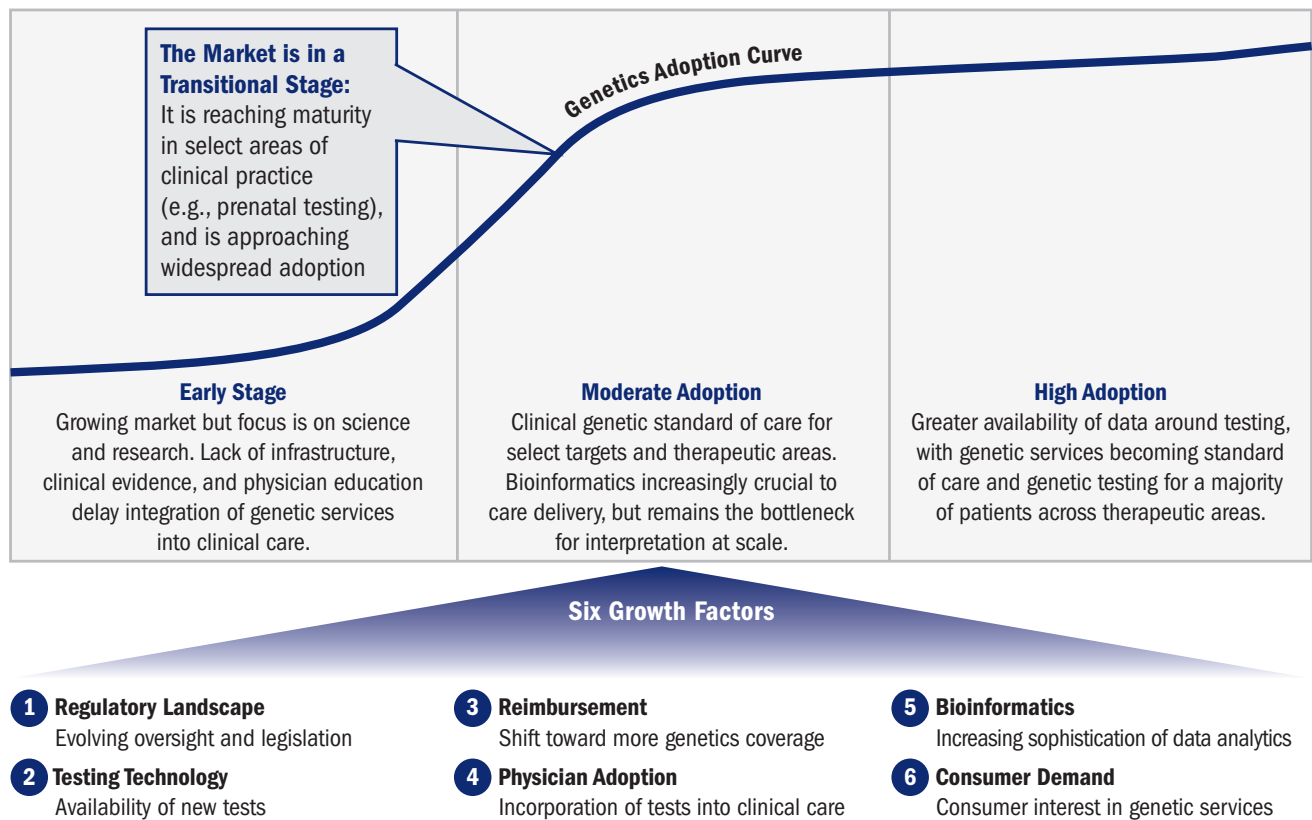
A: Drivers of Adoption

There is significant uncertainty regarding the timing for the future adoption of genetic services. Currently, the industry as a whole is shifting from early stage adoption, where the focus has been on technology and new research, to more moderate-level adoption, where providers are starting to integrate genetic services into more areas of their practice. Though test availability is improving, and testing tool technology and speed is increasing, only a small percentage of testing information is currently actionable. Technology has surpassed what can be validated, interpreted, and applied. At this transitional stage from early to moderate adoption, limited informatics infrastructure and limited clinical evidence are slowing the integration of tests into routine clinical care. However, as the evidence base grows and bioinformatics capabilities

improve, genetics will quickly approach more widespread adoption, where genetics will become the standard of care in many therapeutic areas. As illustrated in Exhibit 2, six key factors are both driving growth and facilitating increased adoption.

