



Stakeholders Assessing Genetics with Employers (SAGE)

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Executive Summary

Rationale

Stakeholders Assessing Genetics with Employers (SAGE) was a federally funded research project designed to characterize the current state of employer-sponsored genetic testing, particularly in the context of wellness programs. Recognizing employers' interest in using genetic testing to support their employee wellness goals and the growing scientific evidence base supporting the use of population-based genetic testing, the National Human Genome Research Institute funded a one year study to support the development of frameworks that could be used by employers and researchers to guide informed decision-making and standardize process and outcomes investigations. The first framework is in the form of a checklist for employers interested in aligning their selection of genetic testing programs with their overall investment in employee health and well-being. The second framework targets both employers and researchers that want to develop robust evidence demonstrating the short and long-term impacts of genetic testing in measurement terms that are meaningful to employers and employees. If these frameworks are adopted in real-world decision-making and future research studies, employees are more likely to benefit in terms of improved health and well-being, and there will be a stronger evidence base to guide employer investment decisions in wellness programs that include genetic testing.

We are at a critical juncture in employer-sponsored wellness programs to both engage employees in their health while also demonstrating how these programs can be most effective in specific employer contexts. While there is a rich literature describing factors that support employee participation in wellness programs, assessing medical costs and productivity impacts, and recommending best practice scorecards to implement and evaluate wellness initiatives, there is limited understanding of the relative contributions of genetic testing to these efforts. The "black box" nature of genetic testing is perhaps predictable given that genetics is a highly technical subject for non-genetics trained professionals and there is a paucity of studies supporting the broad claims of presumed benefits of using genetic testing to personalize wellness recommendations. Since genetic testing is still in the early days of market adoption by employers, there is the need to elucidate both the rationale for genetic testing as part of wellness programs, as well as the current landscape of vendors promoting the use of genetic testing in the wellness context. Ideally it is best to hear directly from early adopters, genetic testing market leaders and wellness program researchers to outline the barriers and enablers to genetic testing implementation in employer-sponsored wellness programs. What has also been missing is the direct involvement of genetics experts and clinicians to evaluate the genetic tests being marketed to employers in terms of the underlying scientific evidence. Finally, it is also critical to understand

the legal and policy environment that affects the use of genetic testing in order to make sustainable and ethical wellness program recommendations to employers and researchers.

Methods

This white paper addresses each of these objectives in separate, but inter-related sections that reflect the specific research questions and methods used by the research team. First, based on a targeted literature review, we described the general wellness program environment with a focus on program goals, participation rates and evaluation metrics. Next we defined the scope of our white paper as focusing on “non-indication based genetic testing” (NIBGT) that occurs as part of employer-sponsored wellness programs, while acknowledging that there is a separate process for assessing and covering medically-indicated genetic testing as part of health insurance. To advance understanding of the types of genetic tests and marketing claims currently represented online to employers, we summarized findings from an internet-based study of all the genetic testing vendors in this space. Building on this foundational description of genetic testing vendors, we recapped in-depth interviews conducted with a subset of vendor representatives, employer-based purchasers and researchers who have experience conducting studies of wellness programs. The purpose of these interviews was to describe the experiences, insights, and outcomes from current NIBGT programs offered by employers as part of wellness programs, as well as critical success factors and major challenges regarding cross-employer data sharing from program evaluations unrelated to NIBGT. We complemented these qualitative interviews with consultation with professional organizations focused on employers and wellness program studies, as well as informal polling of attendees of a genetic testing webinar led by members of the SAGE research team. Conclusions from these collaborations supported the notion that while interest in NIBGT is potentially high, there is limited understanding of NIBGT and a clear need for better information to guide future employer adoption in wellness programs.

Prior to developing our recommendations, SAGE researchers conducted a comprehensive review of the federal laws and regulations potentially affecting genetic testing offered as part of wellness programs (e.g., the Affordable Care Act, the Americans with Disabilities Act, Health Insurance Portability and Accountability Act [HIPAA] and the Genetic Information Nondiscrimination Act [GINA]). The legal picture is currently not entirely clear; however, the most critical factors are ensuring the voluntariness of the program as well as prohibiting employer access to employees’ genetic test results. In addition, the use of incentives for participation in NIBGT is not permissible, particularly when tied to sharing genetic test results with the employer. Finally, if employers want to share aggregated data to support studies of NIBGT impact on clinical and economic outcomes, employers need to proceed cautiously given the current legal environment. Policy education for both employers and employees will be required before such studies are feasible.

Results

The first framework developed by SAGE researchers is essentially a checklist for employers who are considering offering NIBGT as part of their wellness program offering. The four areas to be considered are: 1.) Defining wellness program goals in the context of NIBGT; 2.) The specific types of genetic tests to be offered to employees; 3.) Legal and policy considerations to mitigate liability risks and choose a reputable vendor; and 4.) The types of evidence employers should request to ensure that their NIBGT goals are achieved. Recognizing that there are few studies supporting the claims of employee benefit from participating in NIBGT and no studies of potential employee harms, the second framework focuses on how employers and researchers interested in evaluating these claims can effectively close the evidence gaps. The types of research questions and specific process and outcome measures are described for 4 levels of evaluation, although each level is not intended to be viewed necessarily as stand-alone. These levels correspond to our theory that genetic test results must lead to different beliefs, behaviors, and actions in order to have the intended positive effects on employee engagement, as well as health and economic outcomes. The first level focuses on measuring program activities and represents the

minimum level of evaluation necessary to describe the impact of NIBGT on employees. Metrics designed to assess test uptake (number of employees tested) and deidentified results (number of “positive” results) are routinely captured by genetic test vendors and should be readily available to researchers.

The second level of measurement is critical for evaluating the impact of the program on employee attitudes and behavior and typically involves some type of survey data. We assume this evaluation is being conducted by a third party (not the employer) or is only being conducted by the employer based on aggregated data. These surveys would include questions regarding when employees contacted genetic counselors, participated in counseling or shared their results with their primary care provider. Surveys should also include questions regarding behavior changes related to diet, exercise, and sleep. To evaluate whether NIBGT is having the hypothesized impact on employee attitudes, surveys as well as qualitative data from focus groups and interviews will be necessary. Questions should address satisfaction, anxiety, and feelings regarding the program, their job, and their employer. The goal for the employee benefits and wellness industry should be to develop and validate a standardized set of questions that any researcher and employer can access to evaluate NIBGT consistently. Over time, this will lead to stronger inferences regarding the effectiveness of NIBGT given the ability to compare results across employers and programs.

The third level of evaluation emphasizes the traditional focus on clinical utility. In other words, it shows how use of the test leads to change in clinical management that results in an improvement in health outcomes. Research in this context presupposes that testing is integrated back into an established clinician-patient relationship even though the initial testing and return of results occurred as part of a wellness program. Outcome measures at this level typically rely on access to claims data to document clinical diagnoses and interventions, but also may include surveys to assess patient-reported outcomes such as quality of life. Experts in genomic medicine have recommended relevant outcome measures at the clinical practice application and longitudinal follow-up time frames, however they also point out that important health effects may take decades to manifest and require access to large, diverse populations for study. This may be accomplished by linking medical and pharmacy data with NIBGT testing results by a third party. These requirements necessitate the use of efficient, low-cost strategies for data collection, which increasingly means access to electronic health record data. This approach represents an additional data challenge for employers who are legally limited in their access to employer medical record data by HIPAA and the ADA, therefore collaborations with reputable, third-party data vendors and researchers is essential.

The fourth level of assessment is interrelated with clinical utility in that claims data and employment records form the basis of the assessment of economic impact, which includes both direct (healthcare) and indirect (productivity) costs. A full picture of the economic impact of wellness programs can be provided through an evaluation of dollars spent on medical and disability claims in addition to monetizing employment outcomes such as absenteeism and job tenure. To date, most economic evaluations have focused on comparing costs before and after implementation of a wellness program as measured by claims data. These methods are relevant for employers and researchers interested in evaluating whether NIBGT programs are cost-effective or cost-saving but require access to administrative claims data and researchers with expertise in analyzing this type of data.

Finally, the SAGE team applied the two frameworks to six different categories of tests commonly offered by current NIBGT vendors: *Health-related*; *Pharmacogenomic*; *Traits and Conditions*; *Fitness*; *Nutrigenomics*; *Ancestry*. For each category a brief evaluation of each framework question above is presented and are intended to be illustrative of how a decision maker could collect and prioritize information needed to make an informed decision and could guide questions for prospective vendors. The result is a list of genetic tests that can be reviewed by employers in light of their wellness program goals and evidence requirements.

Conclusions

This white paper provides a substantive assessment of NIBGT in corporate wellness programs, and it is intended to provide useful information for employers interested in implementing NIBGT successfully. The two frameworks developed by the SAGE team can be used to ensure more informed employer and employee decision-making, while also contributing to the expansion of the evidence base demonstrating the value of NIBGT for employees and employers. It is the SAGE team's intention that these frameworks could also be used by NHGRI and other research funders when considering future research investments.

Table of Contents

Introduction	6
Background	8
Landscape Analysis.....	13
Key Informant Interviews.....	17
Online Polling.....	22
Research Barriers and Enablers	25
Legal and Policy Review	28
Recommendations	31
Limitations	42
Conclusions	43
References	46
Acknowledgments.....	49

Disclaimer: The authors acknowledge that the views presented in this document were informed by the research as described above but the document in its entirety and the conclusions reached here are the opinions of the authors and may not represent the views or opinions of those interviewed as part of the project.

Introduction

Precision health has the potential to improve health outcomes for employees by tailoring treatments and risk mitigation strategies based on individuals' unique genetic profiles.¹ In March 2019, the National Human Genome Research Institute (NHGRI) convened self-insured employers, genetic test companies, payers, health systems, and researchers to discuss the opportunities and challenges associated with implementing genetic testing as part of employer-sponsored wellness programs or health insurance.

Topics covered in the meeting included: 1.) employers' level of interest in pursuing a genetic testing program based on a test 'formulary'; 2.) requirements for implementing a pilot program offering genetic testing to employees; and 3.) recommendations for measuring the value of pilot programs.² There was a great deal of interest expressed by the meeting attendees, but this was accompanied by the realization that more work needed to be done before specific recommendations could be developed. In response, the NHGRI funded a one-year grant supplement to develop a framework for working with self-insured employers to implement genetic testing. The grant was also intended to assess the feasibility of evidence generation and evaluation across multiple employers to determine relevant health and economic outcomes. The name for the one-year project was Stakeholders Assessing Genetics with Employers (SAGE).

Why This Study

This white paper summarizes and analyzes research findings from the SAGE project; furthermore, it makes recommendations regarding implementation of genetic testing for employer groups. Specifically, this white paper focuses on non-indication based genetic testing (NIBGT) offered as part of a corporate wellness program to all employees, which is an important distinction from genetic testing that is medically-indicated and reimbursed through employer health plans.

The hypothesized goals of testing include employee engagement in their own health, greater understanding of how genetics can affect health, enhanced well-being, early identification of health risks, safer and more effective medication use, and potential cost savings from improved preventive care.

Non-indication based genetic testing (NIBGT): Voluntary health-related genetic testing in employees with or without a personal and family history of genetic disease. The purpose of testing is to identify inherited risks that are evidence-based and medically actionable.

To date, there is scant information about the role or value of NIBGT in employee health, despite employers taking a heightened interest in precision health. This white paper provides guidance for employers based on answers to the following questions which represent the specific aims of SAGE:

1. What are the experiences, insights, and outcomes from current NIBGT programs offered by employers as part of wellness programs?
2. What are the critical success factors and major challenges regarding cross-employer data sharing from previous program evaluations?
3. Is there sufficient evidence to support NIBGT as part of company wellness programs, and if so, what genetic tests would be appropriate?

To answer these questions, the authors conducted:

- A landscape analysis of genetic testing vendors that target employers.
- Key informant interviews with genetic testing vendors, Chief Medical Officers (CMOs), and researchers to understand the factors influencing the current market, types of tests and employer receptivity, as well as the enablers/barriers to NIBGT as part of wellness programs.
- Meetings with the (National) Business Group on Health (NBGH) staff members to understand employer expectations for evidence-based benefits design.
- Interactive webinar on the topic of genetic testing as part of employee benefits presented to the NBGH members.
- CMO/CHO Summit on Precision Population Health hosted by the Health Enhancement Research Organization (HERO) and sponsored by Janssen Pharmaceutical Companies of Johnson & Johnson. The purpose of one component of the event was to better understand employer receptivity to, and concerns with, adding genetic testing.
- An audience poll conducted as part of a HERO webinar targeting employer CMOs, HR specialists and health benefit consultants on the topic of genetic testing as part of employee wellness programs.
- An ethics and policy review of data sharing, privacy and federal laws governing use on genetic testing by employers.
- A targeted literature review to support the development of recommendations for genetic testing implementation.

As a result of this work the authors present recommendations for:

- Criteria for choosing genetic tests and services as part of wellness programs that are relevant to employers and employees. This will include a discussion of contextual factors that impact implementation decisions.
- Criteria to evaluate genetic testing vendors given corporate wellness program goals.
- Factors to consider before implementing genetic testing as part of a wellness program, in alignment with policy considerations.
- Considerations for evaluating the impact on employees of genetic testing as part of wellness programs.

*The National Business Group on Health changed their name to the Business Group on Health during the writing of this white paper. The original acronym, NBGH, was used throughout.

Background

Wellness Programs are a form of employee benefit many employers provide *in addition to, and often separate from, healthcare insurance*. Optimally, wellness programs should be part of organization-wide support characterized as "... solid strategic plans with measurable goals, active and genuine leadership support, supportive and aligned policies, a workplace environment that contributes to well-being, and ongoing measurement and evaluation to keep making adjustments to ensure the right people are being engaged in the right programs for them and that those programs are implemented effectively."³ Employer-sponsored wellness programs are offered by 73 - 98% of companies, depending on corporate size, and applications extend to over 63 million workers.⁴ These wellness programs may be provided by the employer's health insurance carrier, but are increasingly delivered through third-party vendors.

Employers make these programs available to employees for the purposes of improving their health and reducing healthcare costs related to preventable disease. Other program goals include workforce productivity and employee wellbeing. According to a workplace wellness programs study, the focus on workplace wellness "takes advantage of employers' access to employees at an age when interventions can still change their long-term health trajectory."⁵

Wellness programs vary substantially in the number and types of services offered depending on the program goals, which may range from raising employee health awareness through education to requiring employees to demonstrate changes in biometric measures such as blood pressure, weight, or lipid levels. Typically they involve actions targeting life-style management, risk factor mitigation, early disease detection, or disease management.⁴ To identify individuals who are most likely to benefit from health promotion activities, wellness programs often include screening procedures to risk stratify employees. In 2014 the Rand Corporation sized the US workplace wellness market at \$6 billion, and more recent market research reports estimate current market size at \$7.2 billion.⁶ This growth has been aided by public investments such as the Affordable Care Act (ACA), which encouraged the development of workplace wellness programs.⁷

Make or Buy

Many companies purchase wellness programs directly from independent wellness companies or their insurer.⁸ Because most employers lack the resources and/or expertise to develop their own employer-sponsored wellness programs, brokers, consultants and agents play an important role in the purchase and implementation of employer-sponsored wellness programs.⁹ Considerations about health care data privacy also play a significant role in employers outsourcing the wellness programs to third parties.

Cost

Employer-sponsored wellness programs represent a significant employer expense, with annual cost estimates ranging between \$150 - \$1,200 per employee for these programs, depending on the depth/breadth of offerings.¹⁰ This expenditure is justified by employers as a reflection of their commitment to the health and well-being of their workforce. Another critical rationale is claiming employer-sponsored wellness programs lead to lower healthcare costs and workers' compensation claims, reduced employee health risks, and improved productivity and morale. Other reasons for offering employer-sponsored wellness programs involve marketplace competition for employees and the need to retain top talent.

Participation Rates and Incentives

As of 2012, only 20 - 40% of employees were reported to participate in wellness program components for which they were eligible. Predictors of program participation varied by program component e.g., screening activities alone, interventions to encourage healthy lifestyles, or

support for employees with manifest chronic conditions.¹¹ Older workers were least likely to complete health screenings or biometric testing, and workers with poor lifestyle choices (such as smoking) were often not participating in the intervention programs that would be of most benefit.

Given this reality, incentives became a useful tool to increase participation, particularly in concrete, easily completed actions such as completing a health risk assessment survey.¹² Seventy-eight percent of employers offer incentives, and the average annual incentive ranging from \$600 - 800/employee depending on employer size.^{4,11} Common incentives include a reduction in employees' healthcare premiums, free gym memberships, and gift cards for achieving weight loss or stopping smoking. However, incentives can pose financial and legal challenges for program implementation. For example, incentives may be regarded as employee income and therefore taxable. Additionally, incentives may call into question whether wellness programs are truly voluntary.⁴ The salient legal issues are addressed later in this white paper.

Return on Investment (ROI)

Wellness program vendors often claim that program adoption will show employers a positive ROI in the form of improved health, productivity and reduced related healthcare costs to an extent that exceeds the cost of the program. While earlier studies¹³⁻¹⁵ demonstrated a positive ROI, particularly for comprehensive wellness programs that reflected best practices¹⁶, results from more recent randomized controlled trials are not as encouraging.^{17,18} For example, researchers from Harvard Medical School and the National Bureau of Economic Research conducted an 18-month cluster randomized trial of 32,974 employees at 160 work sites. They examined whether or not a corporate wellness program, focusing on nutrition, physical activity, stress reduction, and related activities, improved employee health and reduced healthcare costs. Although the results showed an improvement in employee self-reported positive health behaviors, there was no significant change in healthcare spending, healthcare utilization, or clinical measurements of health for employees. Likewise, there was no significant impact on employment outcomes such as absenteeism and work performance.¹⁷

For supporters of, and vendors for, employer-sponsored wellness programs, these findings continue to be disputed.¹⁹ Some have argued that ROI calculations are too narrowly focused, suggesting that the indirect and longer-term value these programs may provide are not reflected in this type of analysis.⁸ Whereas a reduction in healthcare costs per employee is relatively straightforward to link to wellness program participation, additional measures — such as employee productivity, performance, morale, retention, or corporate profitability — are more difficult to tie directly to wellness program participation.²⁰ Evolution in how employers define and measure their investment returns from ROI to value of investment (VOI) are addressed below.

Best Practices

Literature evaluating wellness program best practices express the following themes:²¹⁻²⁵

1. Ensure relevance by basing the program on information gleaned from employee surveys and health risk assessments, environmental audits of the corporate culture and health “climate” of the organization, and review of current health plan coverage and gaps.
2. Engage senior leadership support and involvement, as well as accountability for the wellness program goals.
3. Partner with multiple internal and external stakeholders. For example, establish a formal Wellness group or committee composed of motivated members who can represent their peers.
4. Develop comprehensive programs that are linked to specific, measurable, and actionable goals and objectives for the program.

5. Establish a budget. Decide if the program will include employee rewards or incentives for achieving wellness goals, and factor these into the budget.
6. Design the program components that contribute to the program’s goals and objectives, within budget. Assistance from Wellness Program vendors or brokers is helpful to ensure successful implementation.
7. Communicate the plan through multiple delivery channels to reach specific employee subgroups. Sustain communication relative to participation rates, progress toward goals/ objectives, and leadership’s experiences with the program.
8. Ensure compliance with regulatory requirements and individual-level data safeguards.
9. Evaluate the program against established metrics, including a Return on Investment (ROI) or Value of Investment (VOI – discussed below).

Trends - A Movement Toward “Well-being”

As employees are increasingly spending more time working (whether remotely or onsite),¹³ they are expecting more from their employers. They see their employer as responsible for supporting their overall well-being — inside and outside of work. Much of that support is in the form of “well-being” benefits offered outside of traditional health insurance.¹³

TRENDS IN WELLNESS INDUSTRY – From ROI to VOI	
▶	Wellness industry is expanding and becoming more diverse and competitive
▶	Wellness companies are redefining their business models to promote a culture of health
▶	The value proposition of wellness programs is shifting from ROI to a more comprehensive idea: value of investment (VOI)

What is value of investment, or VOI? This term references a revised way of thinking about assessing the value of a wellness program. Rather than focusing on medical cost savings or productivity gains alone, this movement gravitates toward expanding the definition of value to also include organizationally-focused metrics, such as employee engagement, retention, and satisfaction. VOI emphasizes the need to demonstrate a more comprehensive impact of wellness programs in terms of caring for employees and making sure an organization is the employer of choice.^{20,26}

Well-being programs are differentiated from *wellness* programs by shifting the emphasis from healthcare issues to programs and activities that reflect a deeper level of care for employees. This often includes communicating that employee needs are valued and their employer is committed to their success. Well-being can mean a variety of things, but most offer a combination of personal financial planning, social/relational well-being, emotional resilience, and life purpose/meaning.²⁷ This trend is accompanied by a decline in traditional wellness interventions such as biometric screening.⁸

TRENDS IN WELLNESS PROGRAMS - What is Gaining/Losing Popularity				
▲ On the Rise	Financial Wellness		Biometric Screening	On the Decline ▼
	Mental Health		Health Risk Assessments	
	Stress Management		Health Fairs	
	Telemedicine		Fitness Classes	

Genetic Testing in Wellness Programs

Among the well-being needs employees mentioned as part of a 2019 Metlife survey, 38% of those surveyed mentioned “genetic testing” as a desired benefit not currently offered.²⁸ However, it is important to note that in this survey, the use of the term ‘genetic testing’ did not differentiate between medically actionable genetic testing (such as carrier or prenatal testing) and NIBGT (such as population screening).

The analysis in this white paper will focus on voluntary, health-related genetic testing in employees with or without a personal or family history of genetic disease (see definition of NIBGT above). The purpose of testing is to identify inherited risks that are evidence-based and medically actionable. The hypothesized goals of testing include employee engagement in their health, enhanced well-being, early identification of health risks, safer and more effective medication use, and potential cost savings from improved preventive care.

The justification for expanding NIBGT to wellness programs includes evidence that current genetic testing guidelines are both under-utilized and under-inclusive, thereby missing individuals with heritable conditions. Examples of these testing gaps are outlined in the table below:

Evidence Supporting NIBGT

About 2 million “healthy” people in the U.S. are at increased risk for adverse health outcomes due to undetected genetic mutations in “Tier 1” conditions.	<i>“Tier 1 Conditions” have evidence that testing leads to improved health outcomes.²⁹</i>
Screening guidelines that recommend testing for heritable conditions are under-utilized.	<i>Approximately 75% of those at risk for hereditary breast and ovarian cancer (HBOC) are not being tested.³⁰</i>
Many carriers of pathogenic variants do not meet clinical criteria for testing, leading to lost opportunities for prevention.	<i>Fifty percent of women who test positive for HBOC variants would have been missed by current testing guidelines.³⁰</i>

Experience to Date

Companies which provide NIBGT services to their employees typically do so through specialized genetic testing vendors that focus on catering to the employer. This is largely due to a lack of internal expertise among traditional wellness program vendors, as well as data privacy concerns. Employees are generally receptive toward genetic testing, according to Wamberg Genomic Advisors, a consulting firm that markets genetic testing as part of “proactive wellness programs” to employers through benefit brokers (and thereby has a vested interest in employee receptivity to such efforts).³¹ The Wamberg Genomic survey queried 536 U.S. consumers ages 26-64 years of age, of which 33% had direct experience with genetic testing.

PERCENT OF EMPLOYEES RESPONDING TO GENETIC TESTING SURVEY	
75%	Favorable view of genetic testing
69%	Never had genetic testing
65%	Interested in testing if their employer offered it

A recent New York Times article described the early experience of companies that offered NIBGT to their employees.³² Programs were either offered at no cost to employees or subsidized by the employers. Employee participation in this wellness benefit ranged from 17% – 50%; however, there was no description of any additional data collection to demonstrate program effectiveness, such as how or if NIBGT impacted health outcomes or well-being goals.

Landscape Analysis

A landscape analysis of current vendor products and practices was undertaken to better understand genetic services offered by corporate wellness program vendors. The purpose of the landscape analysis was to determine how NIBGT is presented to employers, what specific types of genetic tests are offered, what benefits and features are emphasized, what is the cost, how are potential risks mitigated, and what outcomes are described.

The following is a summary of the landscape analysis *Genetic Testing and Employer-Sponsored Wellness Programs: An Overview of Current Vendors, Products, and Practices*, published by the project team in 2020.³³ A copy of the manuscript can be found in Appendix A.

Methods

A systematic search of vendors offering business-to-business (BTB) genetic testing as part of a corporate wellness program was conducted using the Google search engine (see Figure 1). This was done in order to identify vendors offering corporate wellness programs with genetic services. Website content was abstracted and analyzed for vendor characteristics, descriptive data, marketing points of emphasis, types of NIBGT offered, availability of counseling services, and data sharing and privacy policies.

Figure 1: Systematic Search Methodology

1	<p>Google Searches Performed</p> <ul style="list-style-type: none"> • 16 Unique search strings applied • Advance search features and filters used: Located within the United States; Written In English language; Last updated no earlier than January 1, 2000
2	<p>Search Results Examined</p> <ul style="list-style-type: none"> • The first 30 URLs within Google search results for each of the 16 searches • 480 Total Google search results manually examined
3	<p>Inclusion Criteria Applied</p> <ul style="list-style-type: none"> • Business-to-Business (BTB) Vendor of Corporate Wellness Programs • Offering Genetic Tests and/or Services as part of the corporate wellness program

Results

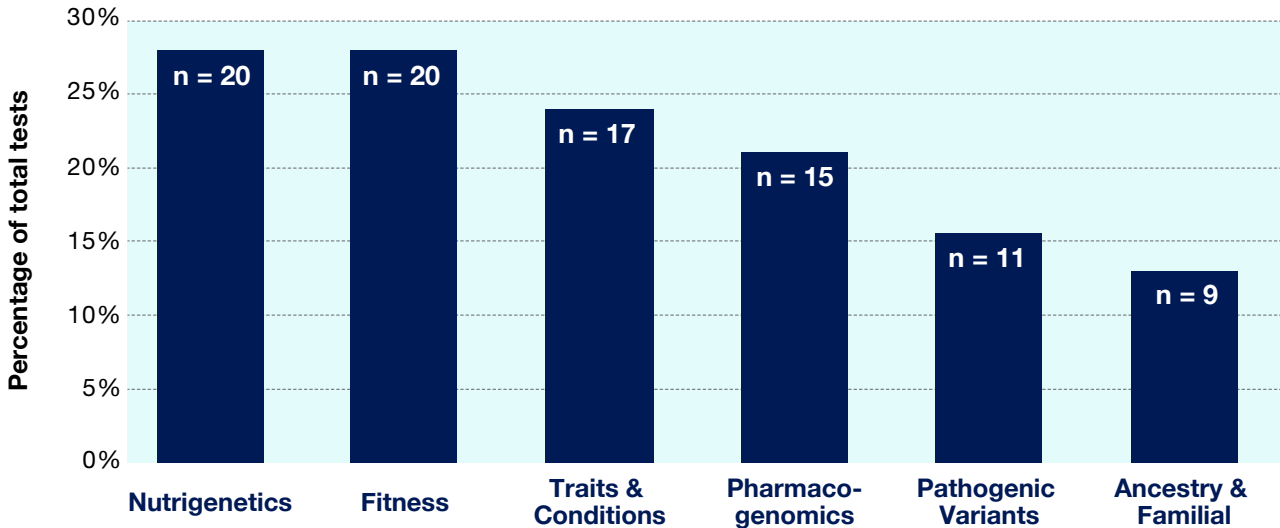
Fifteen vendors were identified and their websites analyzed in December 2019. To determine the types of genetic tests that appear to be sold in the corporate wellness market, all genetic tests on the vendor websites were categorized by six insights:

- Nutrigenetics
- Fitness
- Traits & conditions
- Pharmacogenomics
- Ancestry & familial
- Pathogenic variants

Categories Often Emphasize Lifestyle Applications

A total of 71 genetic tests for all 15 vendors were identified (Figure 2). These were categorized on the basis of the insights they intend to provide. The value within each bar represents the number of genetic testing products identified for each insight category.

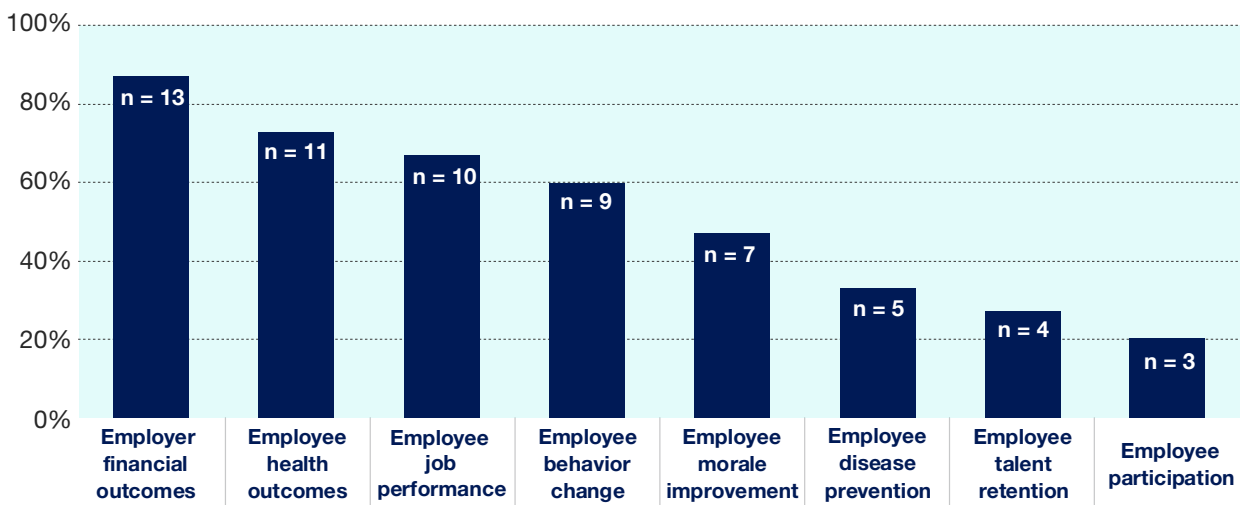
Figure 2: Types of Genetic Tests Offered by Vendors



Reasons to Acquire Genetic Testing

Vendors' claims of why employers would purchase genetic testing generally aligned with typical employer-sponsored wellness program goals (see Figure 2). The marketing points of emphasis on each vendor's corporate wellness page were searched to identify themes in how the benefits of adding genetic testing were advertised. The predominant trend showed that 87% of vendors mentioned employer financial outcomes as a benefit to purchasing their corporate wellness program. The next most commonly mentioned claims were employee health outcomes, employee job performance, and employee behavior change (see Figure 3). No data was available on the websites to support these claims.

Figure 3: Vendor Marketing Points of Emphasis



Data Practices and Vague Guarantees of Privacy

Because data privacy is of significant concern to both employees and employers from a legal and ethical perspective, it is important that vendors explain their policies and guarantees for data privacy. Most of the authors’ attempts to decipher vendors’ data practices led to vague or inconclusive determinations regarding how genetic and other employee data would be shared with employers, third-parties, or employees’ primary care physicians (see Figure 4). Only 60% of vendors mentioned compliance with HIPAA. Most vendors did not post privacy policies with enough explicit detail to ascertain how data protection and sharing would be managed. Transparency regarding data practices typically includes what (if any) data access is provided by the vendors to employers and what (if any) data sharing with third parties is occurring. This is particularly important given existing legal requirements (such as GINA, ADA, ACA, and others as discussed later in this white paper), increasing attention to data justice, and ethical obligations for data stewardship.

