Perceptions of College Students on Direct-to-Consumer Genetic Testing

An Honors Thesis (HONR 499)

by

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Abstract

Direct to Consumer (DTC) genetic testing is a popular way of learning about one's ancestry, genetic health risks, and traits. Common DTC testing companies include 23andMe, Ancestry, and Prometheus. This field continues to expand and deepen as more companies arise proclaiming genetic tests for a myriad of matters. Unfortunately, most individuals that take these tests do not fully understand genetics, relative risk, or the regulation and limits of these tests. For individuals that do not have a biology background, terms like carrier, genetic risk, and SNPs are foreign terms. This study analyzes how Ball State college students perceive genetic testing, their experiences with genetic testing, and common barriers to being tested.

The study found that the main benefits for testing among both tested and untested groups were ancestry and traits. Concerns about results, privacy, and cost were common barriers to testing. Both groups had medium confidence in quality and accuracy of the results and believed that DTC genetic testing was somewhat expensive.

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Process Analysis Statement

I have had an avid interest in genetics ever since my 8th-grade science teacher brought up how genetics influences the health of individuals and populations. Over time, my interest in genetics grew and diversified into how it influences medicine and public health. A few years back I bought a 23andMe Ancestry and Health test and have been fascinated by the results ever since. I was riveted with finding out how they determined these traits and ancestry from a tube full of saliva. I was particularly interested in the things the test got wrong, such as insisting I did not actually have dimples.

I wanted to foster this same avid interest in my thesis. I chose to do a survey to gain more experience in public health research. In prior research conducted, I had performed interviews and analyzed the data from that. Using a survey allowed me to reach more people and gain a new research perspective. Once the survey was completed, I gained IRB approval and began to distribute the survey. When the survey collection period was completed, I analyzed the data.

The target audience of this thesis was anyone curious about direct to consumer genetic testing. The field itself is still fairly new and is constantly expanding. I wanted to begin with a short history of genetics and genetic testing to show how far the field had come in such a short time. Following this history, I focused on how genetic testing actually works, concerns and regulation of the field, common companies, and why college students were selected for this study.

The biggest lesson I learned from this thesis was determination. At all turns it seemed like the process was against me. Between wisdom tooth removal, demanding classes, an international trip, a global pandemic, and more, there were plenty of

distractions and hurdles to cross. IRB approval, although I had completed the process for prior research, is always a beast. Learning a new survey program and how-to best format a survey and distribute it was a challenge. Despite these and many other personal and academic challenges, I persevered to complete this thesis to the best of my ability. This thesis serves as a reminder that although it is impossible to know what obstacles will arise to defy the plans we painstakingly lay, a bit of determination, grit, and hard work can make all the difference.

Introduction

Unraveling the mystery of genetics is a constantly mounting undertaking. Often, it seems that as more is unearthed about genetics, new mysteries float to the surface. The idea that people can learn about their genetic ancestry, health risk, and traits from a tube of spit would seem revolutionary when deoxyribonucleic acid (D.N.A.) was first discovered. Now, that same tube of spit can be used to discover genetic variants between individuals and use them to give customers insights about themselves. This progression is through Direct to Consumer (DTC) genetic testing. Common DTC testing companies include 23andMe, Ancestry, and Prometheus. DTC genetic testing is an emerging field, and thus its regulation, significance, utility, and accuracy are much debated.

This paper will cover the history of genetic testing, how DTC genetic testing works, current trends, existing DTC companies, regulation, and the perceptions of Ball State college students to DTC genetic testing.

Genetic Testing History

In 2017, it is estimated that as many as 12 million Americans used DTC genetic testing (Huml, 2019). How did we reach this point? The field of genetics has continued to flourish after gaining its roots in 1859 when Charles Darwin published his controversial *On the Origin of Species* detailing the idea of Natural Selection. Six years later, the field grew further when Gregor Mendel used pea plants in experiments that upheld Darwin's findings. Mendel found that inheritance of traits occurred through the transmission of discrete units. These discrete units may appear in the offspring as

blended traits or like either parent plant. These ideas helped paint a mechanism by which Darwin's ideas about Natural Selection may work (NIH, 2015).