These six factors are driving growth in distinct ways, and are more active at different instances along the genetics adoption curve. Currently, adoption is driven by advances in technology, combined with growing physician and consumer interest and awareness. This is especially true in select therapeutic areas where genetic tests have more proven clinical utility, such as oncology, neonatology, and inflammation. Genetic tests are already an essential part of advanced prenatal/neonatal care and are becoming the standard of care for certain cancers. Considerable work is underway

Exhibit 2 | Genetics Services Adoption



Source: Booz Allen Hamilton

for other conditions, including obesity, diabetes, and cardiology. As genetics becomes part of the standard of care for these larger therapeutic areas, genetic services will become increasingly relevant for a large number of patients.

Regulatory Landscape

The regulatory framework for genetic services remains nebulous. While the Food and Drug Administration (FDA) is increasing its attention on the genetics industry and is starting to provide greater clarity into the approval process for diagnostics, approval pathways and timelines are still uncertain. Increased regulatory oversight is intended to protect patients, and enable patients and clinicians to make informed decisions, as well as to increase the quality of the genetic testing evidence base. However, the uncertainty created by recent moves has somewhat delayed the development of new technologies. While the regulatory landscape for new diagnostic approvals remains somewhat uncertain, a clear trend is emerging where regulators are increasingly requiring companion diagnostics in the approval of therapies.

Testing Technology

While the discovery of new genetic markers and the creation of testing technologies are enabling new tests, many industry experts believe that the greatest impact will come from Next Generation Sequencing (NGS). NGS is a rapidly evolving technology that enables the sequencing of a whole genome (also referred to as Whole Genome Sequencing [WGS]) or part of a genome and the rapid extraction of genetic information from biological material. For NGS to be adopted in clinical areas like neonatology and oncology, further development is required to manage and interpret NGS data and determine clinical applicability of testing. In the future, we may see NGS for every patient, resulting in both new information by which to prevent or treat disease, and also infrastructure and ethical challenges associated with the data generated. For example, would care providers be responsible for analyzing a previously sequenced genome as new clinical

applications are developed? Would a patient “own” the data and be able to easily port it from one provider to another? Currently, the bottleneck for the widespread adoption of NGS is not the technology itself, but the lack of peripheral infrastructure and bioinformatics support needed to maintain this testing technology and data interpretation. Though NGS is widely considered to be the future of testing, use of NGS in clinical practice is very limited today, and no consensus on a timeline for clinical adoption exists.

Reimbursement

Payors have significant power and control over the introduction and use of new testing technologies through their coverage and reimbursement decisions. Though reimbursement has historically been a barrier to the adoption of genetic services, many payors are shifting their emphasis away from a focus on the cost of genetic services and toward a more comprehensive assessment of total cost of care. For many providers that have considered the laboratory a cost center, it will become an element of the bundled cost of patient care. New payment and care delivery mechanisms, such as accountable care organizations, will serve to shift providers' emphasis away from fee for service models and toward wellness and prevention. Given the power of genetics testing in regard to prevention and detection, this will help to drive adoption. The fast-moving genetic services landscape has spurred the development of innovative coverage models, such as “evidence-development coverage” where coverage for a certain test is provided for the purpose of gaining additional insight into efficacy and value. By developing the evidence base, payors are able to align coverage decisions with clinical effectiveness.

The current procedural terminology (CPT) codes do not include specific codes applicable to genetic testing. Therefore, providers use a “stacked code” approach to bill for genetic tests and services. This results in challenges across the industry as coding, coverage, and reimbursement levels are not fully aligned to the clinical cost and value of services. In January 2013, the Centers for Medicare & Medicaid Services

(CMS) is enacting a new coding standard for genetics that endeavors to improve coding for genetics tests, enhance the revenue cycle process, and provide greater transparency into genetic testing practices. More sophisticated CPT coding will allow payors to better understand utilization and related costs.

Physician Adoption

Physicians see great promise in genetic services diagnostic and care planning benefits. Yet the growing complexity of both the testing options and results are increasingly difficult for a broad base of physicians to understand. As those involved in the process—specialists, pathologists, geneticists, genetic counselors, biostatisticians, psychologists, and bioethicists—collaborate and are provided with more education and decision support tools, appropriate adoption will increase. Physicians will also look to professional associations for recommendations, and to payors for coverage guidance.