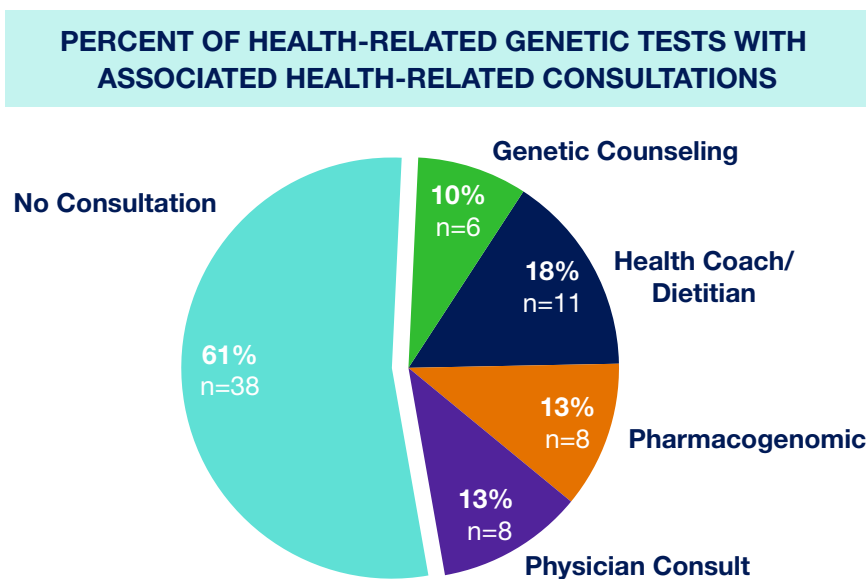
Figure 4: Data Sharing Policies of Vendors of B2B Corporate Wellness Programs

	Data shared with employers?			Data shared with 3rd party?			Data shared with employee user PCP?			HIPAA mentioned?	
	Explicit Yes	Explicit No	Vague Language	Explicit Yes	Explicit No	Vague Language	Explicit Yes	Explicit No	Vague Language	Yes	No
% of vendors	13.7%	27%	60%	40%	27%	33%	27%	6.7%	66.7%	60%	40%
# of vendors	2	4	9	6	4	5	4	1	10	9	6

Test Results Provided Without Access to Professionals

The product page for each genetic test was evaluated to determine if a consultation with a physician, medical geneticist, genetic counselor, or health coach was available for individuals to discuss their test results and any recommended changes to their diet, exercise, medications, or health care. Sixty-one percent of vendors did not mention any health-related consultation available to employees presented with their genetic test results (Figure 5).

Figure 5*: Facilitated access to health-related consultations



*The percentage values accompanying each category is calculated from the total number of tests for each category/ the total number of health-related genetic tests identified (62) *100. Data for each category of consultation were gathered independently.

Summary

Genetic testing vendors did not report their own programmatic successes. Furthermore, they failed to provide evidence to substantiate their claims that including genetic testing in corporate wellness improves health or reduces health-care costs. The omission of this information will likely frustrate attempts by employee benefits managers and employee-rights advocates to evaluate whether vendors are offering products and services that are adequately supported by scientific evidence. The alternative would be that they are offering nothing more than a test with unproven benefits and the potential for clinical harms.

There also was a lack of specificity regarding data privacy and security protections for employees. Understanding GINA and HIPAA compliance is important for the corporate decision-making process when selecting vendors for wellness programs. Corporate leadership might be inclined to implement wellness programs with genetic testing into their organization’s benefits package if wellness program vendors were transparent about their efforts to ensure compliance with GINA and HIPAA.

Effective communication and outreach strategies in the form of genetic and health counseling is apparent among only 53% of corporate wellness vendors’ analyses. Trained professionals are needed to communicate the limitations and risks of specific genetic tests and the implication of any identified pathogenic variants. It is a noteworthy gap that some vendors do not offer the critical benefit of health and genetic counseling to employee-participants. This landscape analysis surfaced a concerning lack of transparency among genetic testing vendors, emphasizing the challenges and risks employers may confront when attempting to make informed purchasing decisions.

Key Informant Interviews

Introduction

Semi-structured interviews with vendor representatives were conducted in 2020 in order to gain insight into current business practices surrounding this market segment.

To ensure a shared understanding of the scope and purpose of genetic testing, the research team drafted a definition of non-indication based genetic testing for employees (see box) offered through employer-sponsored health benefits. Similar interviews took place with company leaders and wellness researchers to understand why self-insured employers are interested in making NIBGT available and how wellness program effectiveness is measured. However, only the vendor results are summarized here. The full report describing the methods and results of all interviews can be found in Appendix B. Copies of the stakeholder interview guides can be found in Appendix C.

Non-indication based genetic testing (NIBGT): Voluntary health-related genetic testing in employees with or without a personal and family history of genetic disease. The purpose of testing is to identify inherited risks that are evidence-based and medically actionable.

Methods

A target list of vendors was developed based on a systematic internet search of companies offering genetic testing as part of wellness programs. Given the small number of vendors who agreed to participate in interviews, the research team determined that an exploratory case study approach would provide greater understanding of how genetic testing was being marketed to employers. Therefore, publicly available information from company websites regarding tests, data sharing practices, and evidence claims was used to triangulate findings regarding the business focus and impact of vendors.

The four vendor case studies were classified into two groups based on the focus of their NIBGT offerings to employers: predominantly **medically actionable** vs predominately **health and wellness** (defined below). This stratification facilitated comparisons across vendors offering NIBGT in a manner that supported NHGRI's conceptualization of genetic testing in employer settings.²

Medically Actionable

Defined as genetic testing that includes CDC tier 1 genetic conditions and/or genes from the ACMG list of conditions.^{29,34} Medically actionable vendor wraparound services included the option to speak with a board-certified genetic counselor, geneticist, and/or pharmacist.

Health and Wellness (H & W)

Defined as NIBGT that includes an association with fitness, nutrition, skin care, or behavioral traits. H & W vendor wraparound services included the option to speak with nutritionists, personal trainers, and/or life coaches.

Themes were identified through detailed review of the interview transcripts using the framework method.³⁵

Results

Across the four vendors, we assessed what tests and services are being sold, why and how they are being sold, and the various claims regarding value propositions. Vendors V1 and V2 were classified as being in the medically actionable category, and vendors V3 and V4 in the health and wellness category.

Service Offerings by Vendor

Vendor (participant)	CDC Tier 1 Conditions	ACMG 59 Secondary Findings List	Health & Wellness Screening	PGx Screening	Board-Certified Genetic Counselor Geneticist Pharmacist	*Other Consultations
V1	✓	✓	✗	✓	✓	✗
V2	✓	✓	✗	✓	✓	✗
V3	✗	✗	✓	✓	✗	✓
V4	✗	✗	✓	✗	✗	✓

*Can be nutritionists, personal trainers, life coaches

Medically actionable vendors endorsed the use of tests with evidence for clinical utility, such as screening for inherited forms of cancer and familial hypercholesterolemia. They also discussed the importance of “end-to-end solutions” involving employee engagement and education, testing, counseling, and personalized care activation. In contrast, health and wellness vendors promoted testing in the areas of nutrition, fitness, stress and skin health tended to distinguish this type of NIBGT from “medically actionable” NIBGT that could lead to anxiety for employees. These vendors also provide access to nutritionists and exercise specialists, but not experts in genetics. One vendor primarily associated with H & W did offer pharmacogenomics testing, but, in contrast to the medically oriented vendors, did not offer consultation with a pharmacist. Differences in vendor types also relates to the underlying clinical evidence base for the specific tests being offered (see final white paper section on “applying SAGE Frameworks to wellness program design” for a more detailed assessment of the strength of the evidence for specific genetic tests).

Rationale for NIBGT

The rationale for adding NIBGT to wellness programs across the four vendors was remarkably similar. Vendors agreed that NIBGT, and genetic testing as a whole, are of interest to many individuals and can motivate many to take control of their own health because the recommendations are “more personalized.”

A common theme heard from both the medically actionable and H & W vendors was that inclusion of NIBGT within a wellness program may serve as a market differentiator and ultimately help to attract and retain valuable employees.

Rationale for NIBGT in wellness programs:

- High interest from employees and employers, promoted by awareness of direct to consumer (DTC) genetic testing
- Can motivate employee to take control of their own health with personalized recommendations
- Supports overall goals of wellness programs to improve employee health and reduce healthcare costs
- Serves as market differentiator to attract and retain top talent

Both vendor groups also saw NIBGT as a way to potentially identify inherited health risks, motivate improved health practices, and ultimately improve employee health. Therefore, NIBGT was viewed as aligned with overall corporate wellness goals.

Financial Compensation

The medically actionable vendors and H & W vendors also shared similarities regarding financial compensation for services provided. All four vendors primarily sell NIBGT as part of corporate wellness programs, which are distinct and separate benefits from health insurance. The exception is V2 which facilitates insurance coverage for genetic tests that are clinically justified following evaluation and counseling by their staff of genetic counselors and medical geneticists.

Our interviews revealed that the self-insured employers who are early adopters of NIBGT generally offer testing as part of wellness programs to employees at no or reduced cost, with employers paying vendors directly for these services under a variety of financial arrangements, such as utilization based fees (paying only for those employees that utilize the service) or per employee per month (PEPM).

Employee Uptake

Another similarity across both medically actionable and H & W vendors is the types of factors that influence NIBGT uptake and participant engagement. Company culture is particularly influential in an employer's purchasing decision. Additional factors considered include characteristics of the employee population such as: age, industry segment, geographic location, and union membership. Who is the ultimate decision-maker at a company appears to significantly impact the success of implementation; all vendor representatives agree that involvement of executive-level personnel is crucial.

Implementation Barriers

One barrier to NIBGT adoption included a lack of data to justify the health and economic benefits claimed by vendors. For example, V2 indicated that there is not enough data to show ROI. Other participants reinforced how the lack of outcomes data limited informed decision-making by employers.

The medically actionable vendors identified the lack of genetic literacy across employers and employees as another barrier to implementation. In addition, V4 discussed how company leaders lacked knowledge about current coverage of NIBGT and would benefit from payment education regarding medically necessary genetic tests under medical insurance. V1 indicated that education gaps surrounding the Genetic Information Nondiscrimination Act (GINA) and relevant privacy regulations also hindered employee testing uptake. Both medically actionable vendors shared that physicians needed to be educated on how to care for patients based on genetic test results.

Value Proposition Claims

All four vendors claim that the use of NIBGT as part of wellness programs will lead to favorable impacts on both the organization and employees. For example, all vendors state that NIBGT will lead to lower long-term healthcare costs. However, none of the vendors provided substantiation for these claims. The two medically actionable vendors provided the most evidence regarding employee engagement and uptake; however, only V2 provided data from studies that

demonstrated the types of variants found from screening and whether individuals with pathogenic variant results would have otherwise met criteria for testing. V2 also published lessons learned from implementing NIBGT with employers, health systems, and large research organizations.

Medically actionable vendors also discussed ROI and VOI as ideal testing outcomes to demonstrate the value of NIBGT in employer-sponsored wellness programs. For example, they assert that NIBGT impacts health care spending, health outcomes, productivity, employee satisfaction, and morale. Additionally, it provides a competitive edge over other companies (VOI).

In comparison, H & W vendors primarily discussed health outcomes related to PGx testing and financial impacts related to lifestyle management. Of note, neither of the health and wellness vendors have conducted studies involving their NIBGT products and services, nor is the evidence they cite related to their offered tests. It appears that some employer purchasers may lack sufficient understanding of NIBGT to demand evidence of clinical utility, relying instead on marketing claims of personalization of wellness interventions based on genetics.

Employers, in an effort to appear innovative by supporting wellness program goals, appear to find vendors' rationale for testing to be compelling (at least currently) while waiting for the development of better evidence. The downside for both employers and vendors, who are trying to purchase medically actionable testing, is that there are not easily accessible criteria to separate the wheat from the chaff.

Data Privacy Concerns

Although both vendors and employers state that they want evidence of the clinical utility of NIBGT, obtaining reliable outcomes data is constrained by employer apprehensions regarding genetic data privacy protections and their willingness to pool de-identified data across employers. Common themes included concerns regarding the adequacy of GINA and genetic exceptionalism, which is a belief that genetic information is special and must be treated differently from other medical or personally identifiable information. Furthermore, it was evident that all vendors had some level of trepidation about how genetic data obtained through wellness programs would be used by the employee and employer. They indicate that a lack of employer understanding of the legality of genetic data utilization could lead to hesitancy about adopting these services into wellness programs.

Strategies to address privacy concerns varied across the four vendors. The two H & W vendors recognized the marketing appeal of strong, clear statements regarding genetic privacy protections; for example, both of their websites declared that they never share genetic test data with anyone other than the employee. Further, during the interviews, both described privacy protections as important selling points to consumers.

Participants in the medically actionable vendor group described their approach to managing genetic privacy by only sharing aggregate data with their employers. Notably, V2's privacy policy specifically highlights what happens if an employer has provided any financial compensation for a test. The employee agrees that his/her de-identified results and personal health information may be anonymized and/or aggregated and returned to the employer. Both the medically actionable vendors have privacy policies that center on protected health information (PHI), their legal obligation to maintain the privacy of PHI, and how setting up an account with said vendor gives them access to PHI.

V1's policy details that the marketing department may utilize PHI and places the responsibility on the employee to limit the vendor's use of their data by requiring an active "opt-out" decision. Given these positions, the medically actionable vendors are set up to pursue evaluations of their employer programs if they choose to do so.

Limitations

This research has several limitations. We aimed to recruit a larger number of participants in three key stakeholder categories in order to gather an abundance of data to achieve thematic saturation. Unfortunately, we were unable to secure a larger sample of participants, in part due to the timing of COVID-19 in relation to our recruitment period but also because of interviewees' reluctance to participate, despite extensive outreach efforts using multiple approaches (e.g., sending emails and presenting webinars). This may indicate that NIBGT was a lower priority for these stakeholders at this time.

Although there was substantial agreement on many of the themes it is unlikely that saturation was reached, given the small number of participants in each category. Therefore, we refocused our analysis on the vendors in the form of a case study post hoc, using rich data from company leaders and researchers to add context and perspective. As such, our conclusions cannot be generalized to all genetic test vendors in the setting of wellness programs. Further research is needed to gain a broader perspective regarding how and why self-insured employers are making NIBGT services available to their employees and subsequent employee outcomes.

Conclusions

While the four vendors clearly differed in their test offerings and access to professional counselors, they expressed similar rationales to employers for purchasing NIBGT. They also all recognized that the evidentiary barriers to entry are lower with wellness program decision-makers as compared to health insurance companies where decision-makers are focused on meeting criteria for medical necessity.

There are also similarities in the manner of financial compensation for wellness programs including NIBGT. V1 stands out in that it only offers education and counseling, and it refers employees to a network of approved laboratories to obtain NIBGT. The barriers and enablers to NIBGT implementation as described by interviewees are also comparable across vendors. Particularly important barriers highlighted include privacy concerns, lack of outcomes data, and the need for education regarding NIBGT.

The biggest differences were whether and how vendors cited evidence for their marketing claims. The medically actionable vendors made efforts to cite evidence of why genetic testing for inherited conditions was scientifically credible in a screening context with employees. The health and wellness vendors cited evidence that was unrelated to their claims and potentially misleading. As of the time of the interviews, they also expressed no plans to measure the impact of their testing and counseling on process or outcome measures. V2 has made the most effort to both assess and present their process evaluations at scientific meetings which involve peer review.

Online Polling

Introduction

In February 2020, Health Enhancement Research Organization (HERO) sponsored a webinar titled “Insights for Genetic Testing and Employee Wellness Programs.” Attendees participated in a live polling exercise to characterize audience beliefs and knowledge about the topic. While it was not possible to know with certainty the composition of the audience, HERO leadership confirmed that based on prior webinar attendance, it was likely that 80% would represent either employers (50%) or wellness benefit vendors (30%). Therefore, the SAGE project team decided that polling webinar attendees would provide a useful snapshot of current thought surrounding genetic testing as part of wellness programs.

Methods

The project team developed polling questions intended to advance understanding of several topics. Questions targeted how employer benefit decision-makers viewed the purpose of genetic testing, how testing should be added to employee benefits, data privacy concerns, and willingness to participate in a pilot study of genetic testing as part of employee wellness program. To be suitable for online polling, Likert scale responses regarding the level of agreement were developed. HERO reviewed and modified the questions to ensure comprehensibility for the typical HERO webinar attendees.

Results

Fifty-seven individuals attended the webinar and the average poll response rate was 52%. When asked to characterize the experience level of their organization with respect to genetic testing, slightly more than half of participants had not considered offering genetic testing as part of their wellness programs. Of the remaining respondents:

- 7% offer genetic testing as part of their wellness program;
- 15% cover medically-indicated genetic testing as part of their insurance plan;
- 25% are currently in discussions about offering genetic testing; and
- 3% considered it but decided against offering genetic testing as part of their wellness programs.

While a small percentage of participants had decided against NIBGT (3%), a quarter of respondents were currently evaluating the possibility of offering NIBGT as part of wellness programs. Additional questions were polled throughout the webinar presentation, with the percentage of respondents either **agreeing, or strongly agreeing** as below.

Question Asked	% Agree
I have a good understanding of how genetic testing fits with employee health and well-being programs.	30%
I have a good understanding of how genetic testing fits with an employer-sponsored health plan.	15%
Genetic testing can add medically-actionable information to an employee health and well-being program.	60%
There is sufficient evidence to support implementing genetic testing as part of employee health and well-being programs now.	30%
Genetic tests should only be used diagnostically to evaluate employees with a personal/family history of genetic disease.	10%
Concerns about data privacy are a significant obstacle to adding genetic testing to employee health and well-being programs.	80%
I am interested in my company participating in a pilot study of genetic testing as part of employee health and well-being program.	33%

Only 15% of respondents agreed that they understood how genetic testing fits with employer-sponsored health insurance, while twice as many said that they understood how genetic testing fits with employee wellness programs. Notably, no one strongly agreed with either of these first two questions, reflecting the educational gap acknowledged by webinar attendees with respect to the role of genetic testing. While the majority of respondents agreed that genetic testing could provide medically actionable information, only 30% of the respondents agreed that there was sufficient evidence to support implementation at the present time. Nevertheless, only 10% of webinar attendees agree to limit genetic testing to diagnostic indications only.

The highest levels of agreement (80% in some level of agreement, comprising 40% agree and 40% strongly agree) were in response to the statement regarding data privacy as a significant obstacle to adding genetic testing to wellness programs. Finally, only a third of respondents indicated that they were interested in having their company participate in a pilot study to evaluate the impact of genetic testing offered as part of wellness programs.

Discussion

Poll responses point to the limited understanding of how to view genetic testing in the context of either health insurance or as part of wellness programs, suggesting an educational opportunity for employer benefit decision-makers. An interesting finding is that twice as many attendees indicated an understanding of genetic testing in the context of a health and well-being program compared with employer-sponsored health insurance. This contrasts with findings described in other parts of this report regarding the lack of evidence for utility for genetic testing done as part of health and well-being products offered commercially. This finding warrants additional study to understand the underlying concepts driving these responses, as that would inform educational approaches.

Perhaps most significantly, only one-third of respondents indicated that they thought their organization would be interested in participating in a pilot study of genetic testing as part of wellness programs. This result may be related to the privacy concerns and was further explored as part of the qualitative interviews with CMOs (see Appendix B).

Limitations

The respondents were individuals with an interest in learning more about the topic as they self-selected to participate in the webinar. The nature of polling makes it impossible to know how subgroups, such as employers vs. vendors, may have responded differently. While webinar attendees are certainly not representative of all employer benefit decision-makers, this was the largest cross-sectional sample of individuals available to the SAGE project team. Notably their responses provided mostly confirmatory evidence of the challenges facing the use and evaluation of NIBGT as part of wellness programs.

Research Barriers and Enablers

Employers pursue evaluations of wellness programs because they want to know if their program is having the intended benefits for employees and for the organization. Research organizations studying wellness programs often involve more than one employer in order to answer research questions that are broadly relevant to employers. Researchers also need access to employee health-related and productivity data from multiple employers to achieve sufficient statistical power to test hypotheses. Due to the nature of genetic testing and the fact that only a small fraction of testing yields the identification of medically actionable genetic variants, pooling data from multiple employers to conduct research on the impact of NIBGT within a wellness program will be necessary.

The project team wanted to explore whether outcomes research focused on NIBGT would pose particular barriers to cross-employer data sharing, as well as to explore any facilitators of this process. We interviewed two researchers with extensive experience in conducting and publishing assessments of wellness program effectiveness. However, neither individual had conducted studies or program evaluations of NIBGT as part of wellness programs. Both interviewees were asked to share their perspectives as researchers in the wellness context generally, making extrapolations to NIBGT when possible.

Both R1 and R2 shared that more barriers are likely to be present when it comes to genetic data than other forms of health-related data due to heightened concerns regarding genetics as a particularly sensitive form of personal health data. R1 discussed that employees don't want their employers to have access to that level of potentially identifying data and therefore may decide not to participate in employer-sponsored NIBGT wellness benefits. This would complicate gaining access to sufficiently large data sets to conduct adequately powered cross-employer studies. R1 also distinguished outcomes research from program evaluation. Outcomes research must benefit multiple employers by addressing wellness program hypotheses that are relevant to employers broadly, while program evaluation focuses on one employer in order to understand what works and what needs to be improved when implementing a particular program in a specific employer context.

The following themes emerged about barriers and enablers for conducting rigorous studies of wellness program effectiveness that rely on employer data sharing. These insights were gained through years of experience working with employers interested in understanding whether wellness programs were having the claimed health and economic benefits at the population level, while developing processes to manage data sharing concerns.

Barriers

- Reliance of outcomes research on clinical data, including genetic information in particular. When asked if gaining access to genetic data presented additional complexity for researchers, R2 stated:

"I do, because that's getting into much more clinical data than employers feel comfortable in dealing with. It's hard enough for them to get behavioral data, risk data from their workers. Once you get the clinical data, then many employers just don't want to go there because they don't think it's in their roles of collecting that data. Now if again it is a third party, if there is a medical clinic like Geisinger or Mayo Clinic, Cleveland Clinic and so forth doing the research, that is different, but typically that would be done through the clinician's office as opposed to

the employer. Now, one hybrid situation might be if the employer has a lot of medical clinics towards employees, then potentially that may be an avenue to go in through there, but I think most employers would be very wary and hesitant about doing that kind of research.”

- Timeframe for observing health and economic outcomes of genetic testing is too far in the future. Employers are generally much less interested in studies that evaluate outcomes beyond one year or perhaps several years.
- Employer legal representatives are typically reluctant to sign off on sharing data with researchers outside their organization and outside their vendors that manage medical claims and disability data on behalf of the employer. Obtaining legal approval often requires multiple interactions between all parties to develop assurances that data would be de-identified, that clients would not be named, and that individual employees would not be identified. Detailed procedures for obtaining and using only aggregated data for specific research objectives must be specified to the satisfaction of all parties, a process that can sometimes take several years.
- Employers are risk-averse, and fear the possibility of litigation. Therefore, researcher requests to conduct evaluations of NIBGT as part of wellness programs, while feasible, will be met by skeptics and individuals with persistent employee privacy and autonomy concerns, despite research protections such as consent forms and use of only aggregated, de-identified data being in place.
- Employers often misunderstand the protections afforded by GINA. Employers may cite GINA as a barrier, despite this being a law that could reduce liability for employers if their program was deemed to be GINA-compliant.
- Researchers that lack experience conducting rigorous wellness program research or who have conflicts of interest will not be successful in attracting employer interest in research studies. The credibility of the researcher and the funding source as well as the relevancy of the research question are important factors to the employer.

Enablers

- Work with an entity or consultant that already has access to the data and permission to use it. It is ideal if the research organization can identify an entity with access to multiple employers, such as data vendors/suppliers, health plans, and other data aggregators. The researchers can provide oversight on the study, but data exchange is not needed.
- Form a collaboration between a research organization and a data supplier for investigations that require study-specific data sharing. The researchers can instruct the data supplier to format and structure the data in the way needed for the study. The data supplier then becomes responsible for de-identifying the data, limiting researcher access to aggregate data, and ensuring the data is compliant with all relevant regulations (e.g., HIPAA, GINA - see section below for more in-depth discussion). As a steward of the data set, the vendor supplier remains in control of the data for the analysis, relying on researchers to define the analysis plan but ensuring procedures to maintain data privacy and security.
- Rely on third party data suppliers to contact employers to gain permission to collect and use data for studies.
- Utilize an existing large data set containing de-identified employee claims data such as the MarketScan Research Database.² This allows the researchers to use that multi-employer claims data set without needing to go and recruit individual employers.
- Partner with an independent health plan that also supports research to conduct the study such as the Mayo Clinic, Geisinger, or the Cleveland Clinic.

²IBM MarketScan Research Databases. <https://www.ibm.com/products/marketscan-research-databases>

- Set up an agreement with employers to enter data into a common aggregate database.
- Offer incentives from research organizations to employers to participate in data sharing. These incentives may include receiving aggregated data to enable comparisons of utilization, cost and health outcomes across employers, stratified by region, type of industry or employee demographics. Additional incentives may include grant funding for the research, proprietary data collection instruments, unique approaches to data analysis and access to subject matter expertise.

Summary

Both research organization representatives expressed similar perspectives regarding how to plan for successful studies of wellness program effectiveness. Assuming that the legal hurdles can be overcome, such studies would ideally rely on de-identified, aggregated data that already exists with a trusted third party such as a health plan data vendor so that the employer doesn't need to share the data specifically for a single research study. In addition, researchers should try to work with data vendors that also have the expertise and resources to analyze the data. In this context, researchers would provide oversight for the analysis, but data exchange is not needed. Ensuring that studies are designed, conducted, analyzed and reported by trained researchers who disclose their conflicts of interest also helps to reassure employers considering participation in research that requires cross-employer data sharing. Trusted sources of research study funding such as the CDC or RWJF also helps strengthen study credibility, making data sharing more likely.

However, researchers need to be aware that genetic data presents additional challenges to wellness program evaluation because of uncertainty regarding the legal environment and distrust on the part of employees regarding sharing personal information with their employer. Both researcher interviewees opined that using any data representing individual health data for research comes with additional hurdles. Education regarding the responsible conduct of research and genetic data privacy protections will be crucial. Additionally, relationship building among researchers, employers, data vendors, and employee benefit consultants are seen as critical enablers of outcome studies to determine the effectiveness of NIBGT as part of wellness programs.

Legal and Policy Review

This review was intended to summarize the relevant legal and policy issues if employers were to pursue implementation of a wellness program for employees that incorporated genetic testing. Using Westlaw Next and standard legal analysis methods, a legal scholar provided an overview of federal law requirements for wellness programs and state issues related employers' acquisition and use of genetic tests and genetic information of employees. Pertinent highlights of the federal laws are summarized here; the full legal research memorandum can be found in Appendix D.

When evaluating the legal compliance of genetic testing, foundational questions include:

- Is the program a group health plan or part of a group health plan?
- Is the wellness program a stand-alone program?

If a wellness program provides medical care or if participation in the program affects cost-sharing for group health plans (part of a group health plan) then the Health Information Portability and Accountability Act (HIPAA), the Affordable Care Act (ACA), and other mandates on group health plans such as ERISA apply. If the wellness program is stand-alone and chooses to offer genetic testing, it must still comply with the non-ACA non-discrimination mandates of the Genetic Information Non-discrimination Act (GINA) and the ADA (Americans with Disability Act), as well as other relevant statutes.

Within the context of these rules are the underlying concerns for employee data privacy, non-discrimination of employees with genetic conditions, and protection for employees from coercive or financial harms on the part of employers as a result of participation/non-participation in genetic testing.³⁶

Genetic Information Nondiscrimination Act (GINA)

This legislation protects employees from genetic discrimination and stipulates when employer-sponsored wellness programs may incorporate genetic testing or information without being unlawfully discriminatory. Title I of GINA relates to health insurance, and Title II relates to employment. GINA Title II makes it unlawful for employers to – for any reason and subject to strict liability – acquire genetic information of employees. There are six exceptions to this statute, one of which is a wellness program exception. This wellness program exception stipulates:

- The employee must provide prior, knowing, voluntary and written authorization;
- Only the employee/employee's family member and a licensed healthcare professional can see the results of the genetic test;
- Only aggregated data, not individually-identifiable genetic information, is disclose to the employer; and
- The information cannot be used for any purpose other the wellness program.³⁷

Finally, financial incentive cannot be used to induce employees to provide genetic information. Financial incentives may be used to help employees who have voluntarily disclosed genetic information to meet health outcome goals only if those incentives are also provided to employees whose lifestyle choices (rather than genetic information) put them at risk for the same identified conditions. Financial incentives for wellness programs within the context of GINA have been very

controversial, and the regulatory guidance regarding their use has been extensively litigated and remains in flux. Incentives can be coercive when incentive reward amounts are too high and make a wellness program lose its perception of voluntariness; therefore the safest route is to avoid the use of incentives when genetic testing is part of the program.

Americans with Disabilities Act (ADA)

This act requires wellness programs to be “reasonably designed to promote health or prevent disease” [N.B. this is also a GINA requirement]. A program satisfies this standard if the following conditions are met:

- It has a “reasonable chance of improving the health of, or preventing disease in, participating employees”
- “It is not overly burdensome”
- It is “not a subterfuge for violating the ADA or other laws prohibiting employment discrimination”
- It “is not highly suspect in the method chosen to promote health and prevent disease.”

Under the ADA, employers cannot require employees “to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information (except to the extent permitted by this part to carry out specific activities related to the wellness program).”

Voluntariness of the wellness program is critical, and programs will be considered voluntary so long as they meet the following requirements: critical, and programs will be considered voluntary so long as they meet the following requirements:

- Employees are not required to participate.
- Employees who do not participate cannot be denied coverage under any of the health plans or benefits.
- Employers do not take any adverse actions against employees (i.e., do not retaliate against, “coerce, intimidate, or threaten”).
- Employers provide notice that is written such that it is reasonably likely the employee will understand it and describing not only the type of information to be collected, purpose for its collection, and specific uses of it once collected but also the restrictions on disclosures.

Health Information Portability and Accountability Act (HIPAA)

As amended by the Affordable Care Act, HIPAA requires that if a wellness program is itself a group health plan or part of a group health plan, the terms must comply with HIPAA’s privacy and security rules. Business associate agreements would be necessary when interacting with third-party wellness program providers. The ACA generally prohibited discrimination on the basis of health status or pre-existing conditions but included an exception to encourage participation in wellness programs that meet certain specifications (see Appendix D). The ACA also stipulates what financial incentives are available to employers to encourage participation in wellness programs, depending on the program type and requirements.

There remain numerous unsettled regulatory issues surrounding genetic testing, largely due to the current administration’s reluctance to defend and enforce the ACA. The Equal Employment Opportunity Commission (EEOC) issued rules implementing GINA, ADA and the ACA; however,

these rules were challenged through litigation and ultimately the challenged portions were vacated. In December 2017 the EEOC reportedly promised the D.C. District Court that it would promulgate new rules by October 2019, and the D.C. District Court warned the EEOC explicitly that “an agency process that will not generate applicable rules until 2021 is unacceptable.”³⁸ While the EEOC placed the item on its Fall 2019 regulatory agenda, text of final rules have not been made public as of September 3, 2020. Although significantly delayed, the EEOC proposed rule on wellness programs is anticipated imminently as it is currently under Office of Management and Budget review. The statutory protections remain in place until a new final rule has been issued.³⁹

In summary, for NIBGT offered through wellness programs, the most critical factors are ensuring the voluntariness of the program as well as prohibiting employer access to employees’ genetic test results. In addition, the use of incentives for participation in NIBGT is not permissible, particularly when tied to sharing genetic test results with the employer. Finally, if employers want to share aggregated data to support studies of NIBGT impact on clinical and economic outcomes, employers need to proceed cautiously given the current legal environment. Policy education for both employers and employees will be required before such studies are feasible.

Recommendations for Employers

This section describes the framework employers can use when deciding if and how they will offer genetic testing to employees. To clarify, the term “framework” describes a system of rules or principles used to govern a process or a decision. The decision in this context is whether an employer will offer NIBGT for employees as part of a wellness program. We are focusing our framework on decisions related to NIBGT as part of wellness programs, because our research indicated that this is the most common modality for adding NIBGT to employee benefits at the present time.

