

# Appendix B

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## ***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 Method<sup>1</sup>, 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 Method<sup>1</sup>. 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 testing<sup>2</sup>, 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.”<sup>3</sup> 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 | ✓ |
|---------------|---|---|---|---|---|---|

*\*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 tests<sup>4</sup>: 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 website<sup>5</sup> 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).<sup>6</sup>

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.<sup>7</sup> According to a case study Vendor#2 conducted with the International Brotherhood of Teamsters<sup>6</sup>, 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 report<sup>8</sup> 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.<sup>9</sup>

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.<sup>10</sup>

Potential impacts<sup>8</sup> 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”<sup>11</sup> 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”<sup>12</sup> 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 commentary<sup>13</sup> 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 project<sup>14</sup>. 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.<sup>15</sup> 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.<sup>16</sup>

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.<sup>17,18</sup>

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 publications<sup>19</sup> 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 policy<sup>20</sup> 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 policy<sup>21</sup> 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 conceptualization<sup>21</sup> 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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