In 1871, Friedrich Miescher discovers "nuclein" in the nucleus of cells (Your Genome, 2016). Cell division was revolutionized in 1879 by the discovery of mitosis, the cell division of a parent cell that results in two genetically identical daughter cells, and by Walter Flemming while studying the effect of cell division on the behavior of chromosomes (NIH, 2015). The Chromosome Theory of Heredity was the next big breakthrough in 1904 by Walter Sutton and Theodor Boveri. They discovered that one of each pair of chromosomes was inherited from each parent. These matched pairs explain the discrete units that Mendel discovered with his pea plants almost 40 years earlier (Your Genome, 2016).

The word gene is used by Wilhelm Johannsen first in 1909. In 1911, genes are shown to be carried by chromosomes and linkage of genes is discovered by Thomas Hunt Morgan in a fruit fly animal model. The conventional thought at the time that proteins could 'transform' cell properties was disproven in 1944 by Oswald Avery, Colin MacLeod, and Maclyn McCarty. Instead, it was DNA, which Miescher had originally called nuclein (NIH, 2015). Erwin Chargaff was the next in the line of discovery when in 1950 he created Chargaff's rules on the pairing of the DNA bases. The findings suggested that Adenine (A) always pairs with Thymine (T). Similarly, Guanine (G) always pairs with Cytosine (C). The ideas of Avery, MacLeod, and McCarty were further expanded upon in 1952 with the Hershey-Chase experiments, performed by Alfred Hershey and Martha Chase. They showed that the true carrier of genetic information was DNA, not protein (Your Genome, 2016).

DNA would be further revolutionized in 1953 when James Watson and Francis Crick discover DNA's structure was a double helix using data collected by Rosalind Franklin (Your Genome, 2016). In 1958, more detail is discovered about DNA when Franklin Stahl and Matthew Meselson find that DNA replicates by the semiconservative model. Previously, there were three models that replication was thought to belong to. The popular opinion was that DNA was replicated using a conserved model. The new strands of DNA would be replicated off of the parent strands of DNA. The new strands would ligate together, and the parent strands would relegate together. In semiconservative replication, the new strands are also copied off of the parent DNA strands. However, the resulting DNA molecules are created from one new and one parent strand of DNA. In Dispersive replication, the entire DNA chain breaks down, is replicated and randomly recombines to form two new DNA molecules (NIH, 2015).

The idea of genetic testing comes into focus in 1959 when the cause of Down syndrome is found by Jerome Lejeune and his lab. They detected that having chromosome 21 three times vs. the usual 2 led to Down Syndrome. Two years later, in 1961, Robert Gunthrie creates a test to detect phenylketonuria (PKU) in newborns. This disease prevents afflicted individuals from metabolizing phenylalanine. The amino acid can then build up in the body and cause severe symptoms if not treated (NIH, 2015). Understanding how amino acids affect the body was further understood in 1966. The Genetic code was cracked by Marshall Nirenberg and his lab. This enabled scientists to better understand which codons (sets of three DNA bases) coded for which amino acids when the DNA was used to create proteins (Your Genome, 2016).

The field of cytogenetics and molecular diagnostics then emerged, in 1959 and 1976 respectively (Botkin, 2015). These brought with them the discovery of restriction enzymes (1968), recombinant DNA (1972), and the cloning of the first animal gene (1973). In 1975, DNA sequencing was developed by two different groups: Frederick Sanger, and colleagues Alan Maxam and Water Gilbert. In 1976, Genentech was formed. This was the first company to specialize in genetic engineering. They would again make a major impact when they market human insulin in 1982. This was the first drug marketed using recombinant DNA (NIH, 2015). The field continued to improve and in the year 1983 the invention of polymerase chain reaction (PCR) technique was developed by Dr. Kary Mullis. This technique allowed researchers to amplify DNA, or create multiple copies of DNA from a single copy in a lab setting (Your Genome, 2016). Also in 1983, the lethal autosomal dominant disorder Huntington's disease, became the first disease to have its gene mapped (NIH, 2015).

In 1990, a massive undertaking in the field of genetics began. The Human Genome project began with the idea that within 15 years they would sequence the entire human genome. The human genome contains 3.2 billion bases. Around this time, many plants (such as tomatoes), animals (such as mice), and bacterium (*E. coli*) were also being sequenced. Just before the turn of the century in 1999, the Human Genome Project succeeds in sequencing its first chromosome, Chromosome 22. Chromosome 22 was selected first due to its small size and some prior research already existed for it (NIH, 2015). In 2003, the Human Genome Project finishes 2 years early. They estimate their accuracy to be 99.99% accurate. They also estimate that humans are made up of between 20,000 and 25,000 genes (Your Genome, 2016).