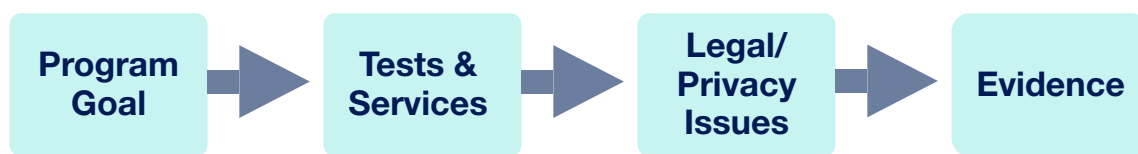
It is worth mentioning why this is the current state of affairs, since employers are attempting to grapple with the appropriate use of genetic testing coverage for their medical plan benefits design. Further, our CMO interviewees indicated that employers are interested in understanding the appropriate use of genetic testing broadly, often included under the “genetic testing” umbrella diverse indications such as microbiome testing, liquid biopsies in cancer, gene therapy, germline testing for inherited risks, and pharmacogenomic tests.

Before being able to discuss NIBGT in the wellness program context, we need to clearly describe the boundaries of this type of testing and the population for which its use is intended. This requires contrasting NIBGT with genetic testing that is currently covered by their medical plan insurers. Indeed, our key informants told us that first, employers should understand what types of genetic tests are covered by insurers as part of their medical benefits and what they hope to add by offering NIBGT as part of wellness programs. Factors impacting the types of genetic tests covered by insurers include lack of evidence of clinical utility (see below), cost concerns or USPSTF (US Preventive Services Task Force) recommendations.

It is helpful to first describe the evidentiary considerations used to determine coverage for indication-based genetic testing. For tests such as prenatal testing, carrier screening, and tumor profiling, self-insured employers typically look to their insurance carriers or third party administrators to have clinical policies in place that dictate what billed diagnostics are covered and what criteria need to be met for coverage. Typically, these decisions are in compliance with the notion of medical necessity, which means that use of the intervention is determined to be reasonable, clinically appropriate and effective based on evidence-based clinical standards of care. In the case of genetic testing, this standard often requires evidence of clinical utility (improvement in net health outcomes). Self-insured employers may decide to modify their insurance benefits and insist on covering novel interventions such as NIBGT. This might occur because insurers tend to be conservative and employers may think that it is simply a matter of time until there will be sufficient evidence of clinical benefit. However, as of July 2020, employers choosing to offer NIBGT for their population do so as part of wellness programs.

We have found that some employers are interested in offering innovative wellness benefits that include NIBGT to their employees based on their general support for precision health and the possibility of proactively engaging employees in education and follow-on actions regarding the genetic risks identified. Below we list a series of recommended questions that employers should use when considering whether to offer NIBGT as part of wellness programs to employees. The figure is organized as a checklist focused on four key considerations (Figure 6).

Figure 6: Employer Checklist for Assessing the Merits of Implementing NIBGT



What is the goal of the wellness program?

Employers should decide if they are interested in promoting a program that focuses on testing for genetic variants that are associated with a high risk of developing a disorder associated with serious morbidity and/or mortality. If so, the testing program must be accompanied by access to evidence-based, specific preventive interventions for those identified as high risk. Examples include genetic tests for conditions such as hereditary breast and ovarian cancer or familial hypercholesterolemia. This could also include promoting the use of pharmacogenomic testing which has the potential to impact prescribing decisions by healthcare professionals for drugs that are commonly prescribed. In contrast, some employers may be more interested in recreational uses of NIBGT intended to promote improvements in diet and exercise behaviors using nutrigenomics and NIBGT for fitness. Overall, these general health and wellness tests have a weaker scientific evidence base, but they also tend to be more easily understood by employees and more in line with the general wellness scope of other programs offered through wellness benefits.

Another reason that employers may choose to pursue health and wellness NIBGT is that every employee will receive some personalized health information, whereas only 1-2% of employees will receive a positive medically actionable genetic test result. Employers primarily interested in employee engagement and promoting personalized behavior change across most employees as their goal may prefer health and wellness NIBGT. Vendors providing this testing also focus on providing access to nutritionists and fitness coaches, while medically actionable genetic testing vendors focus on providing access to genetic counselors and primary care providers to ensure continuity of care and appropriate medical follow-up within a health care system. There are higher levels of employer accountability for providing access to appropriate clinicians when offering medically actionable genetic testing, including pharmacogenomics testing. Employers should determine their risk tolerance, whether they consider themselves an early adopter in terms of employee wellness benefits, and how genetic testing will support their overall wellness program goals.

What are the specific tests being offered, results returned, and the availability of healthcare professionals?

While the majority of genetic tests offered by genetic testing vendors are focused on skin health, nutrition, and fitness, employers should understand the scope of genetic testing offered by genetic testing vendors they engage with. For instance, does testing include pharmacogenomic tests? Does testing include other medically actionable testing such as testing for CDC Tier 1 conditions¹⁴ or expanded testing such as the ACMG 59¹⁹? In addition to asking questions regarding the types of genetic tests, employer benefit decision makers should ask for detailed information regarding how the genetic test results will be shared with employees and the options for sharing this information with the employees' current healthcare providers.

Next, employers should ask if the genetic testing vendor provides employees with access to genetic counselors or other types of health care professionals. For example, we found in our landscape analysis that only a minority of genetic testing vendors offered access to professionals trained in genetics. This may or may not be appropriate given the focus of the genetic testing as either medically actionable testing or health and wellness testing. But employers should be aware that genetic test results are complex and may induce anxiety in individuals inexperienced with receiving inherited risk information or uncertainty regarding what steps to take next. This uncertainty may be true for the primary care provider, as well as the patient. Therefore access to genetic professionals is perhaps the most reliable way to ensure that employees (and their providers) know how to follow-up appropriately on their test results.

Finally, employers should ask questions regarding whether the individuals ordering the tests or referring employees based on test results have a financial relationship with the genetic testing vendor, as this may influence their recommendations. Other relevant areas of inquiry include understanding the business model of the genetic testing vendor. For example, consider whether the vendor owns the genetic testing laboratory or otherwise financially benefits from recommending tests.

What are the legal and policy considerations?

To reduce the risk of legal liabilities associated with offering NIBGT as part of wellness programs, employers should first engage employees to understand their interests and concerns with NIBGT. This step is intended to limit potential downstream problems after the program is implemented and avoid employee misunderstandings regarding how data will be used by employers. Next, employers should ensure the voluntariness of any NIBGT component or request for genetic information (as broadly defined by GINA's statutory – not regulatory – provisions). Requiring employees to participate in testing is particularly problematic given the regulatory uncertainty introduced by the EEOCs failure to issue final rules governing the application of the ACA, GINA, and ADA with respect to wellness programs – not to mention varying state laws that might also apply to genetic testing and related data management issues. For example, data breach notification requirements, consent requirements, and restrictions on disclosure of results.

Employers should also choose a reputable genetic testing vendor, able to provide only high-quality testing services reasonably designed to deliver accurate and actionable information and to promote health and wellness. Due diligence regarding the genetic testing vendor should include, for example, an evaluation of:

- The scientific knowledge serving as the foundation for their products and services and scientific expertise of vendor personnel;
- The adequacy and availability of genetic counseling services;
- The transparency of product characteristics, limitations, and description of reasonably foreseeable downstream medical and financial consequences for participants;
- The user-centered design performance of any online portal or app for the participants;
- The vendor's ethical literacy;
- The adequacy of the vendor's data privacy and security measures (including, but not limited to, transparency of data access and use policies for business associates or third parties to any genetic data collected, whether individual or aggregated, identifiable or de-identified); and
- The vendor's commitment to and resources dedicated to ensure legal and regulatory compliance (local, state, and federal aspects).

Employers should also insist on (and maintain) an informational firewall to eliminate employer access to any genetic information that might be created as part of participating employees and/or their dependents. Finally, employers should avoid tying any financial incentives for the wellness program to the NIBGT process or collection of genetic information that might be gleaned from health risk assessments of participating employees and/or their dependents.

What is the evidence that employer program goals are likely to be achieved?

Employers should stipulate genetic testing vendors explain and demonstrate how they have evaluated the effectiveness of their tests when implemented as part of wellness programs. Traditional outcome measures to demonstrate clinical utility include evidence that the genetic test results led to employee behavior change and improved health outcomes. Realistically, vendors may only be able to create a chain of evidence linking test results to process measures such as a change in medication or reduction in cholesterol level. Although employers may be interested in assessing the ROI for NIBGT, the time period for observing improvements in employee health status and reductions in health care costs can be several years. Hence if employers emphasize VOI, then changes in employee emotional and mental health should be measured for changes over time.

Our landscape analysis of genetic testing vendors revealed major disconnects between the health improvement and cost reduction claims made by vendors on their websites, in promotional materials, and the specific evidence cited. For example, most vendors stated that use of NIBGT in wellness programs leads to healthcare cost reductions; however, the evidence cited did not support this assertion.

Employers should ask who conducted the study, the funding source and if the results are publicly available. If published studies are cited, employers should assess the appropriateness of the study design to support the claims being promoted by vendors. While it seems reasonable to predict that smaller start-up companies lack the resources and incentives to undertake and publish these studies, employers should determine how they will link vendor claims to their wellness program goals.

The Path Forward

Given the current interest of some employers and employees in using genetics to personalize health care interventions, combined with a proliferation of genetic tests and unsubstantiated claims of benefit, it is possible that NIBGT will be a short-lived phenomenon. The most promising path to understand whether the benefits of NIBGT outweigh the harms consists of well-conducted studies across multiple employers using standard process and outcome measures. Although the costs of genetic testing are declining, employers will face tough decisions in the post-pandemic era regarding what discretionary services they will offer to their employees. A framework (Figure 7) for evaluating the claims made by NIBGT vendors could serve as a useful tool for employers and researchers interested in developing the evidence base to support informed decision-making regarding the value of NIBGT.

This framework is organized in four levels of assessment. Given that well-being is a construct that lacks a widely accepted standard definition and has not been comprehensively measured to date, our research framework emphasizes measuring the “utility” or impact of NIBGT at progressive levels. These levels correspond to our theory that genetic test results must lead to different beliefs, behaviors, and actions in order to have the intended positive effects on employee engagement, as well as health and economic outcomes.

Figure 7: Framework for Assessment of NIBGT for Employers and Researchers

DATA PRIVACY AND STEWARDSHIP BY DESIGN	
1	<p>Activity-based</p> <ul style="list-style-type: none"> • Number people tested • Number positive results • Types of genetic variants found • Demographics of people tested (including job-related characteristics)
2	<p>Operational Utility</p> <ul style="list-style-type: none"> • How many employees sent results to their providers? • Are employees satisfied with the process? Feel positively toward their employer? Learned anything? Feel anxious? • Do employees change their health-related behaviors?
3	<p>Clinical Utility</p> <ul style="list-style-type: none"> • Number of new genetics-related diagnoses • Change in clinical management to genetic test result (e.g. drugs, surgeries, imaging, etc.) • Morbidity/Mortality related to genetic test result • Health-related quality of life
4	<p>Economic Impact</p> <ul style="list-style-type: none"> • Direct healthcare costs • Productivity • Disability claims • Employee turnover

The first level focuses on measuring program activities and represents the minimum level of evaluation necessary to describe the impact of NIBGT on employees. Metrics designed to assess test uptake (number of employees tested) and results (number of “positive” results) are routinely captured by genetic test vendors and should be readily available to researchers. To understand how many of these individuals with pathogenic or likely pathogenic variants do not meet guideline-based criteria for genetic testing requires access to employee characteristics such as personal and family history of genetic disease. In addition, employers may be interested in learning if there are patterns in the types of employees that take advantage of NIBGT, such as job role, time in position, and geographic location. This information is useful in designing customized educational materials to ensure effective employee engagement. Another metric to assess engagement could be the number of employees that access educational materials delivered through a specific portal or website.

The second level of measurement is critical for evaluating the impact of the program on employee attitudes and behavior. We assume this evaluation is being conducted by a third party (not the employer) or is only being conducted by the employer based on aggregated data. In order to quantify the number of employees that acted on their NIBGT results, surveys need to be developed and administered to participating employees. These surveys would include questions regarding when employees contacted genetic counselors, participated in counseling or shared

their results with their primary care provider. Surveys should also include questions regarding behavior changes related to diet, exercise, and sleep. To evaluate whether NIBGT is having the hypothesized impact on employee attitudes, surveys as well as qualitative data from focus groups and interviews will be necessary. Questions should address satisfaction, anxiety, and feelings regarding the program, their job, and their employer. Involvement of experienced mixed-methods (quantitative-qualitative methods) researchers to reduce the risk of biased results would be important to include.

The goal for the employee benefits and wellness industry should be to develop and validate a standardized set of questions that any researcher and employer can access to evaluate NIBGT consistently. Over time, this will lead to stronger inferences regarding the effectiveness of NIBGT given the ability to compare results across employers and programs. There is a precedent for this approach established by NHGRI's CSER (Clinical Sequencing Exploratory Research) program which developed a common set of process and outcome measures for genetic testing.⁴⁰ This could serve as a model for how to develop standard measures to evaluate NIBGT.

The third level of evaluation emphasizes the traditional focus on clinical utility. In other words, it shows how use of the test leads to change in clinical management that results in an improvement in health outcomes. Research in this context presupposes that testing is integrated back into an established clinician-patient relationship even though the initial testing and return of results occurred as part of a wellness program. Outcome measures at this level typically rely on access to claims data to document clinical diagnoses and interventions, but also may include surveys to assess patient-reported outcomes such as quality of life. Experts in genomic medicine have developed a specific framework for specifying the relevant outcome measures at the clinical practice application and longitudinal follow-up time frames, however they also point out that important health effects may take decades to manifest and require access to large, diverse populations for study. This may be accomplished by linking medical and pharmacy data with NIBGT testing results by a third party.

These facts necessitate the use of efficient, low-cost strategies for data collection, which increasingly means access to electronic health record data. This approach represents an additional data challenge for employers who are legally limited in their access to employer medical record data by HIPAA and the ADA. Hence it seems an unlikely data source for research at this time. However, researchers have successfully conducted randomized studies of the effectiveness of workplace wellness programs by using personal health assessment surveys, clinical data from workplace biometric screenings, administrative data such as employment records (absenteeism and tenure), and health insurance claims.⁴¹ Similar approaches could be used to measure the clinical utility of NIBGT.

The fourth level of assessment is interrelated with clinical utility in that claims data and employment records form the basis of economic impact, which includes both direct (healthcare) and indirect (productivity) costs. A full picture of the economic impact of wellness programs can be provided through an evaluation of dollars spent on medical and disability claims in addition to monetizing employment outcomes such as absenteeism and job tenure. To date, most ROI evaluations have focused on comparing costs before and after implementation of a wellness program as measured by claims data. These methods are relevant for employers and researchers interested in evaluating whether NIBGT programs are cost-effective or cost-saving, but require access to administrative claims data and researchers with expertise in analyzing this type of data.

Any type of evaluation needs to be embedded in procedures to specifically address data justice and responsible data stewardship issues. While it is beyond the scope of this white paper to describe these processes in detail, the intent is to proactively address anti-discrimination and privacy issues by design whenever any type of research is planned and conducted for NIBGT programs. These issues should be addressed by wellness programs themselves, but are requirements for research studies. From our interviews with researchers experienced with conducting multi-employer wellness program evaluations, we know that there are barriers and enablers to conducting clinical and economic utility studies of wellness programs that are generalizable to NIBGT studies. Working with a trusted third party that has access to aggregated, de-identified claims data will increase the likelihood that employers will agree to participate in NIBGT effectiveness research. Factors such as funding by independent sources such as the NIH or not-for-profit foundations and leadership by experienced investigators are also likely to promote employer participation.

Finally, access to the research results and benchmarking data will also support employer willingness to engage in research. However, we have learned from this project that special attention to genetic data privacy concerns is required for employers and employees to agree to participate in future studies of NIBGT. Without these studies, employers face a challenging environment for informed decision-making regarding the value of novel wellness programs that could tarnish their perceptions of the credibility and usefulness of NIBGT.

Applying SAGE frameworks to health and wellness program design

Employer-sponsored health and wellness (henceforth wellness) programs recently began including genetic testing as part of a package of health benefits to employees. In this section, we summarize lessons drawn from SAGE studies and frameworks that should be considered by designers of these benefits. While a precise “formulary” of genetic tests is outside the scope of this section, we discuss the breadth of genetic tests that could be offered in the context of a wellness program and criteria for making decisions about genetic content included in the test offering.

The genetic tests presented were taken from a list of genetic tests generated by the National Human Genome Research Institute for the initial in-person meeting referenced earlier. In the course of the project, these groups of tests were identified and defined in the landscape analysis and interviews supporting their relevance for inclusion as examples.

Given the focus on wellness programs operating separately from clinical care, the recommendations apply only to NIBGT and do not apply to making test decisions for employees with a medical indication or making coverage determinations by payers.

In a preceding section of the white paper, two frameworks were presented about inclusion of genetic tests in a wellness program which could be used by stakeholders responsible for decision-making. The first framework presented recommended questions to ensure employer decision makers consider all components of NIBGT that will affect program implementation:

1. What are the overall goals of the wellness program and how does genetic testing impact those goals?
2. What are the specific tests being offered and how are results returned?
3. What is the availability of health care professionals to follow-up test results?
4. What are the legal and policy considerations when offering genetic testing as part of Wellness programs?
5. What is the evidence that employer program goals are likely to be achieved?

These questions also encompass the type and quality of evidence available to assess NIBGT program impact, and alignment of this evidence with the goals of the program and programmatic cost. While these are outlined in more detail in the recommendations for employers and researchers, we briefly address each of these questions in the context of an evaluation framework that could be implemented as part of a wellness program.

The second framework addresses the evaluation of the program focusing on the question: are employer goals for employees participating in the program being achieved? There are two categories of goals, one with a focus on health impact and outcomes, and the other with a focus on employee engagement metrics such as morale, tenure and retention, and job satisfaction. These two areas are not mutually exclusive, and a wellness program could be designed to address each of these goals. Depending on the nature of the NIBGT, not all participants would be expected to receive results. This can be described as the reach of the program and will also be discussed in the examples provided.

Application of Frameworks to NIBGT by Category

In this section we applied the two frameworks to six different categories of tests as defined by the landscape paper in Appendix A titled Health-related; Pharmacogenomic; Traits and Conditions; Fitness; Nutrigenomics; Ancestry. For each category a brief evaluation of each question is presented with the exception of legal issues, as they have been reviewed extensively elsewhere in the white paper and also require frequent reassessment to ensure they are up-to-date. These are not meant to be definitive assessments, but illustrative of how a decision maker could collect and prioritize information needed to make an informed decision and could guide questions for prospective vendors. Information to populate each category comes from a number of sources including the landscape analysis; stakeholder interviews performed as part of this project (and reported elsewhere in the white paper); and a pre-conference collection and survey of genomic tests that were assembled and reviewed prior to the employer meeting and discussed at the meeting.

Health-Related

- **Wellness Goal:** Genomic information is used to identify individuals at high risk of developing serious health conditions (e.g., Cancer and Heart Disease) for which medical interventions exist that can reduce or eliminate the risk of developing disease and associated morbidity and mortality. This could result in improved health outcomes and potential reductions in health care costs (clinical utility and economic impact). There could be some impact on employee engagement and satisfaction (operational utility).
- **Test Offered:** Most commonly a panel of medically actionable genes would be fully sequenced. Furthermore, variants would be identified and interpreted to identify those

likely to be disease-causing. Some programs offer exome sequencing where all the genes in the genome are sequenced and variants identified, however the interpretation is usually limited to a subset of genes for which there is defined medical actionability. This practice is expected to increase as costs of exome sequencing decrease.

- **Reach:** Variant information would be available for all participants, but only 1-2% of participants are likely to have a variant that would necessitate notification and changes in medical care.
- **Evidence:** In a word, the evidence is variable. There is strong evidence of clinical utility for testing individuals with elevated risk of conditions associated with a targeted set of genes associated with what the Centers for Disease Control and Prevention call Tier 1 conditions. These conditions include hereditary breast and ovarian cancer syndrome, Lynch syndrome (predisposition to colorectal and endometrial cancer), and Familial Hypercholesterolemia (associated with early cardiovascular disease, heart attack, and stroke). Evidence-based guidelines exist to help clinicians manage individuals that carry a variant in one of these genes. There is reasonably strong evidence for a group of genes reviewed by the American College of Medical Genetics and Genomics (ACMG) for the purposes of analysis and reporting as secondary findings in the context of exome or genome sequencing for a medical indication. It is important for decision makers to consider that with a few recent exceptions, this evidence has not been obtained from population screening programs. This means it is unclear whether the same utility would be seen in a wellness program. This would be an important point to discuss with vendors offering a service of this type.
- **Availability of Health Care Professionals:** This information is best conveyed by genetics professionals (specifically geneticists, genetic counselors, nurse geneticists) or specialists with condition specific expertise. Primary care professionals are increasingly exposed to this information and may be able to manage patients with availability of guidelines and consultation with specialists.
- **Program Evaluation Metrics:** This primarily consists of health outcomes for screened conditions and health care costs (clinical utility and economic impact). Other metrics include employee uptake, engagement, satisfaction, and health behavior changes (activity-based and operational utility). An important caveat to note is that only 1-2% of employees will receive a result that could lead to changes in care.

Pharmacogenomic

- **Wellness Goal:** Pharmacogenomic information is used to advise drug choice, drug dose, and avoid adverse drug events which impacts health outcomes and cost (clinical utility and economic impact). There could be some impact on employee engagement and satisfaction (operational utility).
- **Test Offered:** A panel designed to detect variants in genes associated with how effective a drug might be or whether there is increased risk for adverse drug events.
- **Reach:** Information on pharmacogenomic variation would be returned to all participants. It would only be used by those currently taking or to be prescribed a medication whose response is associated with a variant or variants. Since most drugs are prescribed in a healthcare setting the communication of the results of this testing to employees along with tools to assist sharing the information with their clinicians must be developed as part of the program.
- **Evidence:** In this case evidence is variable, ranging from extremely strong (replicated in multiple studies) to controversial. The Clinical Pharmacogenomics Implementation Consortium performs formal systematic evidence reviews and makes the information (including variant tables) publicly available which is useful for decision-makers regarding

what to include and exclude in such an offering. One drug management program, Tennessee retired teachers' association, has offered a pharmacogenomic benefit associated with counseling. Although it is yet unpublished, it has shown a significant impact on drug utilization and costs.

- **Availability of Health Care Professionals:** Many testing companies offer consultation with pharmacists or genetic counselors specifically trained in pharmacogenomics. Most pharmacists, physicians (including geneticists), and genetic counselors have limited experience with use of pharmacogenomic information.
- **Program Evaluation Metrics:** Health outcomes, pharmacy utilization, adherence rates, health care costs (clinical utility and economic impact). Employee uptake, engagement, satisfaction (activity-based and operational utility). Caveat: It is important for employees to use health care services that will have access to and will utilize this information.

Traits and Conditions

- **Wellness Goal:** By definition, information reported for traits and conditions are not health-related (e.g. hair color, tasting status, alcohol flush, etc.).
- **Test Offered:** Generally, this test is a panel of single nucleotide variants associated with the specific traits and conditions. Note that a single nucleotide variant is a spelling change in a single letter of the DNA code.
- **Reach:** Information would be returned to all participants.
- **Evidence:** Strong. The genomic variants are generally able to accurately predict the traits of interest.
- **Availability of Health Care Professionals:** Not applicable.
- **Program Evaluation Metrics:** Metrics would be based on employees' expressed desires for this type of information. Other appropriate metrics would include goals around uptake, engagement, satisfaction, and retention (activity-based and operational utility).

Fitness

- **Wellness Goal:** In theory, these could have some value for health-related outcomes, but this is not well supported by current evidence (activity-based and operational utility).
- **Test Offered:** This test generally includes a panel of single nucleotide variants associated with physical and activity endpoints (e.g. physical activity, sleep quality and duration, lean body mass, etc.).
- **Reach:** Information would be returned to all participants.
- **Evidence:** Absent. Despite numerous claims, there is presently no reproducible evidence supporting the contention that genomic variation as currently identified and interpreted can be used to design personalized exercise programs.
- **Availability of Health Care Professionals:** Most commercial organizations offer consultations with trainers or physical therapists.
- **Caveats:** Trainers may be associated with the testing company. Testing company may also sell vitamins and other supplements as part of the wellness service. This represents a

potential conflict of interest and could lead to out-of-pocket expenses for employees.

- **Program Evaluation Metrics:** These are mostly uptake, engagement, and satisfaction (activity-based and operational utility). There is some potential for health behavior changes with claims for associated improved employee health and productivity, although health-related outcomes such as reduced medical utilization and related expenses are unlikely to be measurable (economic impact).

Nutrigenomics

- **Wellness Goal:** In theory, goals could have some value for health-related outcomes, but it is not supported by current evidence.
- **Test Offered:** This is a panel of single nucleotide variants within genes identified from genome-wide association studies to be associated with nutritional endpoints.
- **Reach:** Information would be returned to all participants.
- **Evidence:** Absent. Despite numerous claims, there is presently no reproducible evidence supporting the contention that genomic variation as currently identified and interpreted can be used to make effective recommendations regarding diet, vitamins, or supplements.
- **Availability of Health Care Professionals:** For most commercial organizations, consultation with nutritionists is offered.
- **Caveats:** Nutritionists may be associated with the testing company. The testing company may also sell vitamins and other supplements as part of the wellness service. This represents a potential conflict of interest and could lead to out-of-pocket expenses for employees.
- **Program Evaluation Metrics:** These mostly consist of uptake, engagement, and satisfaction (activity-based and operational utility). There is some potential for health behavior changes with claims for associated improved employee health and productivity, although health-related outcomes such as reduced medical utilization and related expenses are unlikely to be measurable.

Ancestry⁴²

- **Wellness Goal:** There is no robust health related information associated with ancestry.
- **Test Offered:** This is a single nucleotide variant panel designed to identify population-specific variants.
- **Reach:** Information would be returned to all participants.
- **Evidence:** In this case, evidence is strong. Ancestry panels perform extremely well in identifying origin based on genomic variation, but also risk increasing racial essentialism if genetic education is not also provided.⁴³ There is also evidence that this type of information is of great interest to people. Furthermore, it is one of the more frequently requested informational items from genomic testing.
- **Caveats:** Genomic information may be in conflict with ancestral stories from families. Country of origin may not be concordant with genetic ancestry information due to changing political boundaries and movements of ancestors.
- **Availability of Health Care Professionals:** Not applicable
- **Program Evaluation Metrics:** Based on desire for this type of information, goals around uptake, engagement, satisfaction, and retention would be appropriate (activity-based and operational utility).

Limitations

The studies that were conducted in support of this white paper have several limitations. First, in our landscape analysis we relied on information provided on the vendor websites regarding their wellness program offerings to employers. It was not always possible to differentiate genetic tests, services, and policies related to wellness programs from those specific to DTC testing, despite the use of unique search strings intended to identify wellness-related NIBGT. Also, vendor websites may not contain complete information about their products and services. For instance, although broad generalizations should be avoided, these vendors actually engaged in such generalizations. It was clear that the employer market segment could be distinct from what their online information suggests. Nevertheless, we identified numerous concerning findings regarding a lack of transparency regarding genetic data uses, privacy protections, and substantiation of effectiveness claims that merit additional research.

Secondly, we made multiple attempts to recruit a larger number of participants in three key stakeholder categories for our key informant interviews. The categories included vendors, employers, and researchers. Despite extensive outreach efforts using multiple approaches (e.g., emails and webinars) we were limited to only 4 vendors, 3 employers, and 2 researchers who agreed to participate in semi-structured interviews. While there was substantial agreement on many of the themes, it is unlikely that saturation was reached given the small number of participants in each category. Further research is needed to gain a broader perspective regarding how and why self-insured employers are making NIBGT services available to their employees and subsequent employee outcomes. Additional studies could further examine the main reasons employers pursue studies of wellness programs and strategies to overcome barriers to conducting and analyzing these studies.

Third, while we endeavored to conduct a formal employer survey through employer coalitions, this was ultimately impossible. We did successfully conduct a direct poll as part of a webinar attended by individuals such as employers and wellness vendors with an interest in learning more about the topic of NIBGT. While webinar attendees are certainly not representative of all employer benefit decision-makers, this was the largest sample (n=25) of individuals available to the SAGE project team and their responses provided mostly confirmatory evidence of the challenges facing the use and evaluation of NIBGT as part of wellness programs.

Finally, we developed recommended frameworks for employers considering NIBGT implementation and researchers and employers for evaluating claims made by NIBGT vendors. The project team conducted a year-long immersion in the complex intersection of employers, NIBGT vendors, and wellness program researchers. We found significant educational gaps regarding how to evaluate genetic testing benefits and harms, as well as strong evidence of genetic exceptionalism. These frameworks will need to be evaluated by employer organizations such as the NBGH and research organizations to assess their real-world applicability. It is our expectation that the frameworks will be refined over time based on input from all stakeholders engaged with selling, purchasing, implementing and evaluating NIBGT services.

Conclusions

We used multiple methods to describe the current landscape with respect to employer-based NIBGT testing, to assess the feasibility of evidence generation and evaluation across multiple employers, and account for ethical and policy issues. After conducting an internet-based landscape analysis, a qualitative analysis of key informant interviews, a legal and policy review, and targeted literature searches, we found the following themes:

- Wellness programs in general have conflicting evidence of benefit. Despite numerous research studies that support the notion that comprehensive, best practice programs can yield health outcomes and a positive ROI, recent randomized controlled trials have called into question claims that multicomponent interventions involving biometric screening, access to professional coaching, and monetary incentives consistently lead to improved employee health outcomes and reduced healthcare costs.
- Adding NIBGT to wellness programs is justified by vendors based on claims (mostly unsubstantiated) that employee knowledge of genetic risk will lead to improved health outcomes and reduced costs.
- The landscape analysis surfaced a concerning lack of transparency among genetic testing vendors, emphasizing the challenges and risks employer-sponsored wellness programs are exposed to regarding:
 - How to determine what genetic tests to offer.
 - The potential benefits of these tests.
 - Adequate privacy protection for employees.
 - The lack of “best practice” for implementing NIBGT as part of a corporate wellness program.
- An online poll of individuals responsible for NIBGT decision-making confirms that there is a limited understanding of how to integrate genetic testing in either health insurance or as part of wellness programs. However, there is receptivity to the notion that genetic testing supports personalized interventions as outlined below:
 - There is a substantial educational opportunity regarding NIBGT for employer benefit decision-makers.
 - Most respondents did not perceive there to be sufficient scientific evidence to justify implementing genetic testing now.
 - These data also clearly reflect the widespread belief that concerns about maintaining privacy is a significant obstacle to adding NIBGT to wellness programs.
 - Perhaps most significantly, only one-third of respondents indicated that they thought their organization would be interested in participating in a pilot study of NIBGT as part of wellness programs. This is most likely an overestimate of the level of interest given the self-selected nature of the webinar attendees
- There is a complex network of federal laws that affect the use of genetic information as part of wellness programs, including the ADA, the ACA, and GINA, among others. The EEOC is also involved in terms of rulemaking guiding interpretation of how these laws are applied in practice and there is substantial controversy surrounding the delayed issuance of final rules regarding employer-sponsored wellness programs. State laws are also relevant, but review and analysis were out-of-scope for this project.
- GINA provides the most directly relevant protections regarding the discriminatory use of genetic information by employers. Employers are prohibited from acquiring individually identifiable genetic information of employees.