Bioinformatics

The genetics industry is undergoing a fundamental shift from a clinical science focus to a bioinformatics focus. As noted above, genetic services demand a greater level of data analytics sophistication than is required for other laboratory testing. Presently, data generated by new tests overwhelms current information technology systems and human interpretation capabilities. It is extremely difficult, in most cases, for testing information to be integrated into the electronic health record and for test results to be aggregated across a patient population. Robust informatics systems and trained bioinformaticists are critical new additions to the clinical team. These specialized staff and systems capabilities are required to collect, store, analyze, and interpret massive volumes of data. Without these capabilities, providers will be limited in what can be done with exponentially richer data sets on personal genomes. As NGS gains in popularity, the data challenges will only grow.

Consumer Demand

The discovery of the genetic basis for a disease is now a frequent topic in the news and is driving consumer awareness and interest in genetics. A recent survey revealed that 81.5 percent of consumers would like to have their genome sequenced if they could afford it and 15 percent of physicians said they had discussed direct-to-consumer genetic testing with a patient.^{5,6} While direct-to-consumer genetic testing services remain a small part of the ecosystem, the providers are working to generate new demand. For example, nearly 200,000 people have subscribed to the direct-to-consumer company 23andMe to learn about their genetic makeup.⁷ Furthermore, as genetic testing becomes more accessible and, in certain cases, less invasive, consumer demand will grow.

B: Market Players and the Genetic Services Ecosystem

As the field matures, a diverse set of players is shaping the future direction of the industry. The genetic services ecosystem is very complex, with some players fulfilling multiple—and often overlapping—roles. Exhibit 3 illustrates the major players and roles in the genetics services ecosystem. All players are grappling with the complexity and uncertainty in the market and are seeking to successfully position themselves for rapidly growing demand and the future potential of genetic services.

Today, the major players in the genetic services ecosystem fulfill one or more of four roles:

- **Research and Technologies.** These players are investing in research and development (R&D) and are bringing new testing innovations, as well as systems technology to market. This segment includes life sciences firms, academic medical centers, and informatics firms.
- **Genetic Service Providers.** These players are providing the genetic testing services. This segment includes independent commercial laboratories,

⁵ National Public Radio, "Your Verdict On Getting a Genome Test, Bring it On", http://www.wgbh.org/News/Articles/2012/10/5/Your_Verdict_On_Getting_A_Genome_Test_Bring_It_On.cfm, accessed November 2012.

⁶ United Health, "Personalized Medicine: Trends and prospects for the new science of genetic testing and molecular diagnostics." Working Paper, March 2012.

⁷ 23andMe.com

patented testing laboratories, laboratories that are part of an integrated health system or other provider network, academic medical centers, and direct-to-consumer providers.

- **Funding Mechanisms.** These players are funding both genetic services research and clinical testing. This segment includes payors and integrated health systems, as well as grant-makers that fund R&D for new testing technology.
- **Industry Oversight.** These players are standardizing technology regulatory pathways and providing industry oversight. This includes professional associations that provide clinical and coverage recommendations and regulatory bodies such as the FDA.