The next advancements centered around completing more sequencings of plants, animals, and bacterium, creating better DNA sequencing technology, and launching projects with the goal to sequence large populations (Your Genome, 2016).

How does DTC Genetic Testing work?

For individuals that do not have a biology background, terms like carrier, genetic risk, and SNPs are foreign terms. SNPs, or single nucleotide polymorphisms, are one of the most common genetic variations and act as biological markers (Roberts, 2017). In certain locations in the genome, SNPs are present. In these locations, the A, T, C, or G nucleotide can differ between people. One individual may have a C and another may have an A in that same location. The human genome is estimated to have about 10 million SNPs. SNPs are important to genetic research, including genome-wide association studies and in tracking ancestry (Genetics Generation, 2015).

There are several types of genetic tests available. The main difference is what the test is looking for. For example, Single-gene tests search for a mutation in a specific gene, such as in sickle cell disease. These are usually ordered by a healthcare professional when a specific mutation is suspected. Direct to consumer genetic testing usually falls under exome or genome sequencing. Exome sequencing test looks at all of the genes present in an individual's DNA. A genome sequencing test looks at all of the genes and non-gene DNA present in an individual (CDC, 2020).

Many DTC genetic testing companies use DNA found in saliva from mouth cells (23andMe, 2020). AncestryDNA uses "microarray-based autosomal DNA testing, which surveys a person's entire genome at over 700,000 locations, all with a simple saliva sample." Autosomal DNA is DNA from the 22 chromosome pairs, not the sex

chromosomes X and Y. Microarray-based tests look at gene expression in the genome (Ancestry, 2020). 23andMe genotypes DNA and then analyzes it (23andMe, 2020).

Concerns about DTC Testing

Concerns about DTC genetic testing are rampant among geneticists, healthcare professionals, and researchers. Major concerns are lack of knowledge and counseling of participants, clinician understanding, privacy, discrimination, lack of regulation, and questionable clinical accuracy and validity. Addressing these concerns and taking steps to improve is critical to enjoying the positives of genetic testing.

When a participant finds out that they are at an increased risk of a disease or are a carrier, fear is a common first emotion. What constitutes increased risk? Increased risk is when an individual has a variant of a gene linked to an increased incidence of developing a certain disease or disorder. This increased risk may be relatively small, or major. Two well-known mutations are found in the *BRCA1* and *BRCA2* genes that can lead to an increased risk of developing breast and ovarian cancers. By the time she is 70, a woman with one of these mutations is estimated to have a 50 to 85% chance of developing breast cancer over her lifetime. This is a significant increased risk from the average population without this mutation. Clinically, knowing that someone has these mutations can be beneficial in knowing to increase cancer screenings and to consider clinical interventions such as a mastectomy (MSKCC, 2020). Other risks may be an increase of only a few percent over the general population. Thus, the concerns of both of these risks are very different (Botkin, 2015).

What does carrier status mean? Carriers carry one allele of a gene that when two alleles are present causes a recessive disorder. One well known example is in cystic

fibrosis. If two carriers of cystic fibrosis had a child, the child would have a 25% chance of having two recessive alleles and cystic fibrosis. Understanding carrier status is important to reproductive planning and the prevention of these recessive disorders. However, not all companies test for the same variants that cause disease. 23andMe tests for 29 variants in the CFTR gene that causes cystic fibrosis. The company states that participants “may still have up to a 1 in 230 chance of carrying a variant not covered by this test.” If someone has a variant not tested by 23andMe, they may believe they are not a carrier and be lulled by a false sense of security about their carrier status (23andMe, 2020).

Further concern is that most individuals do not seek out health care professionals, such as genetic counselors or their primary care physician, to interpret their results (Roberts, 2017). Many primary care physicians are not comfortable addressing DTC genetic testing results with their patients either, which could lead to a larger strain on genetic counselors, greater patient anxieties and mistrusts, and a continuing misunderstanding of DTC genetic testing results (Powell, 2011). This lack of communication and understanding between health care professionals and patients is a major concern. For individuals that discover alarming results or misinterpret results, their psychological well-being may suffer. This may be presented as anxiety, depression and/or anger over their results (Genetics Generation, 2015).