- Pending final rules made by the EEOC, employers should ensure the voluntariness of any NIBGT component of wellness programs, avoid financial incentives to encourage participation, and insist on an informational firewall between the employer and the genetic testing vendor.
- Interviews with genetic testing vendors, which provide services to corporate wellness program vendors, identified a lack of substantiated claims of programmatic success or improved health outcomes for employers. These deficiencies make it difficult for employers to discern clinical benefits or potential clinical harms for their employees.
- There is substantial variation in the type of tests genetic testing vendors provide: some focus solely on “health and wellness” testing, while others include medically actionable-type testing. The lack of genetic expertise among employers may make it difficult to differentiate between the two types of genetic testing vendors, which may lead to confusion.
- Genetic testing vendors recognize that the evidentiary barriers to entry are lower with wellness program decision-makers as compared to health insurance companies, where decision-makers are focused on meeting criteria for medical necessity.
- The rationale for adding NIBGT to wellness programs is broadly understood, however there are both benefits and risks with conducting testing for employers and employees.

Potential Benefits (+) and Risks (-) of NIBGT for Employees and Employers			
Employees		Employers	
+ Increase knowledge of health and potential health risks	- Employers may use incentives to promote participation, so testing may not be truly voluntary	+ Important role in prevention, early detection and disease management	- Unsettled regulatory issues re: how best to implement genetic testing within wellness programs
+ Improve health decision-making	- Genetic information may be shared by vendors, exposing employees to potential discrimination	+ Decrease avoidable healthcare costs	- Variability in quality testing services
+ Avoid serious downstream health outcomes, including cancer or heart attack	- Access to counseling services and coordinated medical follow-up may be lacking	+ Support goals of the wellness program	- Lack of evidence base supporting use of some genetic tests may increase medical costs

- The barriers and enablers to NIBGT implementation as described by interviewees are comparable across vendors, with privacy concerns and the need for education regarding genetic testing highlighted as particularly important barriers.
- Interviews with researchers experienced with conducting multi-employer wellness program evaluations revealed the following research enablers to promote employer participation:

- Working with a trusted third party that has access to aggregated, de-identified claims data
 - Funding by independent sources such as the NIH, not-for-profit foundations, and research leadership by experienced investigators
 - Access to the research results and benchmarking data
 - Special attention to genetic data privacy concerns and processes to mitigate risk of inadvertent disclosure of genetic test results
- Without rigorous studies, employers face a challenging environment for informed decision-making regarding the value of novel wellness programs that could tarnish their perceptions of the credibility and usefulness of NIBGT.

Based on these findings, we developed two frameworks that should prove useful to stakeholders. We then applied them to a range of potential non-indication based genetic tests to illustrate their application. The first is intended for employers and provides a set of questions that they can use with genetic testing vendors when considering whether to offer NIBGT as part of wellness programs for their employees. The key considerations include deciding on the goal of the NIBGT program, the types of tests and services that will be included, the protections in place to ensure genetic privacy, and whether there is any evidence that the vendor's program is effective.

The second framework is intended to advance evaluation of NIBGT program claims and targets both employers and researchers. There are different levels of assessment, focusing on VOI and ROI since both are important for employer decision-making. Most genetic testing vendors produce evidence of program activity, but it is more difficult to assess how the program impacts employee behaviors and attitudes, as these assessments require survey administration or other de novo data collection efforts. Demonstration of clinical utility and economic utility requires access to administrative claims data coupled with survey data to understand whether NIBGT improves health outcomes and lowers health care costs as claimed.

These frameworks can be used to ensure more informed employer and employee decision-making, while also contributing to the expansion of the evidence base demonstrating the value of NIBGT for employees and employers. This white paper provides a substantive assessment of NIBGT in corporate wellness programs, and it is intended to provide useful information for employers interested in implementing NIBGT successfully.

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Genetic testing and employer-sponsored wellness programs: An overview of current vendors, products, and practices

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Abstract

Background: Employer-sponsored corporate wellness programs have spread despite limited evidence of effectiveness in improving health or reducing costs. Some programs have offered genetic testing as a benefit to employees, but little is known about this practice.

Methods: In December 2019, we conducted a systematic Google search to identify vendors offering corporate wellness programs involving genetics. We performed qualitative content analysis of publicly available information about the vendors' products and practices disclosed on their websites.

Results: Fifteen vendors were identified. Details regarding genetic testing offered within wellness programs were difficult to decipher from vendors' websites, including which specific products were included. No evidence was provided to support vendor claimed improvements in employer costs, employee health, and job performance. Only half offered health and genetic counseling services. Most vendors were ambiguous regarding data sharing. Disclaimer language was included in vendors' stated risks and limitations, ostensibly to avoid oversight and liability.

Conclusion: We found a lack of transparency among corporate wellness program vendors, underscoring challenges that stakeholders encounter when trying to assess (a) how such programs are using genetics, (b) the potential benefits of such applications, and (c) the adequacy of protections to ensure scientific evidence support any health claims and genetic nondiscrimination.

KEYWORDS

ELSI, employees, GINA, population genetics, wellness

1 | INTRODUCTION

Employer-sponsored wellness programs have proliferated in the United States since the 1990 s. Projections have estimated that the corporate wellness industry could exceed \$12 billion US sometime in 2020 (Roberts & Fowler, 2017; Wolfe,

2018). In 2018, 82% of large firms and 53% of small employers in the United States offered a wellness program, with key health and wellness components, including nutrition, physical activity, stress reduction, and preventive services (Song & Baicker, 2019). Despite the high prevalence of employer-sponsored wellness programs (Roberts & Fowler, 2017),

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the concept has no universally accepted definition. Generally speaking, wellness programs offer employment-based activities to employees to promote healthy behaviors, prevent and/or manage disease. Congress encouraged wellness programs when it passed the Affordable Care Act (ACA; Patient Protection & Affordable Care Act, 2010), which sets statutory standards for two categories of wellness programs: “participatory” wellness programs and “health contingent” wellness programs (the latter of which may be either activity-only condition management or outcome-based). The ACA defines a “participatory” wellness program as one in which “none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward)” [26 CFR § 54.9802-1(f)(ii); 29 CFR § 2590.702(f)(ii); and 45 CFR § 146.121(f)(ii)] and defines a “health contingent” wellness program as “a program that requires an individual to satisfy a standard related to a health factor to obtain a reward (or requires an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward)” [26 CFR § 54.9802-1(f)(iii); 29 CFR § 2590.702(f)(iii); and 45 CFR § 146.121(f)(iii)].

It has long been promised that employee wellness programs would provide health benefits and also reduce healthcare costs, but evidence for this is scant (Song & Baicker, 2019). An 18-month cluster randomized trial of 32,974 employees at 160 work sites run by Harvard Medical School and the National Bureau of Economic Research aimed to determine if corporate wellness programs improved employee health and reduced healthcare costs. Although the results showed an improvement in employee self-reported positive health behaviors, there was no significant change in healthcare spending, healthcare utilization, or clinical measurements of health for employees, and no significant impact on employment outcomes such as absenteeism and work performance (Song & Baicker, 2019).

Over the last decade, genomic medicine has been promoted as providing the ability to individualize care and improve health outcomes (Manolio et al., 2019). A major challenge to genomic medicine implementation has been the lack of evidence of clinical utility (net benefit of testing) and lack of reimbursement by insurers (Peterson et al., 2019). While privacy concerns remain an important consideration in any genetic service delivery setting, in the context of employer/employee relationships and access to genetic data, these privacy concerns are magnified (Song & Baicker, 2019). Recognizing these challenges, there has been increased interest in exploring the responsible integration of genetic technologies and genetic information in employer-sponsored health and wellness programs. In March 2019, the National Human Genome Research Institute (NHGRI) sponsored a “Genomics in Health and Wellness Meeting” to discuss the potential benefits and barriers to offering pre-emptive

testing for genetic conditions in the workplace. Meeting recommendations included development of a framework for implementing and evaluating employee genetic testing, including assessment of outcomes of relevance to employers and employees such as impact on health status, productivity, and health care costs (Tamburro, 2019).

Proponents assert that genetic testing offered in this way (i.e., voluntary, health-related testing for employees, and their dependents with or without a personal or family history of genetic disease) might improve the identification of evidence-based and medically actionable risks, help participants be more actively engaged in their health and well-being, improve genetic and health literacy broadly, identify health risks earlier, and promote safer and more effective medication use. Knowledge of genetic risk could inform a variety of preventive measures, leading to the avoidance or mitigation of disease and associated costs. This possibility was anticipated by Congress when the Genetic Information Nondiscrimination Act (GINA; Genetic Information Nondiscrimination Act of 2008) was debated and passed more than a decade ago. GINA strictly forbids employers from obtaining or even requesting genetic information from employees (i.e., the statute includes a privacy mechanism as a means to preclude discriminatory uses of genetic information), but there is a statutory exception for employer-sponsored wellness programs that meet enumerated criteria (42 U.S.C§, 2000ff-1). Nevertheless, integration of genetic technologies in employer-sponsored wellness programs has been and continues to be controversial. Scholarly discussion has focused on several controversial aspects of corporate wellness programs, for example, the coercive pressures that financial incentives for wellness program participation exert upon potential participants (thereby undermining voluntariness), the statutory interpretation and implementation (e.g., Blue, 2014; Madison, 2015; Rothstein, Roberts, & Guidotti, 2015; Sarata, DeBergh, & Staman, 2011); and the intensifying concerns about employee privacy (Ajunwa, Crawford, & Ford, 2016; Ajunwa, Crawford, & Schultz, 2017; Areheart & Roberts, 2019; Blue, 2014; Henniger, 2018; Kim, 2019; Madison, 2015; McIntyre, Bagley, Frakt, & Carroll, 2017; Roberts & Fowler, 2017; Rothstein et al., 2015; Sarata et al., 2011; Terry, 2018; Wolfe, 2018).

Much ink has been spilled regarding whether the statutory constraints imposed by the ACA, GINA, and the Americans with Disabilities Act (42 U.S.C§, 2000ff-1; Americans with Disabilities Act, 1990) are complementary or conflicting. This has been the subject of ongoing policy debates as well, including consideration of HR.1313 (American Society of Human Genetics, 2017; Condiles, 2019; Hudson & Pollitz, 2017; Maintaining Protections for Patients with Preexisting Conditions Act of, 2019, 2019; New York Times, 2017; NSGC Position Statement, 2017; Oliphant & Terry, 2016; Protect Act, 2019; Ray, 2017; The Preserving Employee Wellness Programs Act, 2017). Operationalizing these three

statutes (ADA, GINA, and ACA) necessitates a balancing or reconciliation of the nondiscrimination rights (and informational privacy rights) afforded under GINA and ADA with the promotion of health via wellness programs under ACA, and the Equal Employment Opportunity Commission (EEOC) is charged with this responsibility. When the EEOC issued its regulations, they were immediately and fiercely challenged. While voluntariness is a prerequisite to lawfulness of any wellness program as per GINA or ADA, what is “voluntary” is not defined by the statutes, calling into question whether financial incentives under ACA could be permissible when wellness programs implicate GINA or ADA (such as incorporating genetic information or testing). Initially, the EEOC had taken the position that incentives could not be tied to an employee's disclosure of GINA- or ADA-protected information, but the EEOC reversed this position with issuance of its final rules in 2016 (EEOC, 2016a; EEOC, 2016b; EEOC, 2018a; EEOC, 2018b). Litigation ultimately led to the EEOC's regulatory provisions on wellness programs being vacated (*AARP v. EEOC & 292 F, 2017*; *AARP v. EEOC & 226 F, 2017*; *Equal Employment & Fed. Reg. 65296-01, 2018*; *Equal Employment & Fed. Reg. 65296-02, 2018*; EEOC, 2019). While during litigation the EEOC had assured the D.C. District Court that replacement rules would be issued by October 2019 and while this item was on the EEOC's regulatory agenda for fall 2019 with explicit expectation of proposed rules issuing by January 2020, no proposed text for interim or final rules has yet (as of 20 May 2020) been issued. While the statutory provisions and bulk of implementing regulatory provisions remain in place, regulatory uncertainty persists with regard to wellness programs integrating genetic information or testing components and contemplating incentives.

Thus, despite any potential health benefits that the integration of genetic services into employer-sponsored wellness programs might have, there is ample reason to examine the policies and practices of genetic testing products offered by vendors to employers. To better understand genetic services offered by corporate wellness program vendors, we undertook a landscape analysis of current vendor products and practices using information available publicly online.

2 | MATERIALS AND METHODS

To identify vendors offering corporate wellness programs with genetic services, asystematic search of vendors offering business-to-business (BTB) genetic testing as part of a corporate wellness program was conducted using the Google search engine. BTB corporate wellness vendors were defined as companies (i.e., vendors) that sell products (i.e., corporate wellness programs) directly to other businesses (i.e., employers). Search strings were identified from keywords listed in

relevant academic research articles and news coverage that addressed topics on and related to genetic testing as a corporate wellness strategy. Sixteen (16) unique search strings were identified (Table 1). Webpages in the United States, written in English, and last updated no earlier than 1 January 2000 were automatically included in the search results using Google's advanced search feature and filter tool. The first 30 uniform record locators (URLs) results were recorded for each search string and a total of 480 results were recorded for all 16 search strings used. These methods (use of Google and focusing the analysis on the first 30 URLs in the results) were selected based on a preliminary set of searches that were performed to determine a reasonable approach. The preliminary searches was performed using three search engines (Bing.com, Yahoo.com, and Google.com) and a single search string (“Corporate wellness program genetic testing”). The first 100 URLs from each search engine's results were compared. Google outperformed the other two search engines in identifying the most vendors, and saturation was reached within 30 URLs of the results (i.e., reviewing URLs after the

TABLE 1 Search strings used in the Google.com systematic search

	Unique search strings	Number of vendors identified
1	Workplace wellness program genetic testing	1
2	Organizational wellness genetic testing	6
3	Corporate wellness genetic testing	8
4	Workplace health promotion genetics	1
5	Employee Wellness genetic screening	4
6	Corporate wellness program genetic testing	6
7	Employee precision health genetics	3
8	Employee clinical genomics	2
9	Employer-sponsored wellness genetic testing	3
10	Worksite wellness program genetic testing	3
11	Worksite health promotion programs genetic testing	1
12	Employer-based wellness genetic testing	3
13	Wellness vendors genetic testing	1
14	Genetic test & employee	2
15	Employer genetic testing	2
16	Weight loss corporate wellness genetic testing	6

The “unique search strings” column shows the search strings that were used for the Google search. The “number of vendors identified” column demonstrates the number of vendors that were identified in the Google results page with each search string.

30th search result was unlikely to yield any additional unique vendors). Each URL was reviewed to first identify vendors that appear to sell (not merely promote or advertise) a corporate wellness program to employers. Most of the URLs directed to news articles and commentary about corporate wellness programs, direct to consumer genetic testing, and direct to consumer wellness programs. The resulting vendors were further refined by only including those that offer genetic testing as a component of their corporate wellness program (which in some cases was the sole wellness offering). The systematic Google search was performed November 27 to 1 December 2019 (Figure 1).

Like methods used for landscape analyses of various sectors of the DTC industry (Wagner, Cooper, Sterling, & Royal, 2012), content analysis of the websites for each of the vendors identified in the systematic search was performed, and data collection for each vendor was started and completed on a single day (Table S1). Data were collected between 1 December 2019 and 9 December 2019, and each vendor's website was analyzed independently. The data gathered about each vendor included the following variables: vendor characteristics (vendor name, unique search strings used to identify the vendor in the systematic Google.com search [Table 1], URL to the vendor corporate wellness page, foundation date, headquarter address, scientific advisory board, and number of genetic testing products listed on their website) (Table 2). Data collected on vendor policies included the privacy policy, the policies on sharing data with employers, third parties, employee users, and primary care physician (PCP), the Health Insurance Portability and Accountability Act (HIPAA; Health Information Portability & Accountability Act, 1996), mention of GINA, the terms and conditions, jurisdictional areas excluded, stated limitations, and stated risks of the corporate wellness program and the genetic testing products. Vendor marketing points of emphasis (such as improved employee job performance, employee health outcomes, and employer financial outcomes) were assessed from the language used on the vendors' corporate wellness page. Finally, the characteristics of the genetic testing products on the vendors' websites

were also examined, including the DNA collection method, the type of insight the test provides, the number of variants detected, the method at which results are delivered, the availability and type of posttesting counseling, the type of results available to the end user, and identification of the product as a component of the corporate wellness package (Table 2). When there were no explicit links to genetic tests from the corporate wellness program landing page, the entire vendor website was assessed and direct-to-consumer tests were included in the analysis. Investigators WSM, JKW, PAD, and MSW contributed to the development of the codebook of variables to measure. For coding consistency, only one researcher (WSM) performed the coding and content analysis of each website, as consistency of approach was prioritized over the risk of introducing bias. The data were collected and analyzed in Microsoft Excel version 16 in Microsoft Office 365.

3 | RESULTS

A total of fifteen (15) BTB corporate wellness vendors that offer genetic services were identified and analyzed in December 2019 (Table 3). The mode for year of founding was 2015 (26.7%, $n = 4$, range 1993–2017), and 47% ($n = 7$) have corporate headquarters in the state of California (Table 3). The genetic tests listed on each vendor's website were categorized by the type of insight the results provide for the end user; Dynamic DNA labs and Silverberry Genomix had the most diverse offering of genetic tests on their website (Table 3). The number of vendor-branded genetic tests offered was also variable; however, Pathway genomics, Dynamic DNA labs, and Silverberry Genomix appeared to sell the highest number of individual genetic tests ($n = 14$, 13, and 12, respectively). At the time, data collection was completed (9 December 2019), no vendor listed the BTB prices for the corporate wellness program, or clearly disclosed the specific genetic tests included in their corporate wellness program. All prices for genetic tests listed on the vendors websites were

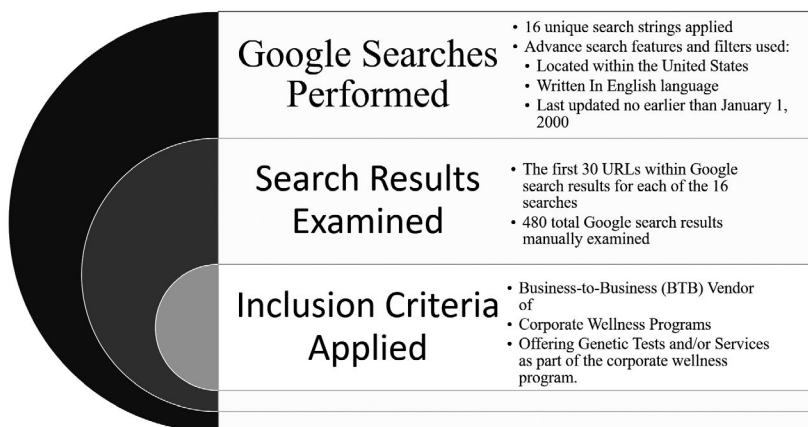


FIGURE 1 Systematic search methodology is a funnel plot of the systematic search strategy used to identify (1) business-to-business vendors of, (2) corporate wellness programs, (3) offering genetic tests and/or services as part of the corporate wellness program.

TABLE 2 Content Analysis Codebook displays the content analysis codebook that identifies and defines the variables used to collect data on each vendor

Category	Variable	Definition	Data structure
Vendor organizational characteristics	Vendor name	Name of the vendor.	Verbatim text
	URL	Uniform Record Locator to the vendor's corporate wellness page.	Website address
	Foundation date	Date the vendor founded the company.	Date
	Headquarter address	Location of the primary offices.	Physical address
	Executive leadership	Name of Founder, President or Executive officer(s).	Name(s)
	Leadership contact information	E-mail address of executive leadership.	E-mail address
	Marketing slogan	Large or bold stand-alone text on the top 30% of the vendors landing page.	Verbatim text
	Laboratory accreditation	Laboratory accreditation acronyms listed anywhere on vendor website.	Verbatim text
	Affiliate companies	Companies with products that integrate with or are a supplement to the genetic products apparently sold by the vendor.	Company name
	Endorsements	Does the vendor mention other organizations that use their products or service?	Yes/No
	Stated market size	The vendor reported market size or products offered.	Verbatim text
	Scientific advisory board	Did the vendor have a group of independent scientists that advise on the scientific and technical aspects of the vendors business?	Yes/No
	Vendor-authored white paper	Did the vendor publish an authoritative report that informs the reader of an issue within their industry and presents their philosophy on the issue at hand?	Yes/No
	Number of genetic testing products	Summation of the genetic testing products apparently sold by the vendor.	Number
Vendor policies	Privacy policy	Did the vendor have a statement disclosing the methods at which the vendor gathers, uses, discloses, and manages the employee user's data?	Yes/No
	Data sharing with employers verbatim	Text addressing the vendors policies on sharing employee user's data with employers.	Verbatim text
	Data sharing with employers (Y/N/na)	Evaluation of vendor policy language on the issue of sharing employee user data with employers to determine if data is (Yes) or is not (No) shared with employers. If the vendor policy language is vague the data is coded as not available (na).	Yes/No/Not available (na)
	Data sharing with 3rd-party (verbatim)	Text addressing the vendors policies on sharing the employee user's data with third parties.	Verbatim text
	Data sharing with 3rd-party (Y/N/na)	Evaluation of vendor policy language on the issue of sharing employee user data with third parties to determine if data is (Yes) or is not (No) shared with third parties. If the vendor policy language is vague, the data is coded as not available (na).	Yes/No/Not available (na)
	Data sharing with employee user PCP (verbatim)	Text addressing the vendors policies on sharing the employee user's data with the employee users primary care physician.	Verbatim text
	Data sharing with employee user PCP (Y/N/na)	Evaluation of vendor policy language on the issue of sharing employee user data with the employee users primary care physician (PCP) to determine if data is (Yes) or is not (No) shared with the PCP. If the vendor policy language is vague, the data is coded as not available (na).	Yes/No/Not available (na)
	HIPAA mentioned	Did the vendor mention the Health Insurance Portability and Accountability Act (HIPAA) on their website?	Yes/No
	GINA mentioned	Did the vendor mention the Genetic Information Nondiscrimination Act (GINA) on their website?	Yes/No

Category	Variable	Definition	Data structure
	Terms and Conditions	Did the vendor have a statement disclosing the rights and responsibilities of any individual using the site?	Yes/No
	Jurisdictional areas excluded	Identifies the physical locations that each vendor cannot conduct business.	Physical location
	Law enforcement coordination	Did the vendor mention that they would use and/or disclose personal health information in order to comply with federal, state or local law enforcement or public health activities?	Yes/No
	Governing law provision	The location in which rules and laws will govern in the event of a legal issue.	Physical location
	Scientific peer-reviewed articles cited	Did the vendor cite scientific peer reviewed articles about corporate wellness programs or the genetic test?	Yes/No
	Stated limitations	Text addressing risks associated with the use of the website or products. No text addressing limitations were listed as "na."	Verbatim text
	Stated risks	Text addressing limitations associated with the use of the website or products. No text addressing risks were listed as "na."	Verbatim text
Vendor marketing points of emphasis	Employee participation	Did the vendors mention phrases such as "increased participation in wellness program" on their corporate wellness page?	Yes/No
	Employee morale improvement	Did vendors mention phrases such as "stress levels," "emotional health," and/or "happiness" on their corporate wellness page?	Yes/No
	Employee talent retention	Did vendors mention phrases such as "keep top talent" and "company loyalty" on their corporate wellness page?	Yes/No
	Employee job performance	Did the vendors mention phrases such as "employee productivity" on their corporate wellness page?	Yes/No
	Disease prevention	Did vendors mention phrases such as "disease prevention" on their corporate wellness page?	Yes/No
	Employee behavior change	Did vendors mention phrases such as "employees exercise regularly" and "employees make healthier diet choices" on their corporate wellness page?	Yes/No
	Employee health outcomes	Did vendors mention phrases such as mention phrases "improve overall health" and "improved medical outcomes" on their corporate wellness page?	Yes/No
	Employer financial outcomes	Did vendors mention phrases such as "positive return on investment," "reduce healthcare costs" and "improved bottom-line" on their corporate wellness page?	Yes/No
	Benefit of corporate wellness program	Text of the business case for employers to purchase the corporate wellness program.	Verbatim text
Genetic testing product characteristics	Product name	Name of the genetic test advertised or appearing to be sold on the vendor website.	Verbatim text
	DNA collection method	Method at which user's DNA is collected for each test: Saliva (1), Cheek swab (2), Blood draw (3), Variable (4), Inquiry required (na).	1,2,3,4, na
	Individual ordering test	The individual that is able to order the genetic test from the vendor: Employee user (1), Employee User PCP (2), or medical professional affiliated with vendor (3), Inquiry required (na).	1,2,3, na
	Individual collecting the DNA	The individual that is able to collect the DNA that will be tested: Employee user (1), Employee Users PCP (2), or health professional affiliated with vendor (3), Inquiry required (na).	1,2,3, na
	Insight	Categories that define each genetic test: Ancestry & Familial (1), Traits & Conditions (2), Nutrigenetics (3), Fitness (4), Pharmacogenomics (5), Pathogenic Variants (6).	1,2,3,4,5,6,

Category	Variable	Definition	Data structure
	Number of traits tested	The number of specific characteristics within an individual that will be evaluated in a given genetic test, if this information is not available, the data is coded as "na."	Number
	Number of variants tested	The number of genetic variations from the reference genome that will be evaluated in an individual's unique DNA sequence. If the information is not available, the data is coded as "na."	Number
	Number of genes	The number of genes that will be evaluated in a given genetic test. If the information is not available, the data is coded as "na."	Number
	Health conditions evaluated	The specific health conditions mentioned on the product page that the genetic test will detect. If no health condition is applicable for the genetic test in question, the data is coded as "none," if the information on the specific health condition is not available, the data is coded as "na."	Verbatim text
	Results delivery	The methods at which results from each genetic testing product are delivered to the user: paper report (1), mobile app (2), website interface (3), one-on-one consultation (4), email (5), and Inquiry required (na).	1,2,3,4,5, na
	Counseling	The method at which the user receives a consult with a learned health or genetic professional to discuss the results of the genetic test: Genetic counselor (1), Health coach/dietitian (2), pharmacogenomics consultant (3), Physician (4), no consultation (none), and inquiry required (na).	1,2,3,4, none, na
	Stated benefits of the test	Text addressing the benefits of the genetic test in question.	Verbatim text
	Stated limitations of the test	Text addressing the limitation(s) of the genetic test in question. If no limitation is listed, the data is coded as "na."	Verbatim text
	Stated risks of the test	Text addressing the risk(s) of the genetic test in question. If no risk is listed, the data is coded as "na."	Verbatim text
	Listed price of the genetic test.	Price (USD) of the genetic test listed on the website. International currencies were converted to USD using the Google Finance Morningstar currency converter. Genetic tests without price information are listed as "na."	(\$)
	Type of data accessible to the end user	The type of genetic result that the individual providing the DNA will have access to be categorized as raw genetic data files (1), summary data (2), no data (3), or inquiry required (na).	1,2,3, na
	Product promoted as part of a wellness package	Evaluate the individual product page and corporate wellness page to determine if the product in question is clearly stated as part of the corporate wellness program.	Yes/No/na

Note: The data structure column identifies the type of data that was collected for each variable and the type of code that will be included in the raw table (see Table S2).

DTC prices (see Table S2). Data regarding all genetic tests that each vendor offers were collected to understand the full range of tests that had the potential to be part of the corporate wellness program. A subsequent check of the vendors' websites on 30 January 2020 revealed that, while many websites updated content, only three vendors updated their content to specify the genetic tests and services involved in their corporate wellness program (footnotes Table 3 and Table S2). The vendor websites were searched to identify their policies on sharing individual or aggregated identified or de-identified data with employers, third parties, and employee user's PCP; vague policy language was also identified and is defined as

language used by the vendor that is inconclusive with regard to their policy on sharing employee user data with employers, third-parties, or employee user PCPs. Most of the vendors were vague about their stance on sharing employee data with employers (60%, $n = 9$), only two vendors (13%) explicitly stated that they would share employee data with employers and four vendors (27%) stated that employee data would not be shared with employers (Table 4). An example statement that employee data are shared with employers and third parties found on the Color website is "if your employer has provided or paid for (in whole or in part) the Test, you acknowledge and agree that your de-identified Results and [Personal and

Family Health Information] PFHI may be anonymized and/or aggregated and returned to your employer or its designee (e.g., plan administrator or pharmacy benefits manager) as

a data analytics resource...We may disclose your [personally identifiable information] PII and PHI to others involved in your care, including healthcare providers...". The results

TABLE 3 Business-to-business corporate wellness vendors offering genetic tests as a component or the entirety of the corporate wellness program displays data about each business-to-business corporate wellness vendor, identified in the systematic google search, appearing to offer genetic test, and services in their corporate wellness program

Vendor name	URL	Foundation date	Headquarter city, state, country	Genetic test insight(s)	No. of genetic tests
AGS Health ^a	https://www.ags-health.com/corporate-wellness-genetic-testing-program	2012	Scottsdale, AZ, USA	Traits & Conditions Nutrigenetics Pharmacogenomics	4
ArcPoint Labs	https://www.arcpointlabs.com/	2005	Greenville, SC, USA	Ancestry & Familial Nutrigenetics Fitness	5
BDS Admin ^b	https://bdsadmin.com/employer/wellness-programs/	1993	Mechanicsburg, PA, USA	Nutrigenetics Fitness	1
Caligenix	https://www.caligenix.com/corporate-wellness	2015	Los Angeles, CA, USA	Traits & Conditions Nutrigenetics Fitness	3
Cambiati	https://www.cambiati.com/corporate-wellness-programs/	2009	Lafayette, CA, USA	Nutrigenetics	1
Color ^c	https://www.color.com/benefits-2	2015	Burlingame, CA, USA	Traits & Conditions Nutrigenetics Pharmacogenomics Pathogenic Variants	3
Dexafit	https://www.dexafit.com/how-it-works/corporate-wellness	2011	Dallas, TX, USA	Fitness	3
DNA Fit-Prenetics	https://www.dnafit.com/us/enterprise/	2013	Orpington, Kent, England, United Kingdom	Traits & Conditions Nutrigenetics Fitness Pathogenic Variants	4
Dynamic DNA Labs	https://dynamicdnalabs.com/pages/corporate-partners	2015	Springfield, MO, USA	Ancestry & Familial Traits & Conditions Nutrigenetics Fitness Pharmacogenomics	13
GenoMaxx Fitness	https://www.genomaxxfitness.com/corporate-wellness/	2016	San Diego, CA, USA	Traits & Conditions Nutrigenetics Fitness	3
Genome Medical ^d	https://www.genomemedical.com/employers/	2016	South San Francisco, CA, USA	Pathogenic Variants	3
GenoVive	https://www.genoviveusa.com/corporate-wellness-programs/	2008	New Orleans, LA, USA	Nutrigenetics Fitness	1
Pathway Genomics	https://www.pathway.com/corporate-wellness/	2009	San Diego, CA, USA	Traits & Conditions Nutrigenetics Fitness Pharmacogenomics	14
Precision Genetics	https://precisiongenetics.com/our-solutions/	2015	Greenville, SC, USA	Pharmacogenomics	1
Silverberry Genomix	https://silverberrygenomix.com/corporate-wellness-program/	2017	San Francisco, CA, USA	Traits & Conditions Nutrigenetics Fitness Pharmacogenomics Pathogenic Variants	12

The “genetic test insight(s)” column represents the six insight categories that each genetic test are defined by; (1) “nutrigenetics,” (2) “fitness,” (3) “traits & conditions,” (4) “Pharmacogenomics,” (5) “ancestry & familial,” and (6) “pathogenic variants.”

^aThe corporate wellness page was updated as of 19 January 2020 to include a product named “Health and Wellness” (see Table S2 [cell S41]).

^bBDS Admin does not have a separate product page detailing the genetic test that is offered as part of their wellness program. The corporate wellness page does provide a brief description of the genetic test offered and from this description, the test was given the insight categories of a Nutrigenetics and fitness genetic test. See Table S2 [cell AM13] for the product description.