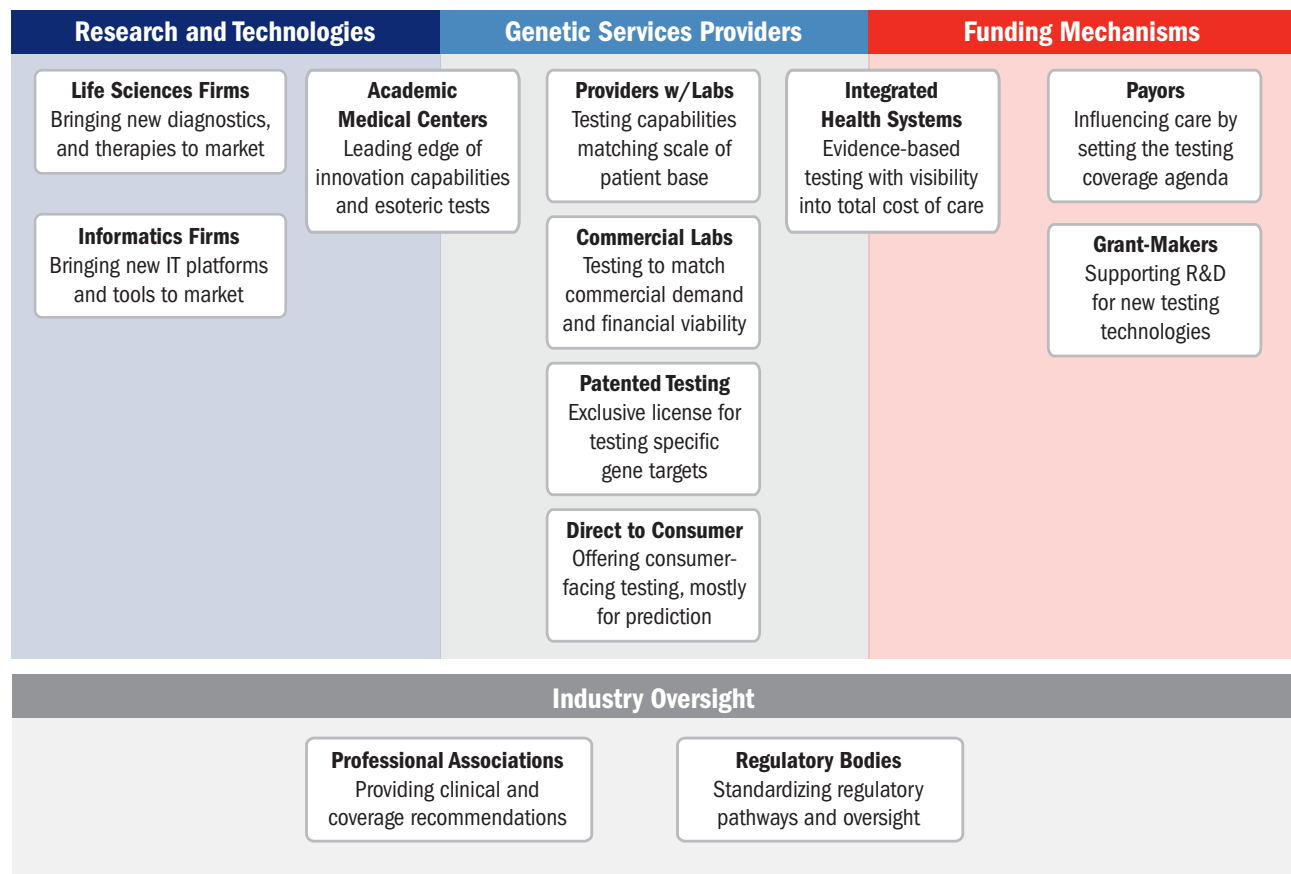
Life Sciences

These companies seek to make discoveries and to bring new technologies to market. Life sciences companies in the ecosystem include pharmaceutical, biotechnology, and diagnostic firms, such as Pfizer and Myriad, that are discovering new gene targets and developing diagnostics. They also include testing tools companies, such as Life Technologies, that develop and sell reagents. Life sciences firms are increasingly looking to link genes to disease and to market companion diagnostics with therapeutics.

Informatics Firms

Informatics firms, such as genetic lab vendors Cerner and SCC, are seeking to develop the information

Exhibit 3 | Major Player Categories and Roles in the Genetic Services Ecosystem



Source: Booz Allen Hamilton

technology platforms with which providers can manage their delivery of genetic services. However, these systems are still struggling to meet the demands of genetics data volumes and data types.

Academic Medical Centers

Academic medical centers (AMCs) are at the leading edge of clinical genetics testing technology, education, and delivery. They are often at the forefront of genetic testing research and are responsible for introducing new tests. For example, Baylor College of Medicine was the first institution in the US to offer full exome sequencing. As providers of genetics services for patient care (often highly specialized care), AMCs also offer the broadest range of tests, including esoteric tests for the widest range of therapeutic areas. Like other providers, AMCs are struggling to integrate the data related to genetic testing into their electronic medical records.