Privacy, discrimination, and regulation are growing concerns as well. These tests are available worldwide and country regulations differ. Addressing this issue would require collaboration on an international scale and is a daunting task to undertake. Often genetic and personal information are stored in other countries. This data can also

be used to identify relatives of the participant. Emerging research shows that even in anonymized datasets, the reidentification of the study participants is not impossible (Phillips, 2016). As genetic technologies continue to improve, this will likely become an even bigger problem (Niemiec, 2016). 23andMe stated in 2015 that law enforcement had requested for their help in providing participant data to find suspects (Phillips, 2016).

Criminals have already been identified using DTC genetic testing. The online database proves a place for individuals to upload raw DNA files they received when participating in DTC genetic testing companies like 23andMe and Ancestry. One of the investigators of the Golden State Killer cold case, Detective Paul Holes, used DNA from the serial killer from a crime scene to create a profile on GEDmatch and matched with a distant relative of the Golden State Killer. Over time, Detective Holes created a family tree and found the Golden State Killer and his distant relative shared a great-great-great-grandparent. This information was later used to find and arrest the Golden State Killer, Joseph James DeAngelo in April of 2018. Other cold cases have since been solved using this or a similar method. Although solving these cases and bringing criminals to justice is important, the capture of the Golden State Killer highlights the potential privacy ramifications of DTC genetic testing (Jeong, 2018).

It is currently unknown how accurate and consistent DTC genetic testing companies are. However, one study used several sets of identical twins to compare the ancestry results between two genetically identical individuals at the same company and between two companies. They found consistency between 94.5 and 99.2% when looking at ancestry results at the same company. However, results were not near as

consistent between companies. This result dropped to between 52.7 and 84.1%. This drop highlights the inconsistency in DTC genetic testing when looking at variants tested and the data sets of SNPs used as references to compare ancestry results to at each company (Huml, 2019). Lack of regulation is further discussed in a later section.

Direct-to-Consumer Companies

There are many different DTC companies worldwide. One study analyzed 246 companies and found that 30% of them looked at ancestry, 36% and 34% looked at non-legal and legal paternity respectively, and 11% offered carrier testing. Two major companies that provide these DTC services are Ancestry DNA and 23andMe (Phillips, 2016). AncestryDNA began as part of a genealogy company in 2012.These tests looked at autosomal DNA to determine ancestry and ethnicity. Years later they would launch their health component, AncestryHealth. Today, AncestryDNA boasts over 16 million people tested, a revenue of over a billion, and over 30 international markets (Ancestry, 2020).

In 2006, 23andMe was established by Anne Wojcicki. The company offers ancestry, trait, and health services. In 2017, 23andMe was estimated to be worth over a billion dollars and has published over 80 scientific articles. They are the only DTC genetic testing company that the FDA approves for validity clinically and scientifically. This was not always the case however, as 23andMe ran into problems in 2013 for not letting the FDA approve the ability to let customers know about any potential health risk. However, in February 2015, the first FDA approved test emerged for the rare disorder of Bloom syndrome (Hayden, 2017).

Regulation

In the U.S., genetic tests are regulated by two main federal agencies: the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA). These genetic tests are assessed based on their validity analytically and clinically, as well as their clinical utility. In other words, can the test reliably and correctly predict the genetic variant, does the genetic variant have an impact on disease risk, and can the test result help improve clinical outcomes. The CMS regulates the analytical validity, but the clinical validity and utility is difficult to address. The FDA is taking steps to address the public health threat caused by unregulated DTC genetic tests and to address this gap in regulation (NIH, 2019).

The FDA does not review certain DTC genetic test categories that relate to "non-medical, general wellness, or low-risk medical purposes." For example, the FDA does not review tests for genetic ancestry or general wellness tests considered low risk. Carrier screening tests are required to follow specific regulations, but they are not reviewed pre-market by the FDA. Tests for cancer predisposition, pharmacogenetics, and genetic health risk require FDA approval in some form. The FDA cautions that companies may test for different variants of the same disorder. Thus, a DTC test may miss variants that would indicate the condition that a different company would pick up on. The FDA recommends meeting with a qualified health provider, such as a genetic counselor, to help DTC genetic test customers better understand their results (FDA, 2019).