^cSince completing the data collection for this study December 2019, the corporate wellness page was updated as of 14 January 2020 to include three products now listed on their corporate wellness page named “Cancer,” “Heart,” and “Medication” none of which were identified during data collection. See Table S2 [cell S80].

^dThis vendor did not appear to sell genetic tests but offered genetic counseling services direct to consumers and employers. In December 2019, the business model was to provide genetic counseling based on three services groups listed on their website (Proactive Genetic exploration, Advanced Genetic Care and Family Variant Insight Program). The descriptions on the website indicated the insight category to be pathogenic variant testing. See Table S2 [cell M38-M40] for descriptions of the three types of genetic services. The corporate wellness page was updated as of 19 January 2020 to include the names of the three genetic services (see Table S2 [cells S38:S40]).

TABLE 4 Data sharing policies of vendors of B2B corporate wellness programs represents the data sharing policies mentioned on each of the vendor websites.

	Data shared with employers			Data shared with 3rd-party			Data shared with employee user PCP			HIPAA mentioned	
	Explicit Yes	Explicit No	Vague language	Explicit Yes	Explicit No	Vague language	Explicit Yes	Explicit No	Vague language	Yes	No
% of vendors	13%	27%	60%	40%	27%	33%	27%	6.7%	66.7%	60%	40%
No. of vendors	2	4	9	6	4	5	4	1	10	9	6

Each page on the vendor website was searched to identify language that addressed policies on sharing individual or aggregated identified or de-identified employee data with employers, third parties, and employee primary care physicians. Each vendor webpage was also searched to identify if HIPAA is mentioned. The language used by vendors on each policy was placed into three categories (1) “explicit Yes” meaning the vendors language used clearly states that the employee data will be shared with employers, third-parties or employee PCP; (2) “explicit No” meaning the vendors language used clearly states that the employee data will not be shared with employers, third-parties or employee user PCPs; and (3) “vague language” means the language used by the vendor is inconclusive with regard to their policy on sharing employee user data with employers, third-parties, or employee user PCPs.

on vendor policies about sharing employee data with third parties show that six vendors (40%) explicitly stated that employee data will be shared, four (27%) explicitly stated that employee data would not be shared, and five (33%) vendors are vague about their policies on sharing employee data with third parties (Table 4). An example statement affirming employee user data will be shared with third parties found on the GenoMaxx website is “GenoMaxx Fitness™ may disclose your PHI to other companies or individuals who need your PHI in order to provide specific services to us. These other entities, known as “business associates” must comply with the terms of a contract designed to ensure that they will maintain the privacy and security of the PHI we provide to them or which they create on our behalf...”. Most vendor policies on sharing employee data with the employee user's PCP are vague about this policy (66.7%, n = 10), although 27% (n = 4) explicitly stated they share employee data with the employee's PCP and 6.7% (n = 1) explicitly stated they do not share employee data with the employee user's PCP. An example policy, found on the Caligenix website, about sharing employee user data with the employee user's PCP is “Only your healthcare professional will be able to access your genetic test results through the Caligenix Portal... All genetic data is sent through a secure 256-bit encryption server...”. The vendor websites were also searched to identify whether

they mentioned HIPAA, and only nine vendors (60%) did so on any of their website's pages (Table 4).

The vendor websites were further examined to identify stated risks and limitations involved in activities such as using their website, ordering products, using products, sharing data, and understanding results. Less than half (46.7%, n = 7) of all vendors stated any limitations on their website. An example limitation found on GenoVive's website was “the information provided by GenoVive and contained in this website, including an individual's results of the GenoVive Nutrition and Fitness Genetic Test, is not intended to prevent, diagnose or treat any medical condition and should not replace the advice of a physician”. Only six vendors (40%) mentioned risks on their website; an example risk found on the Pathway Genomics website was “despite the reasonable and appropriate efforts of you and Pathway, there is always some risk that an unauthorized third party will access without permission our systems or intercept transmissions of your information” (Table 5). Most limitation and risk statements were found on the vendor terms and conditions, privacy policy, or consent pages (data not shown).

The marketing points of emphasis on each vendor corporate wellness page was searched to identify trends in the advertised benefits of corporate wellness program with genetic testing. The majority (86.67%, n = 13) of vendors mentioned

TABLE 5 Variability in risks and limitations mentioned on vendor websites displays examples of risks and limitations listed on the vendor website.

Vendor name	Example of limitation	URL to limitation	Example of risk	URL to risk
AGS Health	<p>"Newborn screening is another problem that arises with EHRs (Electronic Health Records)—and genetic data. Tests done at birth vary from state to state, but all states must screen for at least 21 disorders by law, and some states test for 30 or more. Currently, tests are limited to conditions for which childhood medical intervention is possible and may be beneficial."</p>	https://www.ags-health.com/privacy-state-ment-2017	na	na
ArcPoint Labs	<p>"The contents of our website, including any risk estimates or other reports generated by the services (collectively, "Your Report") and any other information, data, analyses, editorial content, images, audio and video clips, hyperlinks and references (collectively, "Content"), are for informational purposes only and are not intended to substitute for professional medical advice, diagnosis, or treatment nor are they intended to be interpreted as a recommendation for a particular treatment plan."</p>	https://www.arcpointlabs.com/home-kits/terms-conditions/	na	na
BDS Admin	na	na	na	na
Caligenix	na	na	na	na
Cambiati	na	na	na	na
Color	<p>"Limitations of the test: ... However, this test may not detect every variant associated with disease risk, or every variant or allele that may impact how a person processes or responds to medications... Color implements several safeguards to avoid technical errors, but as with all medical tests, there is a chance of a false positive or a false negative result.... In addition, if you have certain rare biological conditions or have had certain bone marrow, kidney, liver or heart transplants, transfusions, or hematologic malignancies, these conditions may limit the accuracy or relevance of the results or prevent the Test from being completed."</p>	https://www.color.com/informed-consent	<p>"The Test is a genetic test that may cause you to discover sensitive information about your health or disease risks, including risk for hereditary disorders other than the one for which you are testing, or for disorders that currently have no treatment. The US Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination on the basis of genetic information with respect to health insurance and employment. However, certain exceptions apply, and we encourage you to review GINA and related laws and regulations. There are currently no US federal laws that prohibit discrimination in life insurance, disability insurance or long-term care insurance, which may be governed by state law. If you live outside of the US, depending on your country of residence, there may be significant differences in the laws and regulations governing the use and disclosure of genetic information...."</p>	https://www.color.com/informed-consent

Vendor name	Example of limitation	URL to limitation	Example of risk	URL to risk
Dexafit	<p>"DexaFit Disclaimer DexaFit technicians do not provide diagnosis or treatment at DexaFit facilities. They only answer basic questions based on the data from your testing, then suggest you follow up with your referring physician or one of DexaFit's licensed medical practitioners for further interpretation and consultations."</p>	<p>https://www.dexafit.com/plans-and-pricing-1</p>	na	na
DNA Fiti-Prenetics	na	na	<p>"Sharing Self-Reported Information through surveys, or other features on Our Site, is voluntary and done at your sole risk. DNAfit cannot take responsibility for Information that you release or that you request us to release publicly."</p>	<p>https://www.dnafit.com/us/legals/privacy.asp</p>
DynamicDNA Labs	na	na	<p>"We are not responsible if information made available on this site is not accurate, complete or current. The material on this site is provided for general information only and should not be relied upon or used as the sole basis for making decisions without consulting primary, more accurate, more complete or more timely sources of information. Any reliance on the material on this site is at your own risk...Any use by you of optional tools offered through the site is entirely at your own risk and discretion and you should ensure that you are familiar with and approve of the terms on which tools are provided by the relevant third-party provider(s)."</p>	<p>https://dynamicdnalabs.com/pages/legal</p>
GenoMaxx Fitness	<p>"4.2) Genetic research is not comprehensive...4.3) The laboratory may not be able to process your sample... 4.4) The laboratory process may result in errors... 4.5) We may not be able to present you with a full complement of results. In rare cases, despite our best efforts, it may not be possible to obtain an unambiguous result for some DNA variations (SNPs) due to biological or technical complications. This means that a result cannot be called clearly... 4.8) The GenoMaxx Fitness™ product range is intended for informational and educational use only and is not intended to be used for medical advice or diagnosis or treatment."</p>	<p>https://www.genomaxxfitness.com/terms-and-conditions/</p>	<p>"4.6) Your Personal Information may be anonymised and used for research and development (R&D) purposes to contribute knowledge to the field and further improve our Products...4.7) Genetic Data you share with others could have social, legal or economic implications. Use of genetic test results by employers in pre-employment medical checks is restricted in the UK by the Equality Act 2010, and in the US by the 2008 Genetic Information Nondiscrimination Act (GINA), which makes genetic discrimination illegal and addresses discrimination in health insurance and employment practices. However, as of yet, this protection does not explicitly cover life or disability insurance providers as these products are considered as more discretionary than health insurance."</p>	<p>https://www.genomaxxfitness.com/terms-and-conditions/</p>

Vendor name	Example of limitation	URL to limitation	Example of risk	URL to risk
Genome Medical	na	na	na	na
GenoVive	“The information provided by GenoVive and contained in this website, including an individual’s results of the GenoVive Nutrition and Fitness Genetic Test, is not intended to prevent, diagnose or treat any medical condition and should not replace the advice of a physician.”	https://www.genoviveusa.com/1126-2/	na	na
Pathway Genomics	na	na	“Despite the reasonable and appropriate efforts of you and Pathway, there is always some risk that an unauthorized third party will access without permission our systems or intercept transmissions of your information.”	https://www.pathway.com/privacy-statement/
Precision Genetics	na	na	Na	na
Silverberry Genomix	“Silverberry Statement of Limitations...DNA-based predisposition is NOT a diagnosis of a disease or condition. Predisposition risk or likelihood is a statistical measure based on the latest advances in genomics science and is provided as an additional layer of information for wellness decision-making. Silverberry recommendations fall within established non-medical guidelines for wellbeing and do not constitute medical advice. Consult with your Physician before making any major changes to your wellness or health choices.”	https://silverberrygenomix.com/our-science/	“Potential Issues and Risks Keep in mind that the results may change how you feel, and there is a chance that some questions will make you uncomfortable. You can choose to not answer...Depending on the package you select, your results can reflect your health risks, fitness potentials, or predisposed personality traits. These could lead to many different emotions. We recommend that you discuss your results with a physician or other certified healthcare professionals before making any major changes to your routines.”	https://silverberrygenomix.com/consent
Percent with stated limitations or risks	46.7%	–	40%	–
Number of vendors	7	–	6	–

Note: The columns titled “example of limitation” and “example of risks” contains verbatim text from the vendor website containing vendor disclosed risks and limitations. The column titled “URL to limitation” and “URL to risks” contains the web address where the example limitation or risk statement was first identified. The “na” indicates that the data is not available.

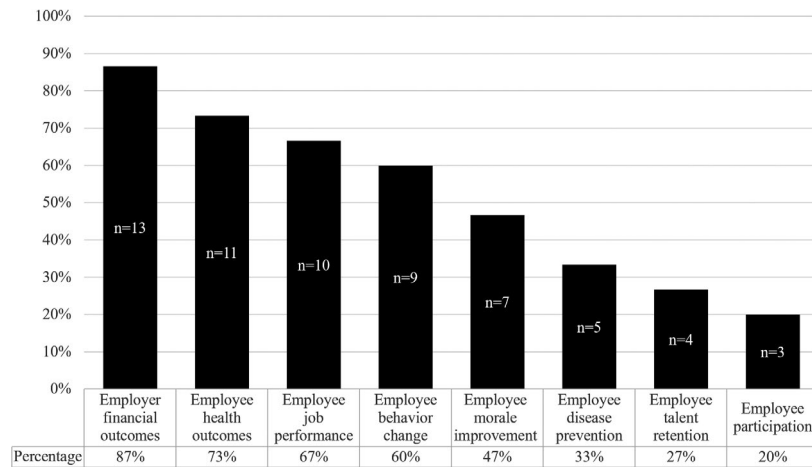


FIGURE 2 Vendor marketing points of emphasis represents the marketing emphasis made on each of the vendors corporate wellness webpage. The “employer financial outcomes” bar represents the percentage of vendors that mentioned phrases such as “positive return on investment,” “reduce healthcare costs,” and “improved bottom-line” on their corporate wellness page. The “employee health outcomes” bar represents the percentage of vendors that mentioned phrases alluding to overall health improvement for employees on the corporate wellness page such as “improve overall health” and “improved medical outcomes. The “employee job performance” bar represents the percentage of vendors that mentioned phrases like “improve employee productivity” on their corporate wellness page. The “employee behavior change” bar represents the percentage of vendors that stated phrases such as “employees exercise regularly” and “employees make healthier diet choices.” The “employee morale improvement” bar represents the percentage of vendors that alluded to changes in employee “stress levels,” “emotional health,” and “happiness” on their corporate wellness page. The “employee disease prevention” bar represents the percentage of vendors that alluded to their corporate wellness programs ability to “prevent disease,” to “identify high-risk patients,” or to “decrease rates of illnesses” on their corporate wellness page. The “employee talent retention” bar represents the percentage of vendors that mentioned phrases such as “keep top talent” and “company loyalty” on their corporate wellness page. The “employee participation” bar represents the percentage of vendors that mentioned phrases such as “increased participation in wellness program” on the corporate wellness page. The values ($n = x$) within each bar represent the number of vendors that made each marketing point on their corporate wellness page. All the categories were coded independently; the percentages are calculated as the number of vendors that mention each marketing point ($n = x$)/total number of vendors identified ($n = 15$) \times 100.

employer financial outcomes as a benefit to purchasing their corporate wellness program. Employee health outcomes, employee job performance, and employee behavior change were frequently referenced by vendors (73.33% ($n = 11$), 66.67% ($n = 10$), and 60% ($n = 9$), respectively) as benefits to purchasing their corporate wellness program. Vendors also promoted their corporate wellness programs’ ability to improve employee morale (46.67%, $n = 7$), prevent disease among employees (33.33%, $n = 5$), and to retain employee talent (26.67%, $n = 4$). The least number of vendors (20%, $n = 3$) mentioned employee participation in the corporate wellness program as a reason for employers to purchase their corporate wellness program (Figure 2).

To determine the types of genetic tests that appear to be sold in the corporate wellness market, all genetic tests on the vendor websites were categorized by six insights: Nutrigenetics, fitness, traits & conditions, Pharmacogenomics, ancestry & familial, and pathogenic variant testing. A total of 71 genetic tests were identified across the 15 BTB corporate wellness vendors. Nutrigenetic testing category that identifies genetic variants associated with an individual’s differential responses to nutrition represented 28% ($n = 20$) of all genetic tests on the vendors websites and fitness genetic tests that identifies

genetic variants in genes associated with body weight, differential responses to exercise, and variants associated with muscle mass and recovery also represented 28% ($n = 20$) of genetic tests on the vendors websites (Figure 3). The traits & conditions tests which identifies genetic variants implicated in an individual’s skin health, personality, food aversions, and allergies represented 24% ($n = 17$) of all genetic tests on the vendors websites. Pharmacogenomic tests which identifies an individual’s differential responses to pharmaceutical drugs and drug doses represented 21% ($n = 15$) of tests that appear to be sold by corporate wellness vendors. Pathogenic variant testing that detects genetic variants associated with the predisposition to inherited or sporadic diseases such as cancers (i.e., uterine, breast, ovarian, melanoma, pancreatic, stomach, and prostate), inherited heart disease (i.e., cardiomyopathy, arrhythmia, arteriopathy, and familial hypercholesterolemia), the American College of Obstetricians and Gynecologists (ACOG) recommended conditions (i.e., sickle cell disease, cystic fibrosis, and beta-thalassemia), and the Ashkenazi Jewish conditions (i.e., Bloom syndrome, mucopolidosis IV, and factor XI deficiency) represented 15.5% ($n = 11$) of all genetic tests that appeared to be sold on the corporate wellness vendors websites. The ancestry & familial tests that

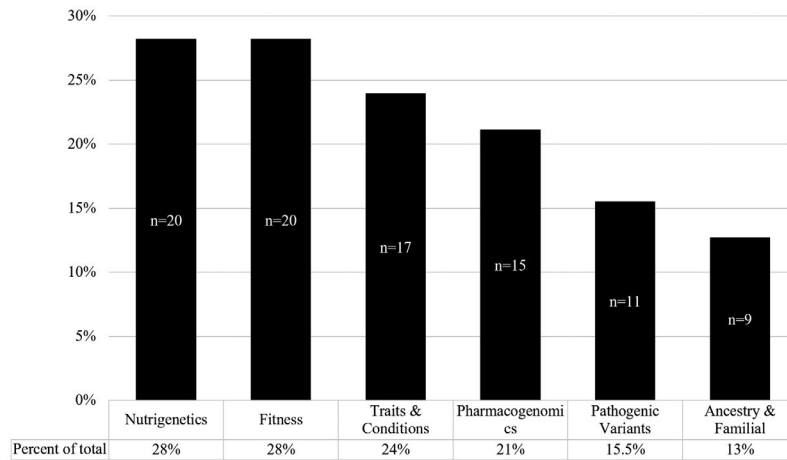


FIGURE 3 Variability in the type of genetic tests offered by vendors who also offer B2B corporate wellness programs illustrates the percentage of each type of genetic test across the vendors identified within the BTB corporate wellness market. A total of 71 genetic tests for all 15 vendors were identified. There are six insight categories: Nutrigenetics, fitness, traits & conditions, Pharmacogenomics, ancestry & familial, and pathogenic variants were determined. The values ($n = x$) within each bar represent the number of genetic testing products identified for each insight category. The percent of total row below the bar graph is calculated from $n = x/\text{the total number of tests identified in the market } (n = 71) \times 100$.

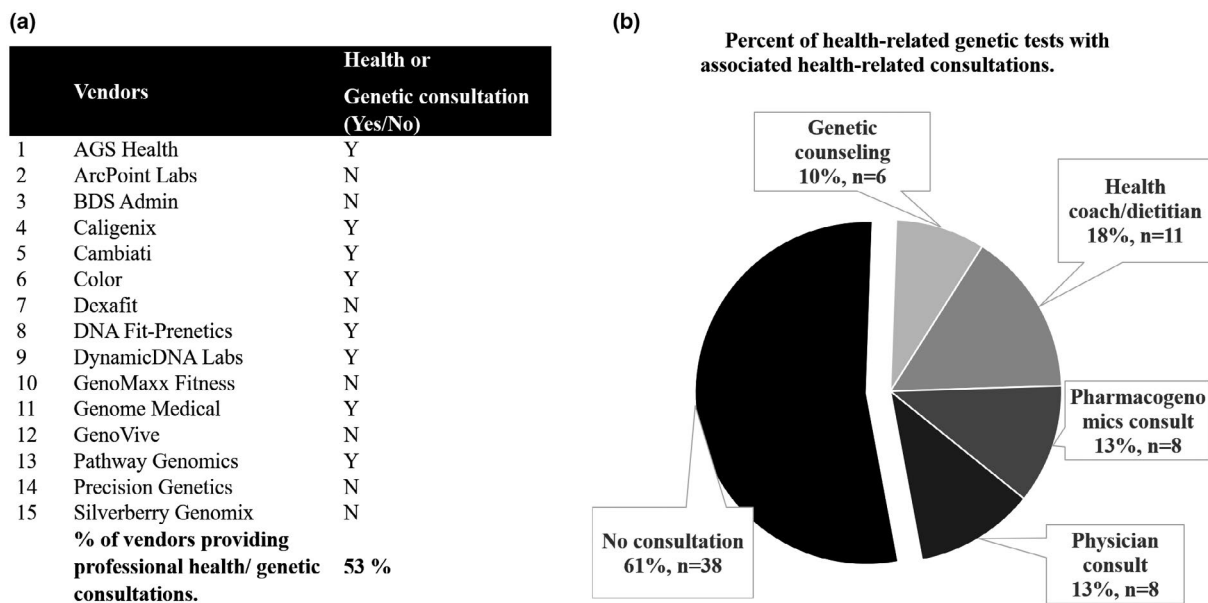


FIGURE 4 Posttesting health and genetic consultations among vendors of B2B corporate wellness programs and their health-related genetic testing products. (A) displays the relative percentage of all vendors that provide consultations with their genetic tests. The percentage of vendors providing professional health or genetic testing consultation was calculated from the total count of “Y” ($n = 8$)/total number of vendors identified ($n = 15$) $\times 100$. (B) pie chart shows the percentage of all health-related genetic testing products ($n = 62$) offered by BTB corporate wellness vendors that contained posttesting health or genetic consultation with a learned professional as a part of the product. The “pharmacogenomics consult” category represents the percentage of products that offered a consult with a health professional to discuss drug sensitivities and medication changes, and the “no consultation” category represents the number of products that did not mention any consultation with a health or genetic professional. The percentage values accompanying each category is calculated from the total number of tests for each category/the total number of health-related genetic tests identified (62) $\times 100$. Data for each category of consultation were gathered independently.

detects familial relationships represented 13% ($n = 9$) of all genetic test offered among the BTB corporate wellness vendors (Figure 3).

The product page for each genetic test was evaluated to determine if a consultation with a physician, medical geneticist,

genetic counselor, or health coach was available for individuals to discuss their test results and any recommended changes to their diet, exercise, medications, or health care. AGS Health, Caligenix, Cambiati, Color, DNA Fit, Dynamic DNA Labs, Genome Medical, and Pathway Genomics were

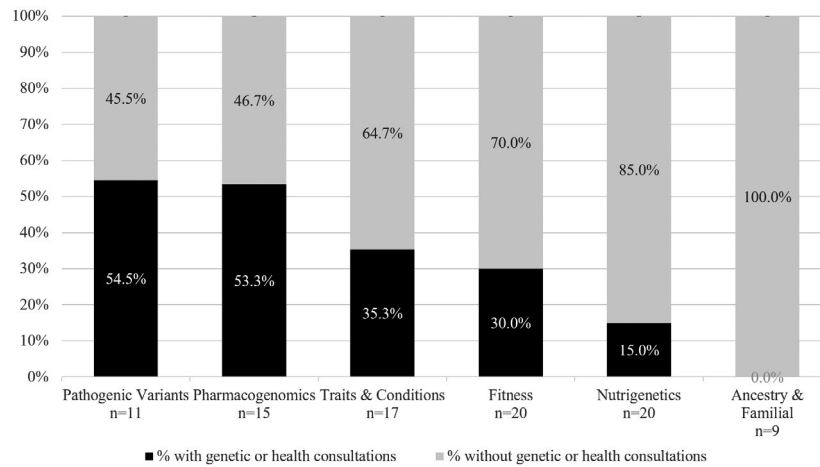


FIGURE 5 Variability in posttesting health and genetic consultations offered by type of genetic test. The percentage of insights providing consultations with a learned professional was calculated independently for each insight. For example, if a single genetic test provides both Fitness and Nutrigenetics insight and offers a genetic or health consult a percentage point is added to both the Fitness and Nutrigenetics insights in the row titled “percent with genetic or health consultations.” $N = x$ is total number of tests in each category. Each category was coded independently.

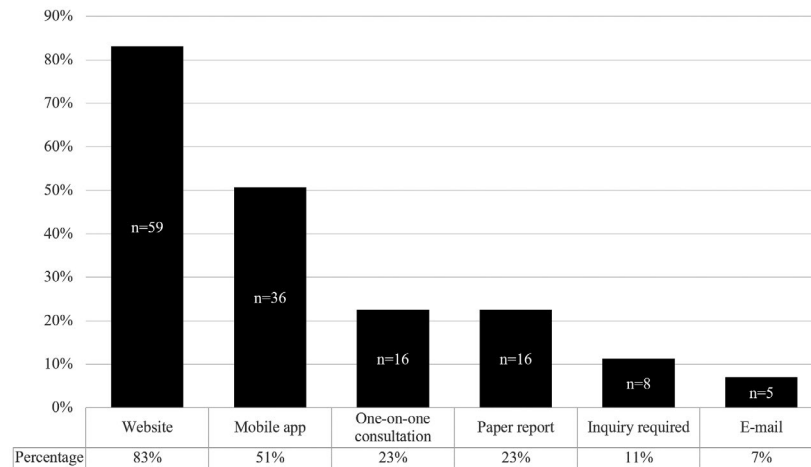


FIGURE 6 Variability in how genetic results are reported by vendors of B2B corporate wellness programs represents the method at which the genetic test results are reported to the user (either a consumer if as part of a DTC service or an employee or participating dependent if the test is provided as part of a corporate wellness program). All genetic tests ($n = 71$) offered by the BTB corporate wellness vendors were assessed to determine the method at which the user would receive their results. Five reporting categories were identified. The “paper report” category represents the percentage of all products that had the ability to mail results to the user and that mentioned the words “paper report” within the description. The “inquiry-required” category represents the percentage of products that had no information about results reporting within their product description. The values ($n = x$) within each bar represent the number of genetic testing products identified for each reporting method. The percentages were calculated using $n = x/\text{total genetic testing products identified } (n = 71) \times 100$.

the only 8 vendors (53%) out of the 15 vendors identified that included health or genetic consultations as part of any genetic test or genetic service offered on their websites (Figure 4a). To identify health-related genetic testing products that include consultations, we excluded ancestry and familial testing from the analysis because we do not expect consultation to be offered with these tests; therefore, the denominator was reduced from 71 total tests to 62 health-related tests. Notably, 61% ($n = 38$) of all 62 health-related genetic tests in the BTB corporate wellness market did not offer any

associated health-related consultation (Figure 4b). A consult with a health coach was included in 18% ($n = 11$) of the 62 tests, a pharmacogenomics consult was included in only 13% ($n = 8$) of the 62 tests, and a consultation with a physician was included in 13% ($n = 8$) of the 62 tests offered among the BTB corporate wellness vendors identified. Finally, products that offered genetic counseling represented only 10% ($n = 6$) of the 62 health-related genetic tests in the BTB corporate wellness market (Figure 4b). A total of 11 pathogenic variant tests were identified, and only 54.5% ($n = 6$) offered health or

genetic consultations. Fifteen pharmacogenomics tests were identified, and only 53% ($n = 8$) offered posttesting health consultations (Figure 5). The traits & conditions, fitness, and Nutrigenetics test insight categories have a total of 17, 20 and 20 tests identified, respectively; however, only 35% ($n = 6$), 30% ($n = 6$), and 15% ($n = 3$), respectively, offered health and genetic consultations. As expected, none of the nine (9) tests in the ancestry & familial insight category offered health or genetic consultations (Figure 5).

The product page for each genetic test was evaluated to determine the method by which individuals received their genetic test results. Five categories of result reporting were identified among all 71 products apparently sold by the BTB corporate wellness vendors: (a) genetic results accessible through the vendor website or a third-party website contracted with the vendors; (b) genetic test results available through a mobile device like a phone or tablet; (c) genetic results available through a one-on-one consultation with a health professional; (d) genetic results available to print; or (e) genetic results available through email (Table 2). Products that are not clear about the method at which results are reported are indicated as “inquiry required.” Most of the product pages mention results are reported through a website 83% ($n = 59$) or through a mobile app 51% ($n = 36$). Select products delivered results through a one-on-one consultation 22.5% ($n = 16$), a paper report 22.5% ($n = 16$), and/or e-mail 7% ($n = 5$). Many of the product pages (11%, $n = 8$) were not clear about the method at which results were reported to the individual (Figure 6).

4 | DISCUSSION

The RAND Corporation identified five attributes for successful corporate wellness programs: (a) develop effective communication strategies about the wellness program to employees, (b) provide opportunities for employees to engage in the wellness program, (c) engage leadership and promote a culture of wellness, (d) use existing resources, and (e) continue to evaluate and improve the wellness program (Mattke, 2013). These five attributes were not readily apparent from the websites of the 15 BTB corporate wellness vendors appearing to incorporate genetic testing into their wellness program that we systematically identified. While broad generalizations should be avoided (as what these vendors are doing could be distinct from what their online information suggests) and while further research is needed to understand vendor and employer behavior when initiating an employer-sponsored wellness program involving genetic testing and services, a few observations are appropriate.

Effective communication and outreach strategies in the form of genetic and health counseling is apparent among only 53% of corporate wellness vendors analyzed. Learned

professionals are needed to communicate the limitations and risks of specific genetic tests and the implications of any identified pathogenic variants. It is a noteworthy gap that some vendors do not offer the critical benefit of health and genetic counseling to employee-participants.

Most wellness vendors identified in the systematic search allow for the individuals to provide DNA samples at home which is a significant convenience compared with a mandatory doctor's visit. A major accessibility concern emergent from our observations was that individuals' access to genetic test results was biased toward users of website and mobile applications, leaving few opportunities for individuals with no access to or limited proficiencies with computers or advanced mobile technologies to participate fully in the program. Known age, race, and economic disparities in the distribution of technologies and information is especially concerning when it comes to genetic information because of the potentially life-changing impact of a pathogenic variant and a pharmacogenomic result. Further efforts are needed to understand and close the “digital divide” and its impacts on uptake of genetic testing services.

Understanding GINA and HIPAA compliance is important for corporate decision-making when selecting vendors for wellness programs. Corporate leadership might be inclined to implement wellness programs with genetic testing into their organization's benefits package if wellness program vendors were transparent about their efforts to ensure compliance with GINA and HIPAA. Given the regulatory uncertainty surrounding, the use of financial incentives for employer-sponsored wellness programs involving genetics and the continued confusion and limited awareness regarding what employer obligations under GINA and related state laws are in this area, it is incumbent on vendors of corporate wellness programs involving genetics to be aware and able to guide their prospective business customers. Our review of online information provided by vendors revealed very few even mentioning HIPAA and GINA among their online materials, which is a potential red flag that the legal and policy issues are not given adequate attention. Furthermore, in the vendor-stated risks and limitations of the corporate wellness program, standard disclaimer language was used to absolve vendors from both regulatory oversight and liability. Best practices for this industry should include, at a minimum, disclosures by the vendors detailing how their program aligns with GINA and relevant state laws protecting employee privacy and non-discrimination rights. Transparency regarding what (if any) data access is provided by the vendors to employers and what (if any) data sharing with third parties is occurring are particularly important details given a variety of intertwined legal requirements (e.g., GINA's mandate that employers not have access to anything more than aggregated, de-identified information; the ADA's prohibition against

employers compelling employees to agree to data transfers to third parties; but HIPAA's allowance for data sharing with "business associates") and growing public discontent over data privacy and governance.

Well-established corporate wellness program vendors, such as Wellness Corporate Solutions, Virgin Pulse, and Provant Health Solutions (Aditi, 2019) were not among those vendors identified as offering genetic testing services, highlighting genetic testing in wellness as a niche business proposition. That mainstream wellness programs have yet to incorporate genetic testing could be due to several factors, including but not limited to the lack of empirical evidence of positive return on investment and the actual or perceived regulatory constraints. Vendors did not report their own programmatic successes or provide evidence to substantiate their claims that genetic testing in corporate wellness improves health or reduces health-care costs. The omission of this information further frustrates attempts by employee-rights advocates to evaluate whether vendors are offering products and services that are adequately supported by scientific evidence, or alternatively, offering nothing more than a test with unproven benefits and the potential for clinical harms. If the observed trends persist, those vendors eager to push genetic testing in corporate wellness may undermine broader efforts to promote evidence-based, medically actionable genetic testing for unselected individuals in the U.S. workforce.

Another profoundly troubling finding is that at the time data collection was completed (9 December 2019), none of the vendors described the details of the genetic tests and services offered *specifically* as part of their corporate wellness program. All understanding about options available to employers is entirely speculative because the vendors' DTC offerings might or might not align with the BTB wellness program offerings. As of 30 January 2020, only 3 of the 15 vendor websites have specified the genetic tests that are offered in their corporate wellness program. Although a small number with substantial room for improvement, this indicates a positive shift toward improved transparency among corporate wellness program vendors. Further research is needed to understand vendor and employer behavior when initiating and participating in an employer-sponsored wellness program involving genetic testing and services.