Commercial Laboratories

Commercial laboratories provide efficient, timely, and often lower-cost testing capabilities due to their large scale efficiencies. Once highly fragmented, the commercial laboratory industry is consolidating, with specialized labs being bought by larger players. The top players in this space now feature scale and skill sets that other laboratories struggle to match. LabCorp and Quest alone account for two-thirds of commercial laboratory business in the US and are likely to continue to acquire specialized laboratories to expand their portfolios into higher-margin tests and differentiate their offerings.⁸ Commercial laboratory staff include bioinformaticists and genetic counselors to review test results and discuss cases with care providers.

Laboratories are investing in information technology to support genetic services as well as their large core businesses. Providers are demanding laboratory results in a variety of ways from the latest mobile technology to hard copy, requiring laboratories to maintain a range of infrastructure that is compatible with both old and new systems.

Patented Testing Companies

Some specialized genetics testing companies possess exclusive rights to diagnostic testing for select genes. Some of these players (such as Myriad Genetics, which owns the patents to BRCA1 and BRCA2 genes) have emerged as influential players based on the strength of a few—or even a single—genetic test.⁹ Larger laboratories may also license the rights to offer these kinds of proprietary tests.

Direct-to-Consumer Testing Companies

Unheard of a decade ago, direct-to-consumer (DTC) testing services are actively working to raise consumer interest in genetic testing. Unlike genetic tests given within the context of clinical care, these tests are intended to provide consumers as much genetic information as possible—typically related to disease prediction—even if it is beyond what is medically necessary. DTC companies generate genetic profile data on consumers, without interpretation by physicians, or integration into clinical care or its supporting information systems. DTC companies seek to draw insights from their data that they can share with members and are also running studies on how members react to learning about disease risk.

Though DTC testing remains a small segment of the testing ecosystem, DTC services are seeking to become more integrated into clinical care. DTC testing companies are also pursuing value-added services for members, such as having Ph.D. staff continually incorporating new findings from industry literature and sharing these findings with members. Though they typically do not include genetic counseling, DTC companies may offer a suite of online educational tools for consumers.

The dominant DTC company, 23andMe, has nearly 200,000 members who have used their service. For \$99, consumers receive information on 50 carrier traits for Mendelian diseases, 20 drug classes, disease risk information, and personal trait information. Presently 23andMe is applying for FDA certification. To date, 23andMe focuses on prediction and prevention, not diagnosis or clinical intervention.

⁸ Clinical Laboratory Management Association, "Laboratory Industry Outlook 2010-2011." ThinkLab 2010.

⁹ Myriad offers BRAC analysis for breast cancer risk assessment

Integrated Health Systems

Integrated health systems (such as Geisinger Health System, Intermountain Health, and Kaiser Permanente) lead the way in evidence-based care delivery.

Whereas AMCs are piloting new testing technologies, integrated health systems are building new evidence that demonstrates the effectiveness of testing from both a quality and cost standpoint. With access to research, claims, and clinical data, integrated health systems have the most complete view of their patient populations and are well-positioned to draw insights from their genetic data assets and apply them to clinical practice. They also typically provide some genetics tests internally and outsource the balance to commercial laboratories and/or AMCs.

Payors

Payors' decisions around coverage for testing play an enormous role in the adoption rate of genetic services. However, coverage decision making in genetics services has been challenging for the vast majority of payors given scant evidence around clinical applicability, effectiveness, and cost for many genetic tests. Shortcomings in coding systems for genetic tests have contributed to the problem; payors remain unable to glean information about context, treatment rationale, diagnosis, and outcomes of tests. Due in part to limited available data on testing, payors differ in genetic testing coverage, both in the scope of tests covered, as well as in the processes required to gain patient-specific approval for use.

Grant-Makers

Grant-making organizations, such as the National Institutes of Health (NIH) and disease-specific organizations and foundations, play an important role in the long-term development of testing capabilities. Their funding of research and new technologies greatly impacts the pipeline of future discoveries. While the NIH provides the vast majority of academic research funding, some disease foundations have played a very influential role in certain rare and orphan genetic conditions, such as Cystic Fibrosis.

Professional Associations and Regulatory Bodies

Professional associations and regulatory bodies are also shaping the genetics ecosystem. Professional associations such as the American Congress of Obstetricians and Gynecologists (ACOG) and the American College of Medical Genetics (ACMG) provide clinical and coverage recommendations and have enormous influence in determining whether or not provision of a genetic test becomes the standard of care. Regulatory bodies such as the FDA and CMS seek to provide standardized “rules of the road” for this rapidly evolving technology.