As genetic testing continues to expand, researchers have several suggestions for increasing and improving regulation. Regulation needs to focus on increasing

transparency and creating standards that are consistent throughout the entire industry. Additionally, customers need better access to pertinent information such as “how to understand risks, benefits, and limitations of genetic testing and DTC services,” (Phillips, 2016). Currently 23andMe is the only DTC genetic testing service that meets validity standards by the FDA both clinically and scientifically (23andMe, 2020). As the field continues to grow, more companies will need to adopt these same standards.

College Student’s Perceptions

College students were chosen due to convenience and to understand how undergraduate students at Ball State University viewed Direct to Consumer Genetic Testing.

Methods

Participants were recruited to take the online Qualtrics survey through flyers posted around Ball State’s campus and emails through campus organizations, the Biology Advising center, and through the Honors College. This enabled the survey to reach a wide variety of majors and age groups. The survey distribution occurred between February 27th to April 19th, 2020. Survey responses were used if the students agreed to the comprehensive consent, met the inclusion criteria, and finished over 90% of the survey. To meet the inclusion criteria, participants had to be over the age of 18, undergraduate students at Ball State University, have access to the survey, and be able to read at a high school reading level. The survey respondents were kept anonymous and no personally identifiable information was collected from participants.

The data from the surveys were analyzed to see how responses differ based on different demographic criteria, student major, age, years of college completed and if they had undergone DTC genetic testing to see if these variables influence perception.

Self-perceptions and self-rated understanding of DTC testing were compared. Barriers and concerns regarding genetic testing were analyzed to understand common reasons students do or do not undergo testing and how this compares to their perceptions. Common perceived benefits and cons of DTC genetic testing were also analyzed.

Results

The study population was found to be overwhelmingly white females with average to above-average health. The age, total family income, and religion varied (**Table 1**). The majority of the students were seniors (53.5%). About half of the tested population had major in a science field, but only 37.1% had a major related to health. The majority of study subjects had a major in Communication, Health and Nutrition, or STEM. The other academic years and majors were about equal (**Table 2**).

Table 3 shows the reported Genetics background. Most participants (37.1%) reported an average perceived knowledge of genetics. Knowledge about genetic testing was reported by 96.6% of participants, with only 4 out of 116 participants reporting no knowledge of genetic testing. The perceived knowledge of DTC genetic testing was reported as fair and average in participants (30.2% and 40.5%). Participants obtained this knowledge through mass media (68.1%), classes (50.9%), and parents (26.7%). Most participants did not perceive DTC genetic testing as useful (**Table 3**).

Biology classes taken by participants were also analyzed. High school biology was taken by 88.8% and college-level introductory biology by 58.6%. About 20% of participants had taken a more advanced biology class such as microbiology, genetics, and cell biology. Upper-level genetics courses were taken by 16.4% of the study participants (**Table 3**).

Of the 116 participants, 13 (11.2%) had taken a DTC genetic test. The main DTC tests taken were Ancestry (69.2%) and 23andMe (30.8%). Most participants stated they either already had or would discuss their results with a Genetic Counselor or physician if they found concerning results. All tested participants experienced either no regret (69.2%) or little regret (30.8%) at being tested (**Table 4**).

About half of tested participants (53.8%) believed that the testing materials provided by the company were adequate to answer any questions they had about testing and their results. Only 1 participant (7.7%) learned something from the test about their health they did not previously know. Most participants (46.2%) expressed disappointment that their results did not tell them more information. The same percentage viewed genetic testing as beneficial overall (**Table 4**).

Table 5 compared the considerations taken into account and barriers of DTC genetic testing between those that had not taken a test and those that had. Most participants that had been tested considered genetic ancestry, genetic traits, family interest, interest in genetics, and the fun associated with testing. Of those that have not been tested, interest was primarily expressed in disease risk, genetic ancestry, carrier status, genetic traits, and an interest in genetics. Barriers to testing for those that were tested were primarily about cost, validity/usefulness of the test, and concerns over privacy. Untested barriers were primarily about cost, privacy concerns, and worry over what results might show. In both the untested and tested participants, medium confidence was reported in both the quality and accuracy of the results. Genetic testing was reported by both groups to be somewhat expensive (**Table 5**).