As scholars such as Anya Prince (Prince, 2015) have rightly noted, the provision of genetic information is not itself prevention but is dependent upon subsequent actions based on that information that are themselves influenced by contextual conditions (such as financial opportunity). If genetic testing and services are to offer opportunities for wellness programs to demonstrate effectiveness in improved health and well-being for participants and reduced health care costs, we must encourage vendors of employer-sponsored wellness programs to consistently contribute standardized performance data so that we can collectively evaluate if genetic testing in

corporate wellness adds value or if, as scholars have already commented (Manolio et al., 2019, at 80) "[i]t is time...to re-think [this] enthusiasm for the wellness movement."

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CONFLICT OF INTERESTS

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AUTHORS' CONTRIBUTION

W.M. conceived the idea, W.M., J.W., M.W., and P.D. developed and designed the study methodology, W.M. collected, and analyzed the data, W.M., J.W., M.W., and P.D. interpreted the data., W.M and J.W drafted the manuscript, W.M, J.W., P.D., M.W., L.W., and J.P. provided editorial assistance and approved the final version of the manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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Appendix B

Introduction

Our goal was to study the experience of offering non-indication based genetic testing through employer-sponsored health benefits by conducting semi-structured interviews with company representatives (large self-insured employers and vendors selling genetic testing) and researchers familiar with evaluating employee wellness programs.

The research team developed specific research questions to guide the qualitative inquiry:

For employers: How and why do self-insured employers purchase or otherwise make available genetic testing services for their employees? What has been the uptake by employees and impact on health, QoL, productivity, absenteeism, or health care costs? What have been the lessons learned regarding implementation?

For vendors: How and why do genetics companies offer genetic testing programs to employers? What are the types of programs currently used in the marketplace by employers? What has been the impact on employers and employees?

For researchers: What are the main reasons employers pursue evaluations/studies of wellness programs? How are these studies typically funded and conducted? What are the study outcomes of greatest interest to employers? What are the barriers and enablers to conducting and analyzing these studies?

To ensure a shared understanding of the scope and purpose of genetic testing, the research team drafted a definition of non-indication based genetic testing for employees (also referred to some audiences as employee genetic testing).

Non-indication based genetic testing (NIBGT):

Voluntary health-related genetic testing in employees without a personal and family history of genetic disease. The purpose of testing is to identify inherited risks that are evidence-based and medically actionable. The goals of testing may include employee engagement in their health, greater understanding of how genetics can affect health, enhanced well-being, early identification of health risks, safer and more effective medication use, and potential cost savings from improved preventive care.

Methods

This study used qualitative methodology guided by the Framework Method¹, as described in Gale et al. 2013, for data collection and analysis due to the limited sample size and exploratory nature of the study aims. Semi-structured interview guides were designed based on a literature review regarding design and implementation of corporate wellness programs. Based on early discussions with representatives from large employer coalitions who expressed interest in the project such as The National Business Group on Health (NBGH), we

also described contextual factors that may influence adoption of genetic testing programs as part of developing the interview questions. For example:

- *Type of employer (industry segment).*
- *Type of employee (age, educational background and role in company).*
- *How the program is paid for (part of wellness program, part of health insurance benefit, out-of-pocket costs).*
- *Internal factors - Employee demand, fit with organizational goals surrounding employee health and wellness, Chief Medical Officer (CMO) understanding of state-by-state legal requirements related to genetics, and corporate decision-making structure.*
- *External factors - market competition for employees, need to retain top talent, state of genetic evidence supporting population screening, laws governing privacy, and uses of genetic data by state.*

Draft interview guides were shared with employer wellness research experts for review and the guides were revised based on this feedback. Interview guides were customized for the three stakeholder groups: vendors, employers (company leaders), and researchers. The interview guides contained the definition of NIBGT, shared questions/themes and probes, as well as questions unique to the individual stakeholder type. Copies of the interview guides are provided in Appendix C.

A target list of vendors was developed based on a systematic internet search of companies offering genetic testing as part of wellness programs. We made numerous attempts to identify decision-makers at self-insured employers that are currently offering genetic testing for their employees. For example, we attempted to identify employer decision-makers through recommendations from genetic testing companies who would share names of current clients. We also made presentations to employer coalitions such as NBGH and to attendees of a Chief Medical Officer Summit on the topic of precision population health as a way to generate interest in study participation. Finally, we searched the literature for authors who had publications exploring NIBGT and wellness programs and by networking with individuals who attended conferences on this same topic. We relied on the Vice President (VP) of research from Research Organization #1 (RO#1) to provide names of researchers familiar with evaluation of employer wellness programs, emphasizing an established publication track record.

The study protocol was deemed exempt (Category 2 exemption) by the Geisinger IRB. An invitation email was sent to our target stakeholder list (N= 27) explaining our research and soliciting participation in a 45-60 minute recorded telephone interview. We targeted senior leaders at each of the 15 vendors identified in the landscape. A one-page study description was shared with attendees of employer coalition-sponsored NIBGT-related meetings and webinars to recruit company leaders. Four researchers with a portfolio of published wellness program studies were invited to participate as interviewees. An honorarium of \$200 was offered to potential participants. Three attempts were made to contact those on the stakeholder list and to solidify a teleconference meeting time. Ten vendor representatives, three company leaders and two researchers responded to the email invitations and a teleconference was scheduled. In total, 9 semi-structured interviews with stakeholders were conducted by a lead interviewer and a co-interviewer responsible for compiling detailed interview notes. Recordings of interviews with stakeholders who

provided verbal consent to be recorded (8) were sent to a transcription service. One vendor representative declined to have the interview recorded.

Data were collected and analyzed in the form of episodic summaries, detailed interview notes, and recorded transcripts. Thematic coding and analysis of stakeholder data were guided by the Framework Method¹. Initial coding was conducted by two study personnel analyzing transcripts for emergent themes within each group and subsequently comparing identified themes. The research team then attempted to consolidate shared themes across all three groups, while also identifying themes unique to each specific stakeholder group. A second round of coding was conducted to look in-depth at each theme. A codebook was created to establish consistent definitions for use across the analysis. Codes with an inter-rater reliability of 80-100% were included in the final codebook.

Given the substantial differences observed across stakeholder groups, the research team determined that an exploratory case study approach focused on vendors would provide greater understanding of how genetic testing was being marketed to employers. Publicly available information from company websites regarding tests, data sharing practices and evidence claims was used to triangulate findings regarding the business focus and impact of vendors. Using insights developed from the March 2019 NHGRI-sponsored meeting on employers and genetic testing², the four participants representing the vendor stakeholder group were split into two categories based on their business focus. Specifically, we split the vendors according to whether they offered primarily “Medically Actionable” genetic testing and services, or “Health & Wellness” genetic testing and services. This exploratory case study of the four vendors, along with stakeholder perspectives from both the company leaders, chief medical officer and research organization groups, helped provide further understanding of both similar and distinct perspectives related to employers seeking genetic testing services for their employees.

Results

Participant Characteristics

We interviewed participants from three different stakeholder categories: vendors (V1, V2, V3, and V4), company leaders (C1, C2, C3), and research organizations (R1 and R2). Company leaders and participants from research organizations were not found to have direct experience with implementing NIBGT in wellness programs. Their perspectives still held value but for the purpose of this report, we will focus on vendor perspectives of NIBGT in wellness programs. Any relevant information from the company leaders or participants from research organizations will be included at the end of each section topic.

Participants from four genetic testing vendors had varying job roles. V1 is the VP for Employer Strategic Partnerships at Vendor#1 and has been in that role at Vendor#1 for six months at the time of the interview but has 20 years of experience in the employer market segment. V2 is the VP of Scientific and Medical Affairs at Vendor#2; he has been at Vendor#2 for four years and in the VP role for two years. V3 is the founder, CEO, and general manager of Vendor#3 for about eight years, two years of that being in the aforementioned role at the

Vendor#3 precursor company. V4 is a co-founder of Vendor#4 and joined the Vendor#4 team full-time in 2017.

Leaders from varying companies included a CMO (C1), a Benefits Manager (C2) and independent consultant, and a VP of Human Resources (C3). Participants from research organizations included the VP of Research (R1) from RO#1 as well as the Senior Scientist and Director of the Institute for Health & Productivity Studies (R2) at Research Organization #2 (RO#2). R2 also holds the position of VP of Consulting at Applied Research at a separate company.

The Association for Molecular Pathology (AMP) which represents the leading global professional society for molecular diagnostics, strongly opposes “consumer testing that provides information that is either not clinically valid or is used to sell secondary products or services, such as unsubstantiated claims concerning athleticism, diet, exercise or cosmetics.”³ As such, we stratified the companies that we interviewed into two categories based on the primary scope of non-indication-based testing: “Medically Actionable” for V1 and V2 and “Health & Wellness” for V3 and V4. These two categories also reflect different approaches to employee counseling - the medically actionable test vendors provide access to board certified genetics professionals, while the Health & Wellness (H&W) vendors rely on nutritionists, personal trainers and life coaches.

Medically actionable genetic testing is defined in this study as including CDC tier 1 genetic conditions or genes from the American College of Medical Genetics and Genomics (ACMG) secondary findings list. The most up-to-date guidelines from the Clinical Pharmacogenetics Implementation Consortium (CPIC) in July 2019 have included 24 genes and 62 drugs to facilitate clinical decision-making, and therefore are considered medically actionable. However, there was substantial variability in the tests offered by vendors, making this category less relevant for stratifying vendors. As such, we did not include pharmacogenomics (PGx) in our decision-making for defining these groups. Health & Wellness testing is defined in this study as recreational genetic testing including an association with fitness, nutrition, skin care, or behavioral traits.

Table 1. Service Offerings by Vendor

Vendor (Participant)	CDC Tier 1 Conditions	ACMG 59 Secondary List	Health & Wellness Screening	PGx Screening	Board-Certified Genetic Counselor/Geneticist /Pharmacist	*Other Consultations
Vendor#1 (V1)	✓	✓	✗	✓	✓	✗
Vendor#2 (V2)	✓	✓	✗	✓	✓	✗
Vendor#3 (V3)	✗	✗	✓	✓	✗	✓

Vendor#4 (V4)	x	x	✓	x	x	✓
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**Can be nutritionists, personal trainers, life coaches*

Vendor characteristics

Vendor#1 was founded in 2016 and focuses on providing education, evaluation, and counseling of employees for potential use of medically actionable tests but does not have an associated testing laboratory. Rather, their team helps to identify the appropriate test for an individual while working in close relationship with a preferred set of external laboratories. Vendor#1 employs a genomic resource center to educate consumers regarding genetics, healthcare, and risk assessment tools in conjunction with personal and family history, with access to care coordinators, genetic counselors, and geneticists. Gene panels commonly recommended are either associated with conditions such as cancer and heart health, or reproductive health and PGx.

Vendor#2 was founded in 2013 and had its public launch in 2015. They market two gene panels: a hereditary cancer panel that includes 30 genes associated with eight common hereditary cancers, and an extended panel that includes 74 genes associated with common hereditary cancers, hereditary forms of heart disease, and medication response with PGx. If a test performed by Vendor#2 comes back with positive results, they conduct confirmatory testing with third party laboratories. V2 was the only vendor to recommend a change in the study team’s definition of NIBGT. The interviewee recommended altering the target population to include employees “with or without a personal or family history” of genetic disease to reflect current practices with employers. This more accurately captures employees that have a relevant family history that may not have been picked up in clinical practice.

Established in 2014, Vendor#3 specializes in H&W genetic testing focused on nutritional benefits, exercise guidance, and behavioral/lifestyle changes. They also offer a Skin Health Genetic Test aimed at helping individuals personalize their skincare regimen and a Drug Sensitivity Test (PGx) intended for individuals who have experienced side effects or adverse drug reactions and those with limited medication response. They market two main H&W tests⁴: The first is a 25 gene panel associated with nutrition, vitamin response, and elevated cholesterol; the second test is a 53 gene panel that includes all previous categories along with predispositions related to stress, blood sugar elevations, and behavioral tendencies. The assay is identical for both panels, what differs is simply the genetic variants reported.

Vendor#4 was incorporated in 2014 and currently markets a 45-single nucleotide variant (SNV) panel associated with Health & Wellness and tendencies such as nutrition, fitness, and skin care. The Vendor#4 website⁵ claims that NIBGT in corporate programs support personalized preventive wellness interventions to “help make employees more aware of their risk factors and point them to ways to improve their health and lifestyle.”

Financial Compensation

The vendors we interviewed predominately offer genetic testing as part of corporate wellness programs. Self-insured employers often offer these programs to employees at no cost or reduced cost and the wellness interventions are not billed to insurers under the medical benefit. If the employee has been found to be at increased risk for a medically actionable condition such as hereditary breast and ovarian cancer or diabetes, then appropriate diagnostic workups and treatments are typically covered by employer-sponsored health insurance. Compensation for vendor services varies depending on the tests they offer. Insurance companies do not authorize coverage for H&W genetic testing that does not demonstrate clinical validity or clinical utility. Alternatively, vendors can submit to insurers for payment for medically actionable genetic testing but based on the interviews conducted this is relatively uncommon. Independent of insurance, some employer wellness programs offer various methods to pay for employee testing through a partner vendor in an effort to minimize any financial cost to employees. V1 from Vendor#1 shared that they offer services along a continuum from education and assessment only on one end, to a total solution on the other, that includes recommending specific genetic tests and then counseling employees regarding their test result. One option for being paid for these services involves a per employee per month (PEPM) model that reflects the intensity of services offered. For example, the PEPM charge for education and assessment might only be \$1-2 PEPM, while the PEPM charge for the total solution would be more in the \$5-7 PEPM range. Alternatively, V1 stated that the compensation model for some employers is based on service utilization (fee for service) or a hybrid of the two approaches. Importantly, all these modes of financial compensation are implemented outside of or as a complement to traditional medical insurance.

V2 from Vendor#2, a company that originally marketed itself primarily to self-insured clients, stated employers pay for employee genetic testing predominantly as part of wellness benefits ("wellness perks") and very rarely through their insurance payer. NIBGT does not meet most payers' definition of medical necessity (a test or procedure that is justified as reasonable, necessary, and/or appropriate based on evidence-based clinical standards of care). V2 elaborates that some payers may use an authorization strategy in the context for research studies called, "coverage with evidence development." This process provides provisional coverage of tests with clear evidence of clinical validity and promising evidence of clinical benefits and harms. This allows participants of an insurance plan to receive coverage while the process of developing evidence is on-going.

V3 mentioned that some employers provide healthcare credits to their employees every year, offering them the option to use these credits to buy one or more non-indication based genetic tests. Other employers have paid for the genetic test as a covered wellness program benefit. In contrast with Vendor#2, neither Vendor#3 nor their client companies bill insurance companies directly.

V4 discussed varying solicitation methods based on financial compensation strategies. Vendor#4 markets their testing as H&W to "fly under the radar" and minimize financial risk. Another method discussed by V4 is to market their services to specific regions. For example,

because of greater restrictions in the state of New York, Vendor#4 has made the decision not to provide their services in that state.

Additional information regarding financial compensation came from responses by corporate leaders. C1 reportedly knows of other self-insured employers who are considering offering NIBGT as a covered benefit, which may require an insurance deductible, but because NIBGT is relatively new it is not typically covered. He recommended PGx for chemotherapy agents to be made part of the insurance authorization process within their employer health plan, labeling the testing as “necessary” under insurance. C1 also mentioned wanting genetic testing for hyperlipidemia to be completely covered under their preventive care category of wellness benefits, but the company and its health plan did not follow his recommendation. These tests are not routinely covered through an employer-sponsored health insurance plan, but reportedly when C1 coaches an employee's physician on how to request coverage, some have success in receiving coverage.

C3 stated they have had a financial support benefit for clinical testing over the past five to six years through their Workplace Genomics Program (WGP). The WGP, offered globally with 70% of participation in the US, helps pay for employee testing that is clinically indicated (medically actionable), but not for H&W NIBGT. C3 also reported that occasionally testing is paid for by institutions not covered under insurance but only to obtain research information, “...you can have a Foundation Medicine test run on a tumor, but then you might have a hereditary test done that would not be paid for by insurance, but institutions are just paying for that to get research information.”

Genetic Testing in Wellness Programs

Vendor participants provided varying perspectives as to why companies choose to include NIBGT within their wellness programs. V1 shared that employers who consider investment in employees over the long-term may believe that providing genetic testing options for employees via wellness programs allows the company to recoup the cost of the program by preventing future catastrophic events. This is a substantial consideration for businesses who tend to keep their employees for life and employ multiple generations of family members. A company-paid genetic testing program offers a potential benefit of improving employee health and productivity while minimizing preventable healthcare costs.

“Employers want employees to be healthy and productive. Unhealthy employees may result in increased costs for employers related to healthcare costs and loss of productivity. As such, employers at companies who analyze employee health trends may identify ways to utilize genetic testing and counseling in order to improve or prevent severe health complications in employees. Identifying potential health risks in employees and allowing them the opportunity to seek intervention offers savings from a medical cost perspective and offers incentive for companies to offer coverage for genetic testing of employees.” – V1.

The Vendor#2 website indicates that genetic testing can “help fill gaps in care and health management by offering personalized screening guidelines and identification of people with high risk for major conditions based on genetic and non-genetic results.” During our interview with V2, it was discussed that they felt that genetic counseling at vendor labs via telehealth is a valuable service. Genetic test results may allow a patient’s physician to change recommendations for surveillance/management based on an individual’s personal and family history, whereas PGx testing may allow for a clinical pharmacy consultation based on the results. In addition, Vendor#2 offers consumers an online service called the “HelpHub” to act as a personalized reminder for compliance with relevant screening guidelines (ex. mammograms, etc).⁶

Another reason companies may include NIGBT in a wellness program is to market themselves as innovative and to differentiate from competitors. For example, V1 states that companies try to recruit top talent and retain those employees through innovative benefits packages such as genetic testing and precision medicine. V2 corroborates this perspective when claiming NIGBT can be used as an incentive for employee retention, especially in a competitive white-collar workspace. These employers are not necessarily thinking of the return on investment (ROI) but they want to differentiate themselves as a company that cares about you as an individual. V4 agreed with this assessment by referring to the phenomenon of companies supplying new and interesting benefits for employees as “The Apple Effect.”

In the H&W testing arena, company culture is a major factor for implementation of genetic testing in a wellness program (V4). If there is a supportive environment where everyone works as a team then participation increases. If that is not the culture, participation is lower. Providing services to consumers and employers primarily in southern California, V4 mentions that “people are extremely health conscious” in the LA region which adds to the supportive culture and increases employee engagement in personalized medicine.

The H&W vendors that we interviewed indicated that results may motivate consumers to engage in better health practices. For example, V4 claims the 45 SNVs Vendor#4 uses for nutrigenomic information provide their team of nutritionists with a way to build personalized recommendations for their patients. V4 shared that Vendor#4 plans to launch “actionability supplements” (vitamins) in 2020 to promote well-being. These vitamins will reportedly be marketed as personalized management that correlates with test results. Similarly, Vendor#3 offers personalized care plans based on H&W tests and PGx testing that enables the customer to adopt better health habits and become more informed patients with medications.

Lastly, V3 from Vendor#3 indicates there is a culture of individualization that leads to consumer-driven testing: “I mean the narcissistic nature of Americans right now has never been more pronounced with social media and Facebooking, and people want to know about their genes. People are very keen on that.”

R1 had a similar perspective to V3 with more individuals taking control of their own health, from colleagues to family and friends who are increasingly willing to pay for these benefits out of pocket. R1 feels that this is a chance to engage individuals who may not have ever participated in a wellness program prior to the inclusion of genetic testing.

C2 discussed an increase in interest surrounding genetic testing and employer benefits. There has been an increase in the number of companies that approach employers about adding genetic testing to their employee benefits, and he has seen growth in PGx capabilities, some new and additional approaches and capabilities of genetic testing, and genetic counseling for employers: "It's a slow growth, but it's increasing. The level of employer curiosity is increasing as well. Both the interest as well as the supply are increasing, and as new and different types of capabilities come to play, there is more excitement."

C3 also thinks people are highly interested in genetic testing and that people are aware that genetic testing has many capabilities, but this can lead to some confusion:

"I mean I think as a cocktail party topic, people love talking about it. They are fascinated by it. I think that there is a lot of mythology and uncertainty around what we can or can't do. I think that there is a recognition that in our genetic code today... we can glean some medical traits, some propensity for development of disease, for development of certain conditions, and I believe that there is also a moderate level of recognition that it might inform how I might eat better, what exercises would make sense for me, and whether or not losing weight is true... There is a recognition that it could detect heart disease and cancer. What is not out there is a full appreciation of where we do have some levels of certainty and what the limits of that certainty is." -C3.

Wellness Program Process Measures for NIBGT

Implementation of genetic testing in a wellness program is measured by looking at variables such as employee uptake and engagement. Multiple factors may play a role in the uptake of genetic testing by employees who work for companies that offer testing through third party vendors. For companies that offer medically actionable testing these factors include surveillance monitoring to identify pressing employer health issues that align with company health goals (V1). For companies that offer H&W testing, these factors may include conducting studies to evaluate the impact of their genetic testing services. For example, V4 from Vendor#4 discussed that one of the reasons they are creating supplements for consumers is to measure gene expression and subsequent lifestyle changes using a "multiomic approach." They receive employee follow-up data that is facilitated by employers through surveys to measure outcomes.

A key difference between medically actionable genetic testing vendors and H&W vendors may be that H&W vendors need to focus on gathering data to legitimize their testing services that are viewed as recreational. Similarities between both medically actionable and H&W testing include company culture which may influence employee decision-making regarding testing, as does the makeup of the employee population. As stated by V4, a company that offers a supportive environment where many employees participate in genetic testing options will facilitate others to make the same decision. Additionally, many direct to consumer (DTC) genetic testing companies, such as 23andMe and Ancestry, have launched large campaigns aimed at creating consumer awareness regarding genetic make-up and ancestry. One participant (V3) indicated that this broader cultural experience with DTC genetic testing predisposes employees to be more receptive to genetic testing as part of wellness programs.

Several vendors mentioned that tracking employee uptake of genetic testing is a crucial process measure. However, half of the vendor companies that we interviewed did not share the percentage uptake of genetic testing by employees at companies they partnered with. At Vendor#2, V2 mentions that while they experience a broad range of employee uptake of their services (10%-90%) the average is closer to 25% of employees who actually pursue genetic testing. This differs from what is presented in the employer services packet where it is mentioned they have a 30% - 50% employee uptake in the Vendor#2 benefits program.⁷ According to a case study Vendor#2 conducted with the International Brotherhood of Teamsters⁶, participant uptake increased 400% compared with average Teamsters wellness programs.

According to V3 at Vendor#3 the range for consumer uptake has reportedly been from about 10% to about 90%, with uptake stated to increase with “strong executive buy-in.” A fitness company client bought tests to sell their members and Vendor#3 trained over 300 of their personal trainers to do a consultation, as well as develop personalized training reports and fitness plans to match genetic reports. V3 claims that on average 38% of the people that bought a genetic test have bought additional personal training sessions.

At Vendor#1, they report⁸ a 20-30% engagement rate in the first year; 87% of employees would recommend the genetic service to friends and family; and 93% found the service to be valuable. V4 from Vendor#4 shared the perspective that people from certain regions of the country such as Los Angeles are extremely health conscious. This quality may increase the likelihood to engage in testing options from Vendor#4, which focuses on nutrition, fitness and skin care. V4 indicated that greater than 50% of employees from companies offering genetic testing services through Vendor#4 pursue genetic testing. To provide another perspective on what factors influence employee engagement and uptake, we evaluated a response from a participant (C3) responsible for making company purchasing decisions. C3, when referring to PGx genetic testing, shared that in her experience people under the age of 35 are more likely to engage with genetic testing. This suggests an employee’s age may influence their decision to pursue genetic testing through a company’s wellness program.

NIBGT Outcomes

According to Medically Actionable NIBGT vendors, return on investment (ROI) and value on investment (VOI) data are what companies look for when implementing a new service. The reasons employers offer wellness programs are to better manage health care costs, improve employee health and improve productivity. When these benefits are monetized and compared to the dollars spent on implementing the wellness programs, this difference is the classic wellness ROI analysis. Most of the information required to assess outcomes exist in the form of health and disability claims data and clinical data such as cholesterol levels, blood pressure, and body mass index (BMI). Similarly, a wellness VOI analysis attempts to assess wellness program impact but focuses on employee-reported measures such as job satisfaction, morale, and team cohesiveness. As companies shift to emphasizing the VOI of wellness programs, they tend to deprioritize traditional wellness ROI evaluations which rely on medical claims data, disability claims data and changes in biometric data. VOI is currently viewed as potentially a better way to assess the impact of wellness programs as it is a more holistic concept of value, but in reality, employers rarely administer surveys or conduct interviews to collect information on employee attitudes and preferences. If resources are unlimited, then it would be ideal to collect both ROI and VOI as they provide a more comprehensive view of the net benefits of wellness programs.⁹

Vendors of NIBGT often emphasize collecting VOI measures to document program effectiveness. V2 claims that employee satisfaction and other psychological impact responses are important outcomes to track:

“So, they’ll ask how many people have taken it. But then, there is also a quality of component to that which is what is the reaction of those individuals to it? Are they happy about it? Are they pissed about it? Are they made anxious by it? So, we do... qualitative post-test surveys to assess exactly these things.” – V2.

Vendor#2 team members reportedly work with each employer on an individual basis since some employers create their own qualitative surveys. A more detailed analysis would be defined as a "research study" to which participants would need to consent: "We actually have to reach out to the individual and say, 'are you interested in a study where we're going to be following up with how you're changing your health behaviors since receiving this test, and then if you say yes, then we'll send you follow-up surveys and collect more information.'" (V2) Vendor#2 staff have reportedly looked across multiple employers regarding the aggregate incidence of pathogenic mutations, as well as pooled follow-up survey responses regarding impact of NIBGT on productivity, overall behavior changes, mammography compliance and the utility of returning genetic variants of nonclinical traits. One ongoing study corroborates this claim: A study protocol between Vendor#2 and Blue Cross Blue Shield of North Carolina called "CHAMP" facilitated through the NC Biotech Center evaluates the impact of NIBGT on consented employees. All posters presented by Vendor#2 at national genetics conferences are located within the "Resource Library" on their website.¹⁰

Potential impacts⁸ of genetic counseling at Vendor#1 include, “reduced cost of care delivery”, “increased patient satisfaction”, “decreased costs for employers”, “improved patient comprehension”, and “increased patient confidence in care plans”. V1 argues that PGx is attractive for this reason stating, “PGx testing is easier for employers to demonstrate ROI and value, compared to testing for specific variants.” V1 also mentions in the interview that patient satisfaction is a primary outcome measure at Vendor#1 documented via surveys.

V3 reports that Vendor#3 does not make any claims that are not supported by peer-reviewed publications. However, Vendor#3 has not conducted any studies of their tests that demonstrate an improvement to health and well-being. Of note, when asked about the clinical validity and utility of their tests, V3 cited CLIA and CAP certification as evidence, although this certification only addresses analytic validity. V3 described in a webinar that their reports include 3-5 scientific citations for each of their claims; while there are 4 citations on their website (the “Aetna study”, the “Meridian study”, a “Harvard study” Business Review article and a “HERO/CDC case study” - see below for descriptions) they have no relation to testing offered by Vendor#3.

The “Aetna study”¹¹ randomized employees with an increased risk of metabolic syndrome to two wellness program groups or a control group. The program groups received “high touch” education about strategies to reduce their metabolic syndrome risks (including a personalized nutrition and activity plan), while one of the groups also received a limited genetic test panel of 3 genes purported to be linked to obesity, appetite and compulsive behavior. V3 referred to successful study outcomes as evidence of weight loss and a reduction in healthcare costs of \$122 per patient per month in the intervention groups, resulting in positive ROI in the program’s first year. Notably, there was no demonstrable positive effect of the gene panel results on enrollment or engagement. The authors rationalized this finding as consistent with “... other data that demonstrate that individuals often appear to be irrational decision-makers when presented with evidence-based information on the risks and safety of various consumer products such as cigarettes and alcohol.”

The “Meridian study”¹² was designed to evaluate the effect of PGx- guided treatment on patients diagnosed with depression and/or anxiety in a diverse clinical setting compared to the standard of care (no PGx testing). This was a randomized trial of 685 patients where PGx results were provided to physicians of patients in the intervention arm and used to guide drug treatment selection. Patients in the PGx-guided arm had higher response rates and remission rates as compared to the control group at 12 weeks post-randomizations. Although this study showed improved mental health outcomes following PGx testing in patients diagnosed with depression and/or anxiety, this study was not conducted in a workplace setting as part of a wellness program and the inferences are only generalizable to patients being treated for depression and/or anxiety.

The 2016 Harvard Business Review commentary¹³ summarized highlights from a recent report entitled, “From Evidence to Practice: Workplace Wellness that Works.” The authors (representing two organizations: Transamerica Center for Health Studies and the Institute for Health and Productivity Studies at the Johns Hopkins Bloomberg School of Public Health)

addressed the information needs of employers interested in creating and implementing a successful evidence-based health promotion program. One of the take-home lessons was that one-time events that are not integrated into a comprehensive workplace health promotion strategy (i.e. solo health risk assessments or hiring vendors to “fix” unhealthy employees) often fail. Practices that they reported to be successful are a supportive, strong commitment from leadership, building a culture of help and offering smart incentives. The report indicates that H&W program evaluation is critical and measures such as ROI and VOI are important metrics to analyze for program success. While a useful overview of how to avoid common mistakes that lead to ineffective wellness programs, this article does not include any information regarding genetic testing despite being cited on Vendor#3’s website.

The Health Enhancement Research Organization (HERO), along with workplace H&W experts, pursued companies from various business types and industries to partake in a case-study project¹⁴. The case studies highlight employers who successfully implemented a healthy culture in the workplace. The results show that key elements like shared health values between the company and employees, supportive leadership, a strong incentive plan and clear communication, funding and resources to deliver the program and empower employees, a healthy environment (sit/stand desks, walking paths or fitness facilities, coverage of flu shots through benefits), and the fostering of community connections through volunteer initiatives linked to H&W program incentives contribute to a culture of health and wellbeing. Like the Harvard Business Review article on factors predictive of successful wellness program implementation, the HERO case study found that it is imperative to measure the success of the program, such as claims analysis, percentage of program uptake by employees, percentage who achieved their health goals, and percentage who saw the H&W program as being valuable. While this is another useful study, the cases did not involve any type of genetic testing.

From the perspective of C1, health plans are reluctant to adopt population based genetic testing because of cost and reliance on the provider and patient knowing how to use NIBGT results appropriately. To date, insurers have no evidence of clinical utility or proven ROI which C1 claims is a weak business case for NIBGT "I have had numerous conversations with health plans about this through Highmark Blue Cross Blue Shield and Aetna and it's still difficult for them to even get it as a covered benefit" (C1). When describing implementation of medically actionable genetic testing, C3 opined, "I think that [genetic testing] will become just a common part of your medical plan, but what is different in our mind is the genetic counseling, and that holds those first 2 pillars about exploration and education. That will continue, I believe in the near term, to be the better employer differentiator versus 'I offer the test.'" She went on to say that genetic testing will become more like population health management offered through the medical policies and payors, and health benefits professionals will not need to show a ROI. Customer satisfaction under VOI is all we have at this point to measure outcomes.