C: KEY CONSIDERATIONS

As organizations consider the changing landscape of genetic services, genetic testing industry experts agreed on the importance of the following four considerations:

- **Evolving Technology and Its Role in Clinical Care.** Genetic testing and personalized medicine will continue to be in a state of transition, as testing moves toward Next Generation Sequencing (NGS) and Whole Genome Sequencing (WGS).
- **Growing Importance of Data and Health IT.** Genetics is at a fundamental inflection point, changing from the clinical science focus to a bioinformatics focus.
- **Reimbursement and Oversight.** The shift in reimbursement models away from fee-for-service and toward wellness and accountable care will increase usage of genetic services. Payors will need capabilities to exchange genetic testing data.
- **Need for Additional Provider and Patient Education.** The growing complexity of both the testing and results are increasingly difficult for a broad base of physicians and patients to understand.

Evolving Technology and Its Role in Clinical Care

Genetic testing and personalized medicine will continue to be in transition toward NGS and WGS for the foreseeable future. Experts have a wide range of opinions on the clinical applications and timing of NGS/WGS adoption.

Genetic testing technology is evolving quickly; for example, smaller point-of-care tests are already on the horizon. Players in the testing ecosystem are struggling to rapidly disseminate evidence on new tests, and to incorporate new testing technologies into clinical care and coverage decisions. In addition, there is significant uncertainty around the timeline for NGS/WGS adoption. Genetic services will be more applicable to select areas in the near term. Primary areas with high current volume include:

- **Oncology.** Oncology testing is particularly high volume in the Medicare population.
- **Infectious Disease.** Infectious disease testing is particularly high volume in the Medicaid population.
- **Inflammation.** An increasing number of genetic tests are becoming available to diagnose immune conditions.
- **Rare diseases.** Rare disease identification is a growing area of interest.
- **Obstetrics.** Non-invasive pre-natal diagnosis is likely going to become the standard of care in the very near term.

Additional diseases with strong potential applications include obesity, diabetes, and cardiac, but these are predicted to be farther out in time. Pharmacogenomics is also expected to be a large area of impact for genetic services given potential improvements in safety, efficacy, and cost of care.

New applications of genetic testing will result in changes to current care teams and processes such as interdisciplinary review teams with pathologists, oncologists, geneticists, genetic counselors, biostatisticians, psychologists, and even bioethicists. Because of the diversity of tests available and the rapidly changing landscape of testing technology, clinicians will also need more decision support tools to manage genetics care.

Growing Importance of Data and Health IT

The growth of the genetic services industry depends on bioinformatics capabilities: there is a clear need

for data analytics tools that complement new data management tools. Experts across the industry cited difficulties in finding bioinformatics experts, tools, and platforms that will support testing data needs. Data collection, storage, and management continue to be a challenge for players across the testing ecosystem. The majority of provider organizations are struggling to get their testing data integrated into the electronic health record.

Both payors and providers cited the lack of coding for genetic testing as a high-priority problem. Many organizations do not know what test has been done for a particular patient, nor do they have good visibility at an aggregate level across their member or patient base. Genetic testing data will be generated across siloed payor and provider organizations, and players in the ecosystem will need the ability to exchange and integrate data from external parties for several purposes, including integrating existing genetics testing data for new patients, exchanging health information for clinical decisions, and driving research.

Reimbursement and Oversight

As new regulations shift coverage models toward accountable care and away from fee-for-service, personalized medicine and genetic services will play a role in wellness, prevention, and cost-saving therapy selection. For example, some experts cited the need to move away from the concept of the laboratory as a cost center, and instead to view it as one piece of the bundled cost of treatment for a patient.

There is an important role for payors to try to leverage their data to generate new evidence for clinical care and coverage decisions. Traditionally, payors have struggled to draw insights from their data, as they have only a limited claims data view. In order to overcome some of the limitations of this lack of visibility, payors are participating in industry coalitions to share data, policies, and coverage practices around genetics services. Going forward, it will also be important for payors and providers to have capabilities to share and exchange health information easily across platforms and health systems—both to better serve patients

and to avoid duplication. Testing coverage decisions should follow a structured process to move from a one-off request to more comprehensive coverage. These coverage requests should have a value or cost analysis component. Some payors are implementing new, innovative coverage models, such as “evidence-development coverage,” where coverage for a specific test is allowed for the purpose of building the evidence base, and helps to inform future coverage decisions.