Table 1: Demographics			
Gender		**Total Family Income**	
Male	19 (16.4%)	<$29,999	23 (19.8%)
Female	92 (79.3%)	$30,000-49,999	9 (7.8%)
Other	5 (4.3%)	$50,000-69,999	14 (12.1%)
Age		$70,000-99,999	28 (24.1%)
18	9 (7.8%)	>$100,000	39 (33.6%)
19	15 (12.9%)	Prefer not to say	3 (2.6%)
20	15 (12.9%)	**Religion**	
21	36 (31.0%)	Catholic/Christian	63 (54.3%)
22	27 (23.3%)	Non-religious/atheist	36 (31.0%)
23+	14 (12.1%)	Other	17 (14.7%)
Race		**Health Status**	
White	105 (90.5%)	Fair	7 (6.0%)
Black	2 (1.7%)	Average	64 (55.2%)
Asian	3 (2.6%)	Above Average	37 (31.9%)
Other	6 (5.2%)	Excellent	8 (6.9%)

Table 2: College Demographics			
Academic Year		**Major**	
Freshman	19 (16.4%)	Teaching	6 (5.2%)
Sophomore	12 (10.3%)	Business	5 (4.3%)
Junior	23 (19.8%)	Communication	18 (15.5%)
Senior	62 (53.4%)	Architecture	6 (5.2%)
Science Major		Health and Nutrition	17 (14.7%)
Yes	59 (50.9%)	Social Sciences	7 (6.0%)
No	57 (49.1%)	Humanities	9 (7.8%)
Health Major		Art	7 (6.0%)
Yes	43 (37.1%)	Nursing	8 (6.9%)
No	73 (62.9%)	STEM	33 (28.4%)

Table 3: Genetics Background	
Perceived Knowledge of Genetics	
Poor	13 (11.2%)
Fair	27 (23.3%)
Average	43 (37.1%)
Above Average	28 (24.1%)
Excellent	5 (4.3%)
Knowledge about GT	
Yes	112 (96.6%)
No	4 (3.4%)
Perceived Knowledge of DTC GT	
Poor	15 (12.9%)
Fair	35 (30.2%)
Average	47 (40.5%)
Above Average	18 (15.5%)
Excellent	1 (0.9%)
Perceived Usefulness of DTC GT	
Useful	13 (11.2%)
Somewhat Useful	37 (31.9%)
Not Useful	66 (56.9%)
Biology Classes Taken	
High School Biology	103 (88.8%)
Introductory Biology	68 (58.6%)
Microbiology	24 (20.7%)
Genetics	24 (20.7%)
Cell Biology	26 (22.4%)
Biometry	14 (12.1%)
Molecular Biology	10 (8.6%)
Upper Level Genetics	19 (16.4%)
Origin of Knowledge	
Parents	31 (26.7%)
Friends	20 (17.2%)
Mass Media	79 (68.1%)
Classes	59 (50.9%)
Siblings	7 (6.0%)
Other relatives	8 (6.9%)
Healthcare provider	12 (10.3%)
Other	5 (4.3%)

Table 4: Testing Experiences			
Taken a DTC GT		**Brand of DTC GT**	
Yes	13 (11.2%)	23andMe	4 (30.8%)
No	103 (88.8%)	Ancestry	9 (69.2%)
		Medical Testing	1 (7.7%)
Would they talk to a GC or Physician about results?			
Yes, already have	2 (15.4%)	Maybe	1 (7.7%)
Yes, if concerned	5 (38.5%)	No	5 (38.5%)
Level of regret at testing			
No regret	9 (69.2%)	Little regret	4 (30.8%)
Experiences			
The educational materials provided by the company about genetic testing were adequate.			7 (53.8%)
Having personal genomic testing made me feel like I have more control over my health.			2 (15.4%)
I learned something to improve my health from my genetic testing that I didn't know before.			1 (7.7%)
The information I received has influenced how I will manage my health in the future.			2 (15.4%)
What I learned about my genetics can help reduce my chances of developing a disease.			3 (23.1%)
I am disappointed that my results did not tell me more information.			6 (46.2%)
Genetic testing was a beneficial experience.			6 (46.2%)