Facilitators & Barriers

Workplace wellness programs capitalize on the employers' access to employees at an age when clinical interventions can positively impact their long-term health. Most employers implement a combination of screening activities and risk mitigation interventions within their wellness program. Screening activities consist of health risk assessments, questionnaires on health-related behaviors and risk factors (smoking, stress managements, eating habits) and biometric screenings (height, weight, blood pressure, and other physical or behavioral data). ***Primary health prevention*** options can be offered to employees with risk factors for chronic disease (diabetes, heart disease, etc.) before the health effects occur, while ***secondary prevention*** options can be offered to identify pre-symptomatic disease, and ***tertiary prevention options*** to improve disease control in employees with existing chronic conditions.¹⁵ Implementation of genetic testing within an employer setting is often more complicated than the aforementioned, well-established screening and intervention offerings because the genetic contribution to chronic disease risk involves numerous genetic variants and the evidence to support use as a screening tool is weak. Implementation may also be relatively more complex due to the significant privacy concerns regarding use of genetic information. This phenomenon is often referred to as genetic exceptionalism.¹⁶

Study participants detailed both facilitators and barriers to implementing NIBGT within corporate wellness programs. Regarding solicitation and subsequent implementation, the company department and individual (executive leadership or supportive decision-maker such as a human-resources expert) who is approached by a vendor is critical. V3 claimed that innovative wellness programs that include NIBGT are often hindered by influencers within the human resources department, while V2 felt that adding insurance carriers to the implementation discussion can be problematic. Some participants indicated that companies do not want to be early adopters of genetic testing within the workplace as the ROI has yet to be demonstrated compared to other wellness offerings. In the absence of compelling data regarding health and economic outcomes, several participants shared that NIBGT as part of wellness programs are most easily implemented when C-suite executives champion genetic testing and drive the decision.

However, without access to the anonymized genetic data generated from employee testing linked to employee outcomes, V2 indicated that there is not enough data to show ROI. Another issue is the large sample sizes required to show how medically actionable genetic tests affect outcomes. For even large employers, addressing this requirement would necessitate pooling data across employers. A barrier to obtaining these data is that companies feel the competition from other industry players, and they do not want to share even their aggregated data with competitors. In turn, this stymies outcomes research. At the same time, the timeline for observing improvements in health outcomes further complicates outcomes research, in that outcomes related to Mendelian diseases require extensive longitudinal follow-up to show health benefits (e.g. avoidance of breast cancer following increased surveillance in a 25-year-old with a *BRCA* mutation). In the H&W genetic testing arena, outcomes assessment is similarly complex as evidenced by V4's statement that there is no easy way to measure effectiveness for some of their test offerings. Nevertheless, both employees and employers continue to expect evidence of health impact. Vendor#4 is

reportedly working on providing outcomes measures for employers in the future, but their priorities are currently centered on business development.

An additional barrier to NIBGT implementation is illustrated by the point made by one participant (V1) who claimed that legislation impacting genetic discrimination, particularly the Genetic Information Nondiscrimination Act (GINA), is poorly understood often by both employer and employee. A lack of a comprehensive understanding about genetic information-related legal protections appears to explain why some employers are reluctant to implement NIBGT as they struggle to address employee fears that their genetic results will be used by employers or insurers in a discriminatory manner. Further exacerbating gaps in comprehension is the complexity of interpreting probabilistic results for most lay persons, including both purchasers of NIBGT services and employees. Unfortunately, vendors can make unfounded claims about the actionability and health benefits of genetic testing which contributes to the confusion of both employer purchasers and their employees who are not formally trained in genetics. For example, V1 of Vendor#1 claims the wide variety of NIBGT services available to employers and their employees can be confusing for end-users: "Consumers can't always differentiate between a valid medical test and one that is purely for interest." V1 further characterized the current situation as the "Wild West" for genetic testing.

Likewise, V1 claims that genetic testing is not widely understood by primary care providers and other clinicians. According to the white paper published by their company, 74% of PCPs rate their knowledge of genetics as very poor or somewhat poor, 87% of PCPs feel unsure about who to test or what to test, and 83% of PCPs aren't sure where to send patients for genetic medical care.^{17,18}

Confusion within the field of genetics is corroborated by C2 who stated that educational challenges are colossal. He discussed that the education process and the product have to be engineered to assume confusion and that providers are going to need regular educational conversations to become comfortable with managing genetic test results for employees. The most appropriate test may not be ordered if there is provider uncertainty, and this is where genetics professionals can assist, but the phenomenon of genetic exceptionalism remains: “An employer audience is going to be far more sophisticated than the employee audience, so in order to make the sale, you have to educate employers; but you are educating a more sophisticated audience where employees you have to assume [have as] little medical knowledge and scientific knowledge as possible.”

C2 goes on to describe how providers will need to stay up-to-date with genetic education: “[For example, let’s say] I tested negative on my genetic test. The doc looks at it, goes back to you saying you don't have a certain genetic condition called familial hypercholesterolemia, but your cholesterol is sky high because you're eating too much. You're eating too much of the wrong things... We are living in a world where providers, in order to stay current more than ever, are going to need ongoing education.”

Unaware of recent publications¹⁹ such as “Clinical outcomes of a genomics screening program for actionable genetic conditions”, R2 mentions there is not enough evidence to support a screening procedure for the general population. He states important factors to consider include cost effectiveness, maximizing benefit and minimizing harm to the patient. R2 also mentioned that some individuals do not have PCPs or a trusted healthcare professional to help explain these results, and the return of results could be tricky as some individuals do not have access to a phone or email.

However, C3 mentioned that program implementation can be facilitated with the help of many experts inside the company including geneticists and genetic counselors. They were able to decide what is in the consent and for what they should offer financial support. The Benefits group is reportedly very collaborative with the internal group of experts that “make implementation or expansion a unique experience.” As opposed to some vendors who claimed C-Suite personnel drive implementation, C3 mentioned that doctors may be the drivers of implementation at other companies since they dramatically help with decision-making:

“I would say if you look at the panel for both Novartis and Cisco for example and probably Apple and Amazon as well, they have physicians on that team that are helping direct what tasks, what environment, what's the payor. That is not necessarily a benefit professional doing that, that's a doctor who is familiar with genomics. I think that the implementation is one of the, for a big, what I call 'population health initiative', you need to have an MD on your team that can help you with those decisions.”

Genetic Data and Privacy

Privacy is an important concern for employers when trying to promote genetic testing services to employees as part of wellness programs. V1 from Vendor#1 states that most employees are not familiar with GINA and what it covers, and this misunderstanding can lead to hesitation or unwillingness to participate. V1 also says enrollment and testing uptake will be limited if employees think protected health information (PHI) will get back to their employers. Vendor#2 has a strict policy where they will not share individual level genetic

data with an employer, but they will make aggregate data available upon employer request. V2 from Vendor#2 added additional nuance to this sensitive situation, stating, “not all employers want [aggregate data]” because many employers feel that is too invasive of their employee’s privacy. If privacy concerns are addressed proactively, V2 did not feel they are a barrier to NIBGT services. V3 and V4 did not mention data privacy as a barrier to testing implementation within employer wellness programs, but both described these protections as important selling points to employers. All vendors described their focus on data privacy and security during their interviews, but the emphasis on these protections varied across vendors. For example, V3 from Vendor#3 highlighted their data policy as a marketing tool, stating, “...our tests combined with our data policy gets us the clients that we have, in that it is very simple that we don’t sell or share client data. No exceptions. And none of our partners or shareholders are ‘Big Pharma’ data companies or insurance companies.”

To gain additional insight into the four vendor data privacy practices we looked at the privacy policy section of each website. While three of the vendors market and sell genetic testing, Vendor#1 differs in that they provide educational and counseling services to consumers.

Vendor#1’s privacy policy²⁰ is centered on PHI, their legal obligation to maintain the privacy of PHI, how PHI is protected, and informing consumers about privacy practices regarding PHI and their obligation to notify clients of any privacy breaches. Their policy describes the types of disclosures that do and do not require patient authorization, as well as special rules for highly confidential PHI such as HIV results or mental health information. Of note, their policy includes a marketing authorization section with an “opt out” option that indicates that by the creation of a Vendor#1 account and agreeing to the privacy policy, the patient thereby consents to having the company use PHI, including email address, for marketing activities. The policy also states that clients have the right to request restrictions on how Vendor#1 uses and discloses PHI for treatment, payment, and other health care operations. During our interview with V1, he noted that it is his experience that privacy is an employers’ greatest concern in promoting genetic testing services to employees, and that most are not familiar with GINA and what that covers.

The Privacy Policy for Vendor#2 contains standard privacy language including the use of cookies and which analytic services are used, that information is shared at the consumer’s own risk, a user terms of service agreement, and how all collected information will be used. It defines the personally identifiable information (PII) and personal and family health information (PFHI) that will be collected when an individual sets up a Vendor#2 account or purchases a test. The policy also details that individuals cannot share any protected health information PHI about another person without full consent from that individual.

Comparable to Vendor#1’s privacy policy, there is information on how and why PII and PHI may be disclosed or shared. Of note, regarding corporate wellness program offerings, Vendor#2 has a strict policy²¹ where they will not share individual level data with an employer. They have an option to make available anonymized and/or aggregated data to employers. The privacy policy explains that Vendor#2 may share aggregated, de-identified information (i.e. aggregated publicly) with partners, and they may author publications using

de-identified information. Further, there is a section that reviews how Vendor#2 protects your information which includes "strict guidelines and access controls" to protect individual-level data. They highlight that Vendor#2 complies with the Health Insurance Portability and Accountability Act (HIPAA) and they have a duty to notify clients of any confidentiality breaches. However it is also important to note that Vendor#2's Policy regarding corporate use of data indicates that, "If your employer has provided or paid for (in whole or in part) the Test, you acknowledge and agree that your de-identified Results and PHI may be anonymized and/or aggregated and returned to your employer or its designee (e.g., plan administrator or pharmacy benefits manager) as a data analytics resource."

As described previously, Vendor#3 believes their data protection policies are crucial to company success with clients. Of note, the promise that they will never sell or share the genetic data of a client is "front and center" on their website home page. Their website reviews information on HIPAA and GINA that is more consumer-friendly than what is contained in most other websites and they highlight areas that are potential sources of genetic discrimination (i.e. life insurance and employment) or present complex ethical dilemmas (i.e. familial DNA and consenting practices) that may arise.

Regarding corporate wellness programs, the Vendor#3 policy details that Vendor#3 will only release test results to employees and/or their authorized Vendor#3 providers (such as personal trainers, athletic coaches, nutritionists, etc). Employers have no access to any employee data apart from de-identified aggregate data upon request. Additionally, they highlight that all data is securely stored on a server, "not in the Cloud", and is password protected. They also note that "unlike other companies," they will never sell or transfer any personal data to third parties. V3 emphasized that Vendor#3 only sends the test report to the client whose DNA was tested, and nothing to the insurance company. He compared Vendor#3 to competitor companies who have a "flimsy consent policy that enables them to buy tests" for a nominal fee but "give up your genetic data to them for 10 years." He noted that Vendor#3 has no partners or shareholders who are part of big pharma data companies or insurance companies.

Last, V4 from Vendor#4 indicates that every client is provided with a consent form, usually in electronic form but with the option of a printed version. The consent details their general privacy policy, data storage safeguards, and de-identified sample retention policy. Their privacy policy states that any test results, personalized nutrition report, or information from the Vendor#4 website is not a substitute for medical advice or treatment. They state that only the individual has access to their genetic test results, and that a barcode is used by the laboratory during sample analysis to anonymously store the sample in case future testing is needed. The option to send a written request to destroy any remaining sample is provided in the privacy policy. Like other websites, they discuss measures taken to encrypt information that is transmitted over the Internet and describe their disclosure policy: "Genetic information will never be disclosed to a third party without written consent unless required by law." As in the Vendor#3 privacy policy, Vendor#4 lists the potential harms of sharing genetic information and further states that consumers may wish to seek legal advice to understand genetic information protections before sharing.

As with the vendors, both company leaders and participants from research organizations have concerns regarding privacy of genetic data. For example, one leader indicated that their health plan does sometimes cover genetic counseling, but there is reluctance from the company to advertise that they will cover this service because of the known fear that genetic information may be used for employment decisions (C1). Beliefs about privacy legislation are also seen as a barrier to implementation of NIBGT. For example, C1 mentioned that adding genetic testing for familial hypercholesterolemia as part of preventative benefits was declined because of fear of violating GINA. R1 similarly shared that there is fear that the employer will get access to an employee's genetic data through a wellness program. R2 feels clinical data in general and genetic data in particular are too much for employers to feel comfortable accessing and suggests that a hybrid situation might be possible if the employer has dedicated onsite medical clinics for employees.

Summary

We undertook case studies with four vendors that we classified into two groups based on the focus of their NIBGT (predominantly medically actionable vs predominately H&W) and the type of counseling services (genetics professionals or other professionals). This stratification was intended to facilitate comparisons across a spectrum of vendors offering NIBGT in a manner that either supported NHGRI's conceptualization²¹ of genetic testing in employer settings (medically actionable) or differed substantially from this framework (H&W). Across the four vendors, we assessed what tests and services are being sold, why and how they are being sold, and the various claims regarding value propositions.

Both Vendor#2 and Vendor#1 emphasize use of genetic tests with plausible links to clinical utility such as screening for inherited forms of cancer and familial hypercholesterolemia. They also discuss "end-to-end solutions" starting with employee engagement and education through testing, counseling and personalized care activation. In contrast, Vendor#3 and Vendor#4 promote testing in the areas of nutrition, fitness, stress skin health (H&W) and tend to distinguish this type of NIBGT from "medical" or "scary" genetic testing. These two companies also provide access to nutritionists and exercise specialists, but not experts in genetics.

Nevertheless, the rationale for adding genetic testing to wellness programs across the four vendors is remarkably similar. Vendors agreed that NIBGT, and genetic testing as a whole, is of interest to many individuals and can motivate those individuals to take control of their own health because the recommendations are "more personalized." A common theme heard from both the medically actionable and H&W vendors was that inclusion of NIBGT within a wellness program may serve as a market differentiator and ultimately help to attract and retain top talent. Both vendor groups also saw genetic testing as a way to potentially identify inherited health risks, motivate improved health practices, and ultimately improve employee health. Therefore, NIBGT was viewed as aligned with overall corporate wellness goals.

The medically actionable vendors and H&W vendors also share similarities in how they receive financial compensation for services provided. All four vendors primarily sell NIBGT as part of corporate wellness programs, which are distinct benefits from health insurance. The exception is Vendor#1 who facilitates insurance coverage for genetic tests that are clinically justified following evaluation and counseling by their staff of genetic counselors and medical geneticists. Our interviews reveal that self-insured employers generally offer NIBGT as part of wellness programs to employees at no or reduced cost, with employers paying vendors directly for these services under a variety of financial arrangements, such as fee for service or PMPE.

Another similarity across both medically actionable and H&W vendors is the types of factors that influence genetic testing uptake and participant engagement. Company culture as well as characteristics of the employee population such as age, industry segment, geographic location and union membership can influence an individual's purchasing decision. Regarding key factors that contribute to the success or challenges of implementing NIBGT within wellness programs, who is the ultimate decision-maker at a company appears to impact the success of implementation, with all vendor representatives agreeing involvement of C-suite personnel is crucial. Barriers to NIBGT adoption included a lack of data to justify the health and economic benefits claimed by vendors. For example, V2 indicated that there is not enough data to show ROI, while other participants pointed out that lack of outcomes data is problematic.

Medically actionable genetic testing outcomes can take a long time to manifest because of the nature of the phenotype of the genetic conditions, while for H&W genetic testing outcomes there is not always a validated way to measure effectiveness of test offerings such as nutrigenomics given the state of the science. The participants from Vendor#4, Vendor#1, and Vendor#2 all indicated that lack of genetics education, at multiple levels, is a barrier to implementation. In addition, Vendor#4 discussed how company leaders lack knowledge about coverage of NIBGT and need payment education. Vendor#1 indicated that education surrounding GINA and privacy also hinder employee testing uptake, while both Vendor#1 and Vendor#2 shared that physicians need education to understand how to care for patients based on genetic test results.

Value Proposition Claims:

All four vendors claim that use of NIBGT as part of wellness programs will lead to favorable impacts on both the organization and employees. For example, all vendors state that NIBGT will lead to lower long-term healthcare costs. However, none of the vendors provided substantiation for these claims. The two medically actionable vendors provided the most evidence regarding employee engagement and uptake, however only Vendor#2 provided data from studies that demonstrated the types of variants found from screening and whether individuals with pathogenic variant results would have otherwise met criteria for testing. Vendor#2 has also published lessons learned from implementing NIBGT with employers as well as with health systems and large research organizations. Medically actionable vendors also discussed ROI and VOI as ideal testing outcomes to demonstrate the value of NIBGT in employer-sponsored wellness programs. For example, demonstrating the impact of NIBGT

on health care spending, health outcomes and productivity (ROI), as well as employee satisfaction, morale, and holding a competitive edge over other companies (VOI). In comparison, H&W vendors primarily discussed health outcomes related to PGx testing and financial impacts related to lifestyle management. Of note, neither of the H&W vendors have conducted any studies involving their genetic testing products and services, nor is the evidence they cite related in any way to H&W tests. What appears to be happening is that some employer purchasers lack sufficient understanding of genetic testing to demand evidence of clinical utility, relying instead on marketing claims of personalization of wellness interventions based on genetics. In an effort to be innovative while also supporting general wellness program goals, employers who purchase NIBGT programs appear to find vendors' rationale for testing to be compelling (at least in the near-term) while waiting for the development of better evidence. The downside for employers and vendors that are making responsible efforts to implement medically actionable testing is that there are not easily accessible criteria to separate the wheat from the chaff.

Although both vendors and employers state that they want evidence of the clinical utility of NIBGT, obtaining reliable outcomes data is constrained by employer apprehensions regarding genetic data privacy protections and willingness to pool de-identified data across employers. The adequacy of GINA and genetic exceptionalism were common themes, and it was evident that all interviewees had some level of concern for how genetic data obtained as part of wellness programs would be used by the employee and employer. They indicate that a lack of employer understanding of the legality of genetic data utilization can lead to hesitancy about adopting these services into wellness programs. Strategies to address privacy concerns varied across the four vendors. The two H&W vendors recognized the marketing appeal of strong, clear statements regarding genetic privacy protections; for example, both vendor websites declared that they never share genetic test data with anyone other than the employee. Further, during the interviews, both described privacy protections as important selling points to consumers. Vendor#3 specifically capitalizes on privacy concerns by marketing data protections and privacy as a primary business model that distinguishes them from competitors.

Participants in the medically actionable vendor group described their approach to managing genetic privacy by only sharing aggregate data with employers. Notably, Vendor#2's privacy policy specifically highlights that if an employer has provided any financial compensation for a test, then the employee agrees that his/her de-identified results and personal health information may be anonymized and/or aggregated and returned to the employer. Both the medically actionable vendors have privacy policies that center on PHI, their legal obligation to maintain the privacy of PHI, and how setting up an account with said vendor gives them access to PHI. Vendor#1's policy details that marketing activities may utilize PHI and offer an opt out, which places the responsibility on the employee to limit the vendors use of their data. Given these positions, the medically actionable vendors are set up to pursue evaluations of their employer programs if they choose to do so.

Limitations

This research has several limitations. We aimed to recruit a larger number of participants in three key stakeholder categories in order to gather an abundance of data and reach saturation. We were unable to secure a larger sample of participants, in part due to the timing of COVID-19 in relation to our recruitment period, but also because of reluctance to participate as interviewees despite extensive outreach efforts using multiple approaches (e.g., using emails, webinars). This may indicate that NIBGT was a lower priority for these recruits at this time. While there was substantial agreement on many of the themes, given the small number of participants in each category, it is unlikely that saturation was reached. Therefore, we refocused our analysis in the form of a case study post hoc on the vendors, using rich data from company leaders and researchers to add context and perspective. As such, our conclusions cannot be generalized to all genetic test vendors. Further research is needed to gain a broader perspective regarding how and why self-insured employers are making genetic testing services available to their employees and subsequent employee outcomes, to understand the main reasons employers pursue studies of wellness programs and strategies to overcome barriers to conducting and analyzing these studies.

Conclusion

In sum, while the four vendors clearly differed in their test offerings and access to healthcare professionals, they expressed similar rationales to employers for purchasing NIBGT. They also all recognized that the evidentiary barriers to entry are lower with wellness program decision-makers as compared to health insurance companies where decision-makers are focused on meeting criteria for medical necessity. There are also similarities in the manner of financial compensation for wellness programs that include NIBGT, except that Vendor#1 only offers education and counseling and refers employees to a network of approved laboratories to obtain genetic testing. The barriers and enablers to NIBGT implementation as described by interviewees are also comparable across vendors, with privacy concerns and the need for education regarding genetic testing highlighted as particularly important barriers. The biggest differences occurred in whether and how vendors cited evidence for their marketing claims. The medically actionable vendors made efforts to cite evidence of why genetic testing for inherited conditions was scientifically credible in a screening context with employees. The H&W vendors cited evidence that was unrelated to their claims and potentially misleading. As of the time of the interviews, they also have no plans to measure the impact of their testing and counseling on process or outcome measures. Vendor#2 (V2) has made the most effort to both assess and present their process evaluations at scientific meetings which involve peer review.

Based on our discussions with all study participants, there is clear support for including NIBGT within wellness programs. For example, R1 stated that, “[genetic testing] has the opportunity to engage employees in taking charge of their health, and in particular, engaging employees who might not have taken advantage of any other wellness offering in the past because it is so interesting to them.” This interest in employee engagement and personalization of wellness interventions explains in large part why employers purchase these services for their employees.

However, NIBGT in wellness programs has had variable uptake and limited evidence of effectiveness as described by these vendors, company leaders and researchers. Though vendors have been successful in securing employer clients as early adopters, employer implementation and employee acceptance can be hindered by several barriers, some of which are unique to genetic testing in an otherwise healthy population.

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Appendix C

Vendor Interview Guide

Project SAGE: Stakeholders Assessing Genetics with Employers

Project funder: National Human Genome Research Institute

Project lead: Patricia Deverka, MD, Geisinger Research

Purpose of the study: Understand the level of interest, opportunities, challenges and real-world experience associated with implementing non-indication based genetic testing as part of employer-sponsored wellness programs or health insurance. This information will be obtained through semi-structured interviews.

Read the following statement:

Before we proceed with the interview, I want to confirm that you understand the purpose of the research and have an opportunity to ask any questions you may have. You understand that, unless you refuse, your interview will be recorded, and any data collected during the study may be looked at by other researchers or regulatory authorities. However, identifying data, such as your name, your employer, and locations will be removed from transcriptions and notes. Recordings will be kept securely, only accessed by select members of the research team, and destroyed at the conclusion of the analysis. You have the right to leave the interview at any time or refuse to answer any questions. Do I have your permission to proceed with the interview?

Before we proceed with the interview, I'd like to ask you a few demographic questions:

- 1. What is your job title?***
- 2. Time in role?***
- 3. Time at company***

And a few questions about your company:

- 1. Company start date?***
 - 2. Time in this market segment?***
 - 3. Number of employer clients?***
 - 4. National or regional presence?***
-

Interview questions:

Definition of employee genetic testing:

Voluntary genetic testing in employees with or without a personal or family history of genetic disease. The purpose of testing is to identify inherited risks that are evidence-based and medically actionable. The goals of testing may include employee engagement in their health, greater understanding of how genetics can affect health, enhanced well-being, early identification of health risks, safer and more effective medication use, and potential cost savings from improved preventive care.

- ***Clarify that medically actionable variants includes disease risk and PGx***
- ***Health-related physical and behavioral traits/conditions include nutrition, fitness, sleep, stress***

Please provide your feedback regarding the definition of non-indication based genetic testing for employees. Anything that you would change or add? Why?

1. ***What are the types of genetic tests that you offer to employers?***
2. ***What are the factors that led you to choose these types of tests?***
3. ***Can you provide access to examples of a typical client report (if available)?***
4. ***What types of wrap-around services do you provide in addition to testing?***

Now I'd like to ask you a few questions about who purchases your services and why.

1. ***Why do self-insured employers purchase or otherwise make available genetic testing services for their employees?***
 - ***Probe: How does non-indication based genetic testing support health and wellness goals of employers? Of employees?***
2. ***Are there certain types of employers that tend to offer these services to their employees?***
 - ***Industry***
 - ***Geography***
 - ***Self-insured***
3. ***Do any of these factors influence the purchasing decision?***
 - ***Internal factors - Employee demand, fit with organizational goals re employee health and wellness, Employer understanding of federal and state-by-state legal requirements related to genetics and wellness programs, corporate decision-making structure***
 - ***External factors - market competition for employees, need to retain top talent, state of genetic evidence supporting non-indication based genetic testing, laws governing privacy, laws governing uses of genetic data by state***

4. *Are there advantages or disadvantages associated with offering these services as part of wellness programs?*
5. *What is the process for employers to 'purchase' or otherwise make available non-indication based genetic testing services for their employees?*
 - *Who are the key employer decision-makers involved in this process?*
 - *What are their role and title in their organization?*
 - *How do federal and state laws governing genetic testing and wellness programs influence employer decision-making if at all?*

Now I'd like to ask you a few questions about how you demonstrate the value of your services to clients:

1. *What types of reporting or outcomes do employers tend to ask for to assess the value of offering these services to their employees?*
2. *Has your company evaluated the impact of these service? What do you typically measure in terms of impact?*
 - *For example, the impact on employee health, quality of life, productivity, absenteeism, or health care costs for any of your clients?*
 - *If yes, can you describe your key findings now?*
 - *Can you provide access to any written reports?*
 - *If no, do you have any anecdotal evidence of general findings?*
3. *If feasibility or resources were not an issue, what types of outcomes or reporting or evidence would you like to provide to your clients to support the value proposition of these types of services?*
4. *What has been the range of uptake of genetic testing by employees?*
 - *By uptake, I am referring to a range of potential interactions, e.g., employees may express interest in genetic testing but not follow through with testing; scheduling a test, engaging in pre-and/or post-test counseling; seeking reimbursement for a test*
5. *What have been the lessons learned by your company regarding implementation?*
 - *What barriers get in the way of employees taking advantage of these services?*
 - *What enablers support employees taking advantage of these services?*
6. *Would you be able to provide the names of employer clients that may be willing to be interviewed?*

Thank you for participating in this interview. I'd like to collect some information to ensure that we can send your honorarium promptly:

Name, address for mailing check.

CMO Interview Guide

Project SAGE: Stakeholders Assessing Genetics with Employers

Project Funder: National Human Genome Research Institute

Purpose of the study: Understand the level of interest, opportunities, challenges and real-world experience associated with implementing non-indication based genetic testing as part of employer-sponsored wellness programs or health insurance. This information will be obtained through telephone-based semi-structured interviews with experts such as you. We are asking you to represent your organization's experience in response to the interview questions. In circumstances where your organization has limited or no experience, we ask you to represent your own professional experience.

Employee Genetic Testing: *Voluntary, health-related genetic testing in employees with or without a personal or family history of genetic disease. The purpose of testing is to identify inherited risks that are evidence-based and medically actionable. The hypothesized goals of testing may include employee engagement in their health, greater understanding of how genetics can affect health, enhanced well-being, early identification of health risks, safer and more effective medication use, and potential cost savings from improved preventive care.*

Before we proceed with the interview, I want to confirm that you understand the purpose of the research and have an opportunity to ask any questions you may have. You understand that, unless you refuse, your interview will be recorded and any data collected during the study may be looked at by other researchers or regulatory authorities. However, identifying data, such as your name, your employer, and locations will be removed from transcriptions and notes. Recordings will be kept securely, only accessed by select members of the research team, and destroyed at the conclusion of the analysis no later than the end of August, 2020. You have the right to leave the interview at any time or refuse to answer any questions. Do I have your permission to proceed with the interview?

Job Title:
Job Role:
Years at Company:
Years in Role:

Interview questions:

1. *What is your general experience or familiarity with non-indication based genetic testing for employees at self-insured employers?*
2. *What is your understanding of the evidence supporting a relationship between genetic testing and employee health?*
3. *How does non-indication based genetic testing support the health and wellness goals of employers? Of employees?*
4. *What are the potential benefits of offering non-indication based genetic testing as part of company-sponsored wellness programs?*
5. *What are the potential challenges of offering genetic testing as part of company-sponsored wellness programs?*

Probes for potential benefits/challenges:

- *Type of employer (industry segment)*
 - *Type of employee (age, educational background and role in company)*
 - *How program is paid for (part of wellness program, part of health insurance benefit, out-of-pocket costs)*
 - *How communication about offering genetic testing is conducted*
 - *Internal factors - Employee demand, fit with organizational goals re employee health and wellness, CMO understanding of federal and state-by-state legal requirements related to genetics, corporate decision-making structure*
 - ***External factors*** – *market competition for employees, need to retain top talent, state of genetic evidence supporting non-indication based genetic testing, laws governing privacy, laws governing uses of genetic data by state*
6. *What types of outcome measures would be useful to you to inform your assessment of the value of non-indication based genetic testing in wellness programs?*

For CMOs at companies that currently offer non-indication based genetic testing:

1. *If your organization currently offers population genetic testing for your employees, what are the categories of tests that are included?*
2. *What were the factors that led your organization to choose these categories?*
3. *Why do self-insured employers purchase or otherwise make available genetic testing services for their employees?*

- 4. Describe the decision-making process that led to your organization making genetic testing services available to employees?**
 - *Who were the decision-makers involved in this process?*
- 5. What is your current assessment of the net balance of benefits and challenges affecting implementation of genetic testing for employees?**
 - *What are the key factors from your perspective that would affect this balance?*
 - *What have been the lessons learned regarding implementation?*
- 6. What has been the uptake of genetic testing by employees?**
- 7. Are there certain types of employees that seem to be more or less interested in this type of offering?**
- 8. Are you aware of any data regarding the impact of these services on employee health, quality of life, productivity, absenteeism, or health care costs?**
 - *If yes, can you share these findings now?*
 - *Can you provide access to any written reports?*
 - *If no, do you have any anecdotal evidence of general findings?*

Researcher Interview Guide

Project SAGE: Stakeholders Assessing Genetics with Employers

Project funder: National Human Genome Research Institute

Purpose of the study: Understand the level of interest, opportunities, challenges and real-world experience associated with implementing and evaluating non-indication based genetic testing as part of employer-sponsored wellness programs. This information will be obtained through telephone-based semi-structured interviews with experts such as you. Given the importance of evaluating the health and economic impact of non-indication based genetic testing for employees, we are interviewing researchers with experience evaluating employee health and wellness programs. We are asking you to represent your experience as a researcher in response to the interview questions.

Definition of non-indication based genetic testing for employees: ***Voluntary, health-related genetic testing in employees with or without a personal or family history of genetic disease. The purpose of testing is to identify inherited risks that are evidence-based and medically actionable. The hypothesized goals of testing may include employee engagement in their health, greater understanding of how genetics can affect health, enhanced well-being, early identification of health risks, safer and more effective medication use, and potential cost savings from improved preventive care.***

Before we proceed with the interview, I want to confirm that you understand the purpose of the research and have an opportunity to ask any questions you may have. You understand that, unless you refuse, your interview will be recorded, and any data collected during the study may be looked at by other researchers or regulatory authorities. However, identifying data, such as your name, your employer, and locations will be removed from transcriptions and notes. Recordings will be kept securely, only accessed by select members of the research team, and destroyed at the conclusion of the analysis no later than the end of August, 2020. You have the right to leave the interview at any time or refuse to answer any questions. Do I have your permission to proceed with the interview?

Interview questions:

- 1. Please provide your feedback regarding the definition of non-indication based genetic testing for employees. Anything that you would change or add? Why?***
 - To let you know, as we have already discussed the 'non-indication based genetic testing' definition together, I will be referring to 'employee genetic testing' as 'genetic testing services' throughout the rest of our discussion.*
- 2. How might genetic testing services support health and wellness goals of employers? Of employees?***

3. *Are you aware of any wellness program companies that currently include employee genetic testing as part of their program? As a stand-alone intervention?*
4. *Are you aware of any employers that currently offer these types of testing services to employees?*
 - *If yes, have these employers discussed the need for research regarding impact of genetic testing?*

The next set of questions relate to your experiences with conducting evaluations of wellness programs with employers.