Need for Additional Provider and Patient Education

Providers, payors, and laboratories interviewed cited the need for additional education for providers and patients. Given the limited time in the medical curriculum dedicated to genetic testing and results, and the fast-paced evolution of the field, there is a need for more physician training in genetics. While continuing medical education curricula, symposia, and literature have some value, the key need is the creation of case-based, experiential-learning opportunities.

Patients can also play a major role as their own care activists. Consumers should have an idea of what to ask for in terms of genetic testing, and should be empowered to take on more accountability for their care. Some provider organizations expressed concern around the educational level of an individual patient affecting the ability to understand genetic test results—organizations need to make a conscious effort to have clear educational materials for all patients.

Labs and providers highlighted the role of genetic counselors as a critical part of the patient education team. In addition, interviewees mentioned the need for scientific communications staff to translate difficult concepts into digestible materials, and more patient education staff to disseminate information and materials.

About the Authors

Timathie Leslie is a Vice President at Booz Allen where she leads the Western and Pacific healthcare practice. Ms. Leslie has over 20 years of experience in the health care industry assisting payers and providers with technology strategy and innovation, government relations, product development and implementation. She works with a wide variety of clients to improve clinical information sharing and apply new insights from data analytics. Ms. Leslie also leads government initiatives focused on health IT financing, privacy and security policies, health information exchange (HIE) and health insurance exchange (HIX).

Daniel Agar is a Senior Associate at Booz Allen where he helps to lead the strategy and decision analytics practice. This practice combines deep industry expertise, technical insight, and cutting edge analytics to help clients develop growth strategies, align operational capabilities, and develop innovative approaches to organizational challenges. Mr. Agar has led numerous strategy and market assessment engagements across the health care, energy, and technology sectors and has supported both public and private sector clients. Mr. Agar holds an MBA from the Stanford University Graduate School of Business.

Contact Information:

Daniel Agar

Senior Associate
agar_daniel@bah.com
703-377-1161

Sarah Fielding

Associate
fielding_sarah@bah.com
703-902-5764

Sophie Miller

Senior Consultant
miller_sophie@bah.com
415-281-4961

Sarah Fielding is an Associate in Booz Allen's strategy and decision analytics practice. Ms. Fielding has supported healthcare and life science companies in strategy, operations, financing and business development. At Booz Allen, she has led a range of market assessments and strategy engagements for clients in both the public and private sectors. Ms. Fielding holds an MBA from Harvard Business School, and an MS from the Harvard-MIT Division of Health Sciences and Technology.

Sophie Cain Miller is a Senior Consultant in Booz Allen's health care practice. Ms. Miller's work focuses on health policy, health reform, and program evaluation where she has served federal, state and commercial clients. Specifically, she has worked on quality measurement and health reform implementation while at Booz Allen. Ms. Miller has been working in health care for five years and holds a Master's degree from the Harvard School of Public Health.

About Booz Allen

Booz Allen Hamilton has been at the forefront of strategy and technology consulting for nearly a century. Today, Booz Allen Hamilton is a leading provider of management and technology consulting services to the US and international governments in defense, intelligence, and civil sectors, and to major corporations, institutions, and not-for-profit organizations. In the commercial sector, the firm focuses on leveraging its existing expertise for clients in the financial services, healthcare, and energy markets, and to international clients in the Middle East. Booz Allen Hamilton offers clients deep functional knowledge spanning strategy and organization, engineering and operations, technology, and analytics—which it combines with specialized expertise in clients' mission and domain areas to help solve their toughest problems.

The firm's management consulting heritage is the basis for its unique collaborative culture and operating model, enabling Booz Allen Hamilton to anticipate

needs and opportunities, rapidly deploy talent and resources, and deliver enduring results. By combining a consultant's problem-solving orientation with deep technical knowledge and strong execution, Booz Allen Hamilton helps clients achieve success in their most critical missions—as evidenced by the firm's many client relationships that span decades. Booz Allen Hamilton helps shape thinking and prepare for future developments in areas of national importance, including cybersecurity, homeland security, healthcare, and information technology.

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