Table 5: Perceived Notions of Genetic Testing		
Considerations in Participating	**Untested**	**Tested**
I wanted to know if I was at risk for a certain disease.	51 (49.5%)	3 (23.1%)
I wanted to contribute my data to scientific research.	14 (13.6%)	2 (15.4%)
I wanted to test my sensitivity to certain medications.	13 (12.6%)	1 (7.7%)
I wanted to find out about my genetic ancestry.	55 (53.4%)	9 (69.2%)
I wanted to know my carrier status for different disorders.	39 (37.9%)	3 (23.1%)
I wanted to find out more about my genetic traits.	43 (41.7%)	4 (30.8%)
I was curious about how genetic testing works.	15 (14.6%)	2 (15.4%)
I am interested in genetics in general.	35 (34.0%)	6 (46.2%)
I took the test for fun.	24 (23.3%)	10 (76.9%)
A healthcare professional advised the test	6 (5.8%)	0 (0%)
My family wanted me to take the test.	3 (2.9%)	5 (38.5%)
The test was available to me for free.	7 (6.8%)	1 (7.7%)
I wanted to find relatives.	16 (15.5%)	3 (23.1%)
Other	7 (6.8%)	0 (0%)
Barriers to Genetic Testing	**Untested**	**Tested**
I was worried about the results of the test.	16 (15.5%)	0 (0%)
I did not think the results were valid.	10 (9.7%)	3 (23.1%)
I did not think the results were useful.	12 (11.7%)	2 (15.4%)
I was concerned about the privacy of my data.	44 (42.7%)	2 (15.4%)
I was skeptical of genetic testing in general.	16 (15.5%)	1 (7.7%)
I was concerned about the cost of genetic testing.	55 (53.4%)	4 (30.8%)
I was concerned about the time involved in testing.	8 (7.8%)	1 (7.7%)
I was concerned about the test not being recommended by a healthcare professional.	6 (5.8%)	0 (0%)
I was not interested in my genetic data.	3 (2.9%)	0 (0%)
I was not interested in genetics at all.	2 (1.9%)	0 (0%)
Genetic testing goes against my religion and/or morals.	0 (0%)	0 (0%)
I was worried about my genetic information being used to discriminate against me.	15 (14.6%)	1 (7.7%)
Confidence in Quality of Results	**Untested**	**Tested**
Little to no confidence (0-3)	10 (9.7%)	2 (15.4%)
Medium confidence (4-7)	73 (70.9%)	7 (53.8%)
High confidence (8-10)	20 (19.4%)	4 (30.8%)
Confidence in Accuracy of Results	**Untested**	**Tested**
Little to no confidence (0-3)	11 (10.7%)	4 (30.8%)
Medium confidence (4-7)	64 (62.1%)	6 (46.2%)
High confidence (8-10)	28 (27.2%)	3 (23.1%)
Opinion of Genetic Testing Cost	**Untested**	**Tested**
Not expensive	10 (9.7%)	1 (7.7%)
Somewhat expensive	69 (67.0%)	9 (69.2%)
Expensive	24 (23.3%)	3 (23.1%)

Discussion

DTC genetic testing is a personal decision with many considerations and potential barriers. For the 13 participants that had undergone DTC genetic testing, the companies used were primarily Ancestry and 23andMe. Participants primarily wanted to take the test to learn about their ancestry, traits, and for fun. Those that were untested cared more about certain disease risk, ancestry, carrier status, and traits. Those that had already taken a test were more concerned about the “fun” categories of genetic testing. These areas likely will not lead to health problems. Additionally, they had likely already been exposed to their genetic health reports if their test included them. The novelty may have worn off. Finally, the sample size is small and may not be truly representative of the population. The data suggests that the main considerations for genetic testing between both populations are ancestry and traits.

Barriers followed a similar trend. Those that had been tested were not worried about the results, likely because they had already taken the test and were not worried by them. More of the tested population did not think the results were valid (23.1% vs. 9.7%). However, the percentages were more similar between the groups for usefulness. Privacy was a higher concern in those that had not been tested. Their testing status may mean they do not place as much weight on the testing categories because they had already had the test. Both groups agreed that they had medium confidence in the quality and accuracy of the results and believe DTC genetic testing is somewhat expensive. The data suggests that concerns about results, privacy, and cost may be the main barriers to testing in this population.