1. *What are the main reasons employers pursue evaluations/studies of wellness programs?*
2. *What are the typical sources of funding for wellness program evaluations? Any sources viewed as more or less desirable from an employer perspective?*
3. *How feasible is it to conduct wellness program evaluation with a single employer (can have multiple worksites)? Please describe the process you followed to initiate, conduct and publish research on wellness programs with employers.*
4. *How feasible is randomization?*
5. *How feasible is it to conduct wellness program evaluations across multiple employers? Please describe any incremental challenges of working with multiple employers*
6. *What are the wellness program study outcomes of greatest interest to employers (e.g., self-reported health and behaviors, clinical outcomes, healthcare resource utilization and spending, employment outcomes)?*
7. *Are easy or difficult is it to gain access to the data sources for collecting and evaluating these study measures/outcomes?*
 - *What are the employer concerns?*
 - *What are the employee concerns?*
8. *What have been the biggest challenges of developing a data sharing plan for employer wellness program evaluations?*
9. *How have you overcome these challenges?*
10. *Are there best practices?*
11. *Are all your past wellness program evaluations publicly available? If not, what are the reasons for not sharing the results?*
12. *Please describe any good governance practices that you have used in conducting research with employers*
13. *Do you think that genetic data presents additional challenges to wellness program evaluation?*
 - *Can you describe any proactive steps that should be taken to mitigate these potential concerns?*

Appendix D



To: Marc Williams, MD, and Patricia Deverka, MD, MBE
From: Jennifer K. Wagner, JD, PhD
Date: November 29, 2019
Subject: Relevant Law & Policy Issues for “Stakeholders Assessing Genetics with Employers” (SAGE)

RESEARCH MEMORANDUM

I. Background

This memorandum is the culmination of a narrowly framed law and policy research project to identify and summarize relevant legal and policy issues if employers were to pursue the implementation of a wellness program for employees that incorporated genetic testing. Specifically included are an overview of federal law requirements for wellness programs and state issues related to employers’ acquisition and use of genetic testing and genetic information of employees. Standard legal and policy methodologies were used, and research was performed using Westlaw Next. The federal laws summarized here are the exclusive basis for this memorandum. Other federal and state laws that might be relevant and affect wellness program compliance were not reviewed as part of this work.

This research was conducted as part of the “RISE Supplement: Employer Genetic Testing Consortium,” a project funded by the National Human Genome Research Institute (NHGRI) Grant No. R01HG009694-03S1 (Peterson, PI). The author is solely responsible for the content. The content is provided as-is and for informational purposes only. Nothing in this memo shall be construed as legal advice or the substitute for a legal opinion on the compliance of any wellness program under development or consideration for implementation. In-line references have been minimized to improve readability.

II. Summary of Federal Laws Affecting the Design and Implementation of Wellness Programs

a. *Genetic Information Nondiscrimination Act of 2008 (GINA)*

The Genetic Information Nondiscrimination Act (GINA) protects employees from genetic discrimination from employers. Title I relates to health insurance, and Title II relates to employment. Both titles are potentially implicated by employer-sponsored wellness programs. Bradley Areheart and Jessica Roberts (2019) reported that, in the 10+ years of GINA, there have been only 48 unique court cases resolved involving GINA, 30 of which hinged on the application of GINA. Courts faced with deciding alleged GINA violations have stumbled on definitional issues (often getting it wrong). Definitions of particular importance for compliance are *family member*; *family medical history*; *genetic information*; *genetic monitoring*; *genetic services*; *genetic test*; and *manifestation or manifested*. *Family member*, for example, includes not only those related by blood but also those individuals who become related through marriage or adoption.

GINA Title II makes it unlawful for employers to – for any reason and subject to strict liability – acquire genetic information of employees. Contained in this statutory ban on genetic information acquisition, however, were six exceptions, one of which is a wellness program exception providing as follows:

“Where—

(A) health or genetic services are offered by the employer, including such services offered as part of a wellness program;

(B) the employee provides prior, knowing, voluntary, and written authorization;

(C) only the employee (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and

(D) any individually identifiable genetic information provided under subparagraph (C) in connection with the services provided under subparagraph (A) is only available for purposes of such services and shall not be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees;”

42 USC 2000ff-1. Sec. 202(b)(2). When the Final Rules for GINA Title II were issued in 2010 by the Equal Employment Opportunity Commission (EEOC), the agency addressed concerns about inducements to participate and considered four different approaches to “voluntariness:”

1. Issue incentive caps similar to those applicable under HIPAA;
2. Issue a rule that combines elements of HIPAA and ADA rules (where a program is voluntary if it does not require participation and does not penalize non-participation along with a determination that incentives below the HIPAA 20% cost of coverage cap would not be considered a penalty);
3. Issue a rule allowing incentives but not indicating whether inducements should have any limitation; and
4. Issue a rule banning incentives for participation in wellness programs that include collection of genetic information (including family medical history inquiries).

Recognizing that employers offering wellness programs have to comply with Title II and the health plans themselves must comply with Title I, EEOC offered examples to illustrate how incentives may be used. The final regulations implementing the wellness program exception in 2010 contained the following verbatim requirements:

(i) This exception applies only where—

(A) The provision of genetic information by the individual is voluntary, meaning the covered entity neither requires the individual to provide genetic information nor penalizes those who choose not to provide it;

(B) The individual provides prior knowing, voluntary, and written authorization, which may include authorization in electronic format. This requirement is only met if the covered entity uses an authorization form that:

(1) Is written so that the individual from whom the genetic information is being obtained is reasonably likely to understand it;

(2) Describes the type of genetic information that will be obtained and the general purposes for which it will be used; and

(3) Describes the restrictions on disclosure of genetic information;

(C) Individually identifiable genetic information is provided only to the individual (or family member if the family member is receiving genetic services) and the licensed health care professionals or board certified genetic counselors involved in providing such services, and is not accessible to managers, supervisors, or others who make employment decisions, or to anyone else in the workplace; and

(D) Any individually identifiable genetic information provided under paragraph (b)(2) of this section is only available for purposes of such services and is not disclosed to the covered entity except in aggregate terms that do not disclose the identity of specific individuals (a covered entity will not violate the requirement that it receive information only in aggregate terms if it receives information that, for reasons outside the control of the provider or the covered entity (such as the small number of participants), makes the genetic information of a particular individual readily identifiable with no effort on the covered entity’s part).

75 Fed. Reg. 68935. (See also 75 Fed. Reg. 68922-68924; §1635.8(b)(2)). The regulatory provisions continue with an explanation that financial incentives cannot be used to induce employees to provide genetic information; that financial incentives may be used to help employees who have voluntarily disclosed genetic

information to meet health outcome goals only if those incentives are also provided to employees whose lifestyle choices (rather than genetic information) put them at risk for the same identified conditions; and that GINA does not relax the employers' obligations to comply with ADA and HIPAA nondiscrimination requirements, which include making reasonable accommodations to enable similar situated individuals to enjoy equal benefits and privileges of employment (by adjusting the plan) or allowing a reasonable alternative to or waiver of the specific program requirements. 75 Fed. Reg. 68935-68936. Regulatory updates were issued in 2016, but the challenged portions have since been vacated (see *infra*). The EEOC website contains additional information (such as FAQs, webcasts, etc.); however, caution is warranted in light of the removal of the 2016 rules.

In sum, to comply with GINA the wellness program must be reasonably designed to promote health or prevent disease; the provision of information must be voluntary (i.e., genetic testing cannot be mandatory and people cannot be penalized for not participating in those components); prior knowing, voluntary, and written authorization is required; the disclosures must be limited (individual-level raw data and interpretation only to the licensed professionals and individual employee; employers can at most gain access to aggregated information); and the information cannot be used for *any* purpose other than the wellness program. Incentives can be coercive and undue influences, making a wellness program lose its voluntariness.

b. Americans with Disabilities Act (ADA)

Title I of the Americans with Disabilities Act (ADA) protects qualified individuals from discrimination by employers on the basis of a disability with regard to hiring, promotions, firing, compensation, training, and other terms, conditions, and privileges of employment. *Disability* has a specific meaning and can refer to whether a person

- (1) has a physical or mental impairment that substantially limits one or more major life activities;
- (2) has a record of such an impairment, or
- (3) is regarded as having such an impairment (perceived to be impaired).

The ADA, an anti-discrimination statute based in non-subordination theory rather than mere anti-classification theory (which underlies GINA) not only requires non-discrimination but also use of affirmative action measures known as "reasonable accommodations" when necessary. To protect employees, ADA generally prohibits disability-related inquiries and examinations unless it is "job-related and consistent with business necessity." There is an exception for "voluntary" medical examinations and inquiries that are part of a health program available to employees. (See Sec. 102 (c)(4)).

The ADA requires that wellness programs be "reasonably designed to promote health or prevent disease." A program satisfies this standard if the following conditions are met: (1) it has a "reasonable chance of improving the health of, or preventing disease in, participating employees," and (2) "it is not overly burdensome"; (3) it is "not a subterfuge for violating the ADA or other laws prohibiting employment discrimination;" and (4) it "is not highly suspect in the method chosen to promote health and prevent disease." 29 C.F.R. §1630.14. The Under the ADA, employers cannot require employees "to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information (except to the extent permitted by this part to carry out specific activities related to the wellness program)." Voluntariness of the wellness program is critical, and programs will be considered voluntary so long as they meet the following requirements:

1. Employees are not required to participate;
2. Employees who do not participate cannot be denied coverage under any of the health plans or benefits;
3. Employers do not take any adverse actions against employees (i.e., do not retaliate against, "coerce, intimidate, or threaten");
4. Employers provide notice that is written such that it is reasonably likely the employee will understand it and describing not only the type of information to be collected, purpose for its collection, and specific uses of it once collected but also the restrictions on disclosures.

Like GINA, ADA does not permit employers to have access beyond potential aggregated data that is not reasonably likely to disclose the employees' identities. As with resources on GINA, the EEOC website contains

additional information (such as FAQs, webcasts, etc.); however, caution is warranted in light of the removal of the 2016 rules. Disability and genetic rights advocates (such as Erin Oliphant and Sharon Terry) have expressed concern that wellness programs are merely “data mining operations” and that employers have disingenuously turned to “sharing” data with business partners to evade the ADA’s restriction against forcing employees to agree to sale or transfer of their otherwise protected health information.

c. Health Information Portability and Accountability Act (HIPAA) as amended by the Patient Protection and Affordable Care Act (ACA)

If a wellness program is itself a group health plan or part of a group health plan, the terms must comply with HIPAA, including its privacy and security rules. Business associate agreements (BAAs) would be appropriate and necessary when interacting with third-party wellness program providers.

ACA generally prohibited discrimination on the basis of health status or pre-existing conditions but included a carve out exception to encourage participation in wellness programs that meet certain specifications. The relevant sections of ACA are §1001 (reporting requirements), §1201 (prohibition on discrimination on the basis of health status), §4303 (technical assistance for employer-sponsored wellness programs), and §10408 (workplace wellness grants). Specifically, ACA §1201 codified the HIPAA wellness program regulations—29 CFR §2590.702(b)(1)(ii), 45 CFR §146.121(b)(1)(ii), and 26 CFR §54.9802.1(b)(1)(ii)—that prohibit discrimination on the basis of health status. These regulations notably distinguish between “Participatory” wellness programs and “Health-contingent” wellness programs (with the latter consisting of two types: “Activity-only” or “Outcome-based”) and set different standards for each. There is no cap on financial incentives for “participatory” wellness programs. The cap on financial incentives for health-contingent wellness programs set by HIPAA (i.e., before the ACA) was 20% of the cost of coverage; however, with the passage of the ACA, this cap was increased to 30% and further expanded to allow for an additional 20% incentive if the program involves tobacco prevention and cessation (i.e., a cap of 50% in those situations).

For a health-contingent wellness program to be lawful under HIPAA/ACA, it must be (1) “reasonably designed to promote health or prevent disease” (i.e., that “it is not overly burdensome” or “a subterfuge for discriminating”); (2) all individuals must have at least one opportunity each year to qualify; (3) the size of the award must be below the applicable cap (i.e., which is based on the total amount of employer and employee contributes towards the cost of coverage for which the employee and any dependents are enrolled); and (4) the program’s full reward must be available to “all similarly situated individuals” (i.e., if an individual does not meet an initial measurement, test, or screening standard, there must be a reasonable alternative standard and/or opportunity for a waiver). The ACA does allow for employer-sponsored wellness programs to treat individuals with adverse health factors *more* favorably (e.g., if a plan allows participation of dependent children until age 26 but extends participation eligibility to dependent children with disabilities beyond age 26).

In essence, GINA stipulates when employer-sponsored wellness programs may incorporate genetic testing or information without being unlawfully discriminatory, and the ACA stipulates what financial incentives are available to employers to encourage participation in wellness programs. The Congressional Research Service has concluded that it is possible for employers to comply with both GINA and ACA wellness program requirements and that these provisions are complementary rather than in conflict with one another (See Sarata, Jones, and Staman 2011, Pp 6-7). Scholars concluded similarly, with Hudson and Pollitz likening one set of rules as speed limits and the other set of rules as stop-for-pedestrian signs, both of which drivers can and must obey.

Type of Wellness Program	Definition	Non-Discrimination Requirements
Participatory Wellness Program	“If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward), the wellness program is a participatory wellness program.” 26 CFR §54.9802.1(f)(1)(ii)	So long as the program “is made available to all similarly situated individuals, regardless of health status” it is considered not discriminatory. 26 CFR §54.9802.1(f)(2)
Health-Contingent Wellness Program – Activity-Only	“An activity-only wellness program is a type of health-contingent wellness program that requires an individual to perform or complete an activity related to a health factor in order to obtain a reward but does not require the individual to attain or maintain a specific health outcome.” 26 CFR §54.9802.1(f)(1)(iv)	In order to be non-discriminatory, the program must meet requirements for the frequency of opportunities to qualify; the size of the reward/incentive; a reasonable design to promote health or prevent disease; and allow the full reward to all similarly situated individuals (through offering of reasonable alternative standards or waiver options). 26 CFR §54.9802.1(f)(3)
Health-Contingent Wellness Program – Outcome-Based	“An outcome-based wellness program is a type of health-contingent wellness program that requires an individual to attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward...” 26 CFR §54.9802.1(f)(1)(v)	In order to be non-discriminatory, the program must meet requirements for the frequency of opportunities to qualify; the size of the reward/incentive; a reasonable design to promote health or prevent disease; and allow the full reward to all similarly situated individuals (through offering of reasonable alternative standards or waiver options). 26 CFR §54.9802.1(f)(4)

d. Unsettled regulatory issues

The implementation of GINA and the ACA has been plagued with controversy, as the EEOC faced fierce criticism and opposition to its proposed and final rules from professional genetic societies as well as advocacy and business groups. When the rules were issued, they were immediately challenged by the AARP, which initiated litigation in the D.C. District Court.

At “central issue” was the balancing of the nondiscrimination rights afforded under GINA and ADA and the promotion of health via wellness programs under ACA, a task of reconciliation that is/was ultimately the EEOC’s responsibility. A key question was whether incentives under ACA were permissible when the wellness programs implicate GINA or ADA and what is “voluntary” (an element neither defined by the GINA nor ADA statutes but a prerequisite to lawfulness). AARP argued that provision of incentives involving disclosures of GINA- and ADA-protected information would render wellness program involuntary. In the initial rules issued (see EEOC enforcement guidance 2000 on ADA and EEOC 2010 regulations on GINA), the EEOC had taken the position that incentives could not be tied to the employee’s disclosure of GINA- or ADA-protected information, but the new rules issued in 2016 reversed this position. Additionally, the new incentive limits were applied to both participatory and health-contingent wellness programs (whereas the prior 2013 HIPAA regulations only capped health-contingent wellness programs). AARP argued that the EEOC changed its

position and also set the 30% cap on incentives arbitrarily without sufficient explanation that such incentives would not render the plan coercive and involuntary. AARP further argued the EEOC had not adequately addressed the public comments in opposition to the proposed rules and that the rules were internally inconsistent (changing the definition of “genetic information” and distinguishing different types of genetic information when it indicated it would allow collection of an employee’s spouse’s medical information, which is *by statutory definition* included as the employee’s genetic information).

In August 2017 the Court had found that the EEOC did not provide any reasonable explanation for its issuance of rules that would allow employer-sponsored wellness programs to provide discounts (or penalties) of up to 30% of the health coverage costs for providing (or refusing to provide) certain medical information and alter the meaning of “voluntary.” In December 2017, the Court was unmoved by the EEOC’s suggestion that it planned to issue final rules in October 2019 and, instead, decided to vacate the challenged portion of the rules given its concerns about the “potentially widespread disruption and confusion” that could ensue and its concurrent belief that by vacating the rules effective January 1, 2019 the 2019 wellness program plans could be developed without “substantial disruptive effects.” The Court warned the EEOC,

“Because the Court issued its summary judgment decision in August 2017, EEOC will thus have over sixteen months to come up with interim or new permanent rules by the time the vacatur takes place. The Court will also hold EEOC to its intended deadline of August 2018 for the issuance of a proposed rulemaking. But an agency process that will not generate applicable rules until 2021 is unacceptable. Therefore, EEOC is strongly encouraged to move up its deadline for issuing the notice of proposed rulemaking, and to engage in any other measures necessary to ensure that its new rules can be applied well before the current estimate of sometime in 2021.” (292 F. Supp. 3d at 245, internal citations omitted).

Despite its assertion to the D.C. District Court that final rules would issue in October 2019, the EEOC has shown little urgency to replace the vacated rules on wellness programs under GINA and the ADA. However, the EEOC has placed the item on their regulatory agenda for Fall 2019, and proposed rules could be expected as early as January 2020. As of the date of this memo, no proposed text for interim or final rules has yet been released to the public. The statutory protections remain in place despite the regulatory uncertainty following the vacation of the challenged portions of the rules on wellness programs set by GINA and ACA. At least for now, wellness programs involving disability-related inquiries or medical examinations (health risk assessments, biometric screenings, etc.) can be considered “voluntary” so long as (1) employees are not required to participate; (2) the employer does not deny coverage or limit benefits to those employees who don’t participate; (3) the employer does not take any retaliatory actions (adverse employment decisions or interference, coercion, intimidation, etc.); and (4) the employer provides a detailed confidentiality notice that meets specifications. What remains unclear is whether incentives tied to the GINA- or ADA-protected activities (e.g., genetic testing or genetic information requests or disability-related inquiries, respectively) would be permitted.

e. Notable Caselaw

A few cases brought by the EEOC to enforce nondiscrimination in employer-sponsored wellness programs caught employers’ attention prior to the issuance of the now vacated 2016 rules. These include EEOC v. Flambeau, Inc.; EEOC v. Orion Energy Systems; and EEOC v. Honeywell Int’l Inc.. In Flambeau, Inc., the Western District of Wisconsin considered actions of an employer who offered a self-insured health plan (with coverage a benefit but not a requirement of employment) and launched a wellness program involving a health risk assessment (HRA) consisting of a questionnaire and blood analysis. Flambeau offered a \$600 incentive to employees participating and completing the HRA. The company later changed the program, discontinuing the \$600 incentive and instead only offering health insurance coverage to those who participate in the wellness program (i.e., making the wellness program mandatory). The Court held that the ADA safe harbor provision could apply to employer-sponsored wellness programs and further ruled that the specifications of this particular wellness program was not subterfuge to deny employees their right to disability-related informational privacy. In Orion, at issue was whether an employer could require employees who refused to complete a health risk

assessment to pay 100% of their monthly premium for the self-insured plan. Orion (employer) argued that its wellness program was either within the ADA safe harbor or it was voluntary (and, either way, therefore lawful). The wellness program consisted of an attestation that the employee is not a smoker, agreement to exercise 16 time per month at Orion's fitness center, and completion of a health risk assessment, which included a questionnaire and blood analysis. The Eastern District of Wisconsin ruled that the safe harbor did not apply (agreeing with the EEOC that ADA safe harbor was not intended to apply to wellness programs that require involuntary medical exams and inquiries) but also ruled that the wellness program was voluntary. In Honeywell, the EEOC sought a preliminary injunction against Honeywell's issuance of penalties (in the form of reduced contributions to employee Health Savings Accounts) against employees who refuse biometric testing as part of their employer-sponsored wellness program. The program used Quest Diagnostics to perform blood testing, the results of which Quest relay to a third-party actuarial firm and subsequently provides aggregated data to Honeywell directly. Honeywell successfully defended the suit by arguing its plan fell into the ADA safe harbor provision in 42 U.S.C. §12201(c)(2) or, in the alternative, was voluntary. This case also illustrates courts interpreting GINA contrary to its own definitions, as Honeywell argued that the use of a blood test for an employee spouse was not a *genetic test* (overlooking the specific definition of protected *genetic information* set by GINA, which is broader than *genetic tests*). The District of Minnesota Court lamented, "great uncertainty persists in regard to how the ACA, ADA, and other federal statutes such as GINA are intended to interact." (at 5).

There have not been many reported court decisions involving employer-sponsored wellness programs in recent years, but there have been some notable exceptions. As previously mentioned, AARP initiated a lawsuit that ultimately resulted in the final regulations for GINA and the ADA regarding employer-sponsored wellness programs to be vacated and removed. At least four other lawsuits have been on point. Two cases in the Seventh Circuit involving the same plaintiff-employee who alleged that the employer-sponsored wellness program violated his rights by charging him a surcharge after he refused, because of privacy concerns, to complete a medical screening and questionnaire. The defendants were ACS Human Services LLC (employer), Xerox Corporation (an affiliate of the employer with significant input into employee-related health insurance decisions), and Quest Diagnostics, Inc. (vendor authorized by the employer to administer the health benefits and online access to health information). The case against ACS and Xerox was dismissed, and the plaintiff-employee was compelled to resolve his dispute via arbitration (per the terms of the employment contract). The case against Quest failed, as it was unsuccessfully based upon the argument that Quest was an "employer" for purposes of the statutory violations through its control of a portion of the plaintiff-employee's wages. The other two cases involved the employer-sponsored wellness program of the Fire Department for the City of San Antonio, Texas. An employee (Ortiz) alleged the mandatory wellness program violated GINA (the plaintiff separately alleged violations of Title VII of the Civil Rights Act) and that the employer engaged in retaliation by placing him on alternate duty (which cost him potential overtime wages) for his refusal to engage in a GINA-protected activity (i.e., participation in the wellness program). The program was adopted for the stated purpose "to provide early detection of serious medical conditions and encourage better health, thereby allowing ... employees to do their job more safely and effectively" and included a job-related medical evaluation that included a medical history, complete physical exam, blood and urine tests, and hearing, vision, and lung capacity tests. Summary judgment was awarded to the City, as (1) there was nothing in the record to indicate that genetic testing or information was requested or required as part of the mandatory wellness program or that the employee was discriminated against on the basis of any genetic information and (2) the City provided a legitimate unrelated business reason for the alternate duty. The Fifth Circuit Court of Appeals upheld the decision to grant summary judgment for the City. A second employee sued shortly thereafter alleging that the City's fire department violated GINA by requiring him to provide personal health information without a voluntary and written authorization and by retaliating against his failure to comply with the mandatory wellness program. The court rejected claims that the mandatory wellness program violated GINA because there was no evidence on the record indicating that the blood tests within the wellness program involved analysis of DNA, RNA, chromosomes, proteins, metabolites, genotypes, mutations, or chromosomal changes. The court also did not find any evidence that there was a requirement to provide genetic information or family medical history as part of the mandatory wellness program. The court similarly granted summary judgment on the retaliation

claim, finding that he had not been engaged in a GINA-protected activity (as the court deemed relevant that the employee’s initial objections to the mandatory wellness program noted privacy concerns without explicitly mentioning GINA).

These emerging cases illustrate the importance of a clear employer-employee relationship and potential insulation from liability that the vendors of wellness programs might have if mere business partners. The cases also illustrate the scope of GINA-protected activities for which retaliation by employers is forbidden, underscoring that disputes will be fact-intensive inquiries and that courts likely will give plaintiffs more favorable treatment if evidence clearly indicates the wellness program included DNA testing or genetic information, thereby making per se violations and retaliation claims under GINA viable. Moreover, as the punitive damages awarded in the infamous case of the “devious defecator”—*Lowe v. Atlas Logistics Group Retail Servs. Atlanta, LLC*, 102 F. Supp. 3d 1360 (N.D. Ga. 2015)—signaled, employers must be cautious whenever contemplating genetic information or testing, as strict liability is imposed unless the conditions for an exception (such as a wellness program) are plainly satisfied.

f. Other Applicable Laws not covered in this memorandum

When an employee receives something “of value” from the employer, it is generally taxable as income. So designing an employer-sponsored wellness program should include a compliance check not only with GINA, ADA, and HIPAA/ACA but also with the Internal Revenue Code. Zimmer and Wakefield (2019) have indicated that some incentives (such as water bottles, t-shirts, etc) would not be taxable (as merely de minimus fringe benefits) but cash and cash equivalents (such as gift cards) would be taxable income. They note that generally the IRC does not consider discounts on health plan contributions, deductibles, co-pays, and co-insurance; health savings accounts; or health flexible spending accounts to be taxable.

Additionally, the design should be reviewed for compliance with the Fair Labor Standards Act. According to the Department of Labor (DOL) website, the FLSA does not require employers to provide a wellness program. However, wellness programs that contain activities outside of working hours (such as exercising a certain amount of time, attending health fairs, or completing biometric screenings) invite the question as to whether the employee is “on the clock” or doing job-related work for which he/she/they are entitled to be compensated. The DOL issued an opinion letter (FLSA2018-20) in 2018 on this very issue, and the DOL has issued proposed rules that would add an example to §778.224 clarifying that the costs of wellness programs (i.e., likening wellness programs to on-the-site medical care and recreational facilities that are conveniences to employees) may be excluded from an employee’s regular rate of pay (See 84 Fed. Reg. 11896). Nevertheless, wellness programs that are mandatory or involve various trainings (e.g., nutritional classes, tobacco cessation classes, etc.) during work hours could potentially run afoul of FLSA or worker’s compensation laws.

III. Summary of State Issues Regarding Genetic Testing and Employers

Two landmark 50-state surveys have been performed to detail the state variation in laws related to genetic testing. First and foremost was the National Conference of State Legislatures (NCSL) work done prior to GINA’s passage which, unfortunately, has not been updated since GINA’s passage. The second is that performed by Anya Prince that was published in 2013. The appendix is particularly the most useful part of the publication, which reviews state legislation on provisions covering employment or health insurance; covering other insurance; providing a property right; and providing privacy right. A related update regarding reporting of genetic results was performed as part of the *All of Us*SM Research Program by Megan Doerr and colleagues in the development of their uniform consent process. That provides as its Appendix A, a review of the state and territorial laws on age of majority, patient’s bill of rights, primary consent, HIPAA authorization, and return of genomic results. A comprehensive 56 jurisdiction (50 states, District of Columbia, and five territories) would require far more effort than what has been budgeted in this supplement, so I direct you to those resources. The variation of state laws regarding biometrics more broadly (i.e., not in the narrow context of wellness programs but, rather, in the context of data privacy and security considerations within precision health) has been proposed as part of an R01 application submitted to NHGRI on October 7, 2019.

IV. Relevant ELSI/Policy Concerns

The design of any wellness program integrating population genetic testing must, in addition to ensuring legal and regulatory compliance, anticipate skepticism from the scientific and bioethics community regarding voluntariness of the program. Issues of coercion, duress, and undue influence, for example, might be particularly problematic for wellness programs that seek to include individuals residing in rural areas or individuals with lower educational attainment who might, as a result of those circumstances, have limited employment options and/or limited accessibility to affordable health coverage.

While not specific to wellness programs, the ELSI research community is increasingly critical of employer-based data collection efforts and bioethical vulnerabilities of employees (among others) related to data-exposures and never-ending data surveillance. With regard to genetic privacy specifically, there is a growing concern about law enforcement and third-party access to genomic databases. Moreover, there is limited recognition of the HIPAA Privacy Rule exception allowing law enforcement access to some information (including name and address) without the patient's authorization (See 45 C.F.R. 164.512(F)(1)(ii)) and similarly low awareness that the NIH Certificates of Confidentiality, even in their expanded form pursuant to the 21st Century Cures Act, do not shield identifiable information or non-research data effectively. The data privacy, security, and confidentiality issues should be of utmost priority, and examination of emerging state laws (including but not limited to CA's Consumer Privacy Act of 2018, AB-375, signed into law on 6/28/2018; SB-822 signed into law on 9/30/2018; and CalGINA, SB-559, signed into law on 10/9/2011, and VT's Data Broker Law, Act 171 of 2018) will be necessary to ensure that employer-sponsored wellness programs that are not conducted in-house but involve relationships with vendors have responsible, equitable data stewardship policies in addition to their business associate agreements.

Equitable data practices for wellness programs would relate to what level of information is actually given to the participating employee (e.g., raw data, only interpretative summaries, both) and what permissible uses for the generated/collected data relating to the employees the vendor providing the population genetic testing has (e.g., use for research). Moreover, participant engagement (in this context, employer engagement) and corporate culture will be critical components for evaluating wellness programs, employee buy-in, and ultimately success.

Finally, there are scant empirical data to support employer-sponsored wellness programs effectiveness in improving health and wellness, which will continue to draw criticism regarding the reasonable collection of these "sensitive" data (not only genetic data but geolocation data imbedded in data generated by wearables/fitness trackers) by employers. Trustworthiness (i.e., a factor that focuses on the employer or wellness program vendor's actions) will be a substantial area for future ELSI work, as it relates to willingness of employees to participate, cost/benefit tradeoffs made in those decisions, and evaluation of appropriate financial incentives for the actual benefits and risks involved.

V. Conclusion

A foundational question when evaluating the legal compliance of a specific wellness program is first whether the program is a group health plan or part of a group health plan (i.e., if it provides medical care or if participation in the program affects cost-sharing for group health plan), in which case ACA and other mandates on group health plans (e.g., ERISA and COBRA) are applicable. If the wellness program is not providing medical care or part of a group health plan, the wellness program must still comply with the non-ACA non-discrimination mandates of GINA, ADA, ADEA, Title VII of the Civil Rights Act of 1964, and the Fair Labor Standards Act. GINA Title I and Title II compliance should be considered separately. However, because of the current regulatory uncertainty, designers of employer-sponsored wellness programs would be wise to avoid tying *any* rewards intended to encourage participation (whether in the form of discounts or surcharges) to the GINA-protected or ADA-protected activities, which would involve any type of population genetic testing, health risk assessment that is likely to elicit genetic information (as broadly defined statutorily by GINA as opposed to the more narrow common understanding) or disability-related inquiry or exam. Design of wellness programs must take care to ensure that those activities are genuinely voluntary, that firewalls be established and data aggregation practices imposed to prevent employers from having any possible temptation to use the

information pertaining to any specific individual in an employment decision and to protect the confidentiality of the employees' (and employees' dependents) participation and resulting information.

For purposes of this NHGRI-funded work, it would be useful to use the opportunity provided by key informant interviews to examine the extent to which these compliance-related issues influence employer preliminary interests in integrating population genetic testing in their current or future wellness programs and subsequent design decisions. One could anticipate a wide range of perspectives given sizes of employers (e.g., GINA's mandates do not apply to private employers with fewer than 15 employees) and given the geographic range of employees (e.g., GINA did not preempt more stringent state laws, which could affect compliance costs and complexity of wellness program designs for employers with multi-state business locations or employees located in different states). Wellness programs have, potentially, dual benefits: (1) health promotional benefits to the participating employees and their dependents and (2) cost-saving benefits to the employers. It could be useful to examine the extent to which an employer's outlook emphasizes one or the other, as it might be a predictor of mistakes or obstacles to successful implementation of a sustainable wellness program.

If additional information or resources would be useful to you in further development of your project, please let me know.

VI. Appendix: Relevant Resources

a. Primary Sources

i. Cases

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