Most participants had a perceived average understanding of biology and DTC genetic testing. Knowledge primarily came from the mass media and classes. High school and introductory biology courses were both taken by over half of the population. About 20% had taken at least one upper-level biology classes. These classes would influence perceived

knowledge of DTC genetic testing, as students would learn more about genetics. This would increase their perceived knowledge of both genetics and DTC genetic testing.

Of the 13 individuals tested that had participated, 53.8% had already or would discuss their results with a genetic counselor or physician. Very little regret was expressed over being tested. Predominantly, participants were satisfied with the educational materials provided but were disappointed they did not learn more from their results. Overall, 46.2% believed that genetic testing was a beneficial experience.

Overall, these results may be skewed due to a small sample size, especially for the tested population. The majority of participants were white (90.5%), female (79.3%), Catholic or Christian (54.3%), and seniors (53.4%). Additionally, the survey was distributed during a global pandemic, which may increase health anxieties. Future studies should be aimed at a larger and more diverse population not in a global pandemic. Other studies may look at considerations and barriers to DTC genetic testing before the tested populations seeing their results to see if knowledge of the results influences these categories.

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Appendix 1: Questionnaire

Start of Block: Informed Consent

Q1 **Study Title** Perceptions of College Students on Direct-to-Consumer Genetic TestingIRBNet# 1525218-1

Study Purpose and Rationale

The purpose of this study is to determine the perceptions of Ball State University undergraduate students to Direct-to-Consumer (DTC) genetic testing. The information collected will be analyzed to see the results of different majors, genders, and class year have on perceptions. Additional analysis will determine the interests, concerns, and barriers that go into the decision of testing. Perceived understanding of the results is also analyzed.

Inclusion/Exclusion Criteria

For eligibility in this study, you must be 18+ and an undergraduate student at Ball State University. You must also have access to a computer to take the survey and be able to read at a high school reading level.

Participation Procedures and Duration

The survey begins with demographic information and then asks questions about experiences and perceptions about genetic testing. The survey will last approximately 15-20 minutes.

Data Confidentiality and Anonymity

All data collected is anonymous. The survey is collected online and no personal identifying information will be collected.

Storage of Data and Data Retention Period

Data will be stored on a password protected computer and will be kept for 4 years. Data will not contain any identifiable information.

Risks or Discomforts

The only anticipated risk attached to this study is that the study asks questions about personal feelings about genetic testing that may make you uncomfortable to answer. You are not required to answer any question that makes you uncomfortable and you are able to quit the study at any time without penalty. Ball State's Counseling Center can be found in Lucina Hall, Room 320 in Muncie, IN 47306 or can be contacted at 765-285-1726 or counselctr@bsu.edu to address any discomfort that arises from the study.

Benefits

There are no direct benefits to the survey participant for participating in this study. The results of this study will show the perceptions of Ball State University undergraduate students towards third-party genetic testing. The results will show how different student experiences influence their views on third-party genetic testing. This

research may also show gaps in the understanding of genetic testing and the need for greater science literacy among BSU undergraduate students.

Voluntary Participation

Your participation in this study is completely voluntary and you are free to withdraw your permission at any time for any reason without penalty or prejudice from the investigator. Please feel free to email any questions to the investigator before signing this form and at any time during the study.

IRB's Contact Information

For one's rights as a research subject, you may contact the following: Office of Research Integrity, located at Ball State University, Muncie, IN 47306. They can be reached at 765-285-5088 or ORIHELP@bsu.edu.

Researcher Contact Information

Feel free to contact the individuals that are conducting this study with any questions or concerns. Contact information is listed below:
Principal Investigator: Taylor Johnson (tpjohnson2@bsu.edu)
Faculty Supervisor: Dr. Jagdish Khubchandani (jkhubchandan@bsu.edu, 765-285-8345).

Consent

By selecting "I consent, begin the study," below, you agree that you are at least 18 years old, a Ball State undergraduate student, and willingly consent to participate in this study. If you do not consent to participate in this study, please select "I do not consent, I do not wish to participate," and exit your internet browser.

- ○ I consent, begin the study
- ○ I do not consent, I do not wish to participate

Skip To: End of Survey If Study Title Perceptions of College Students on Direct-to-Consumer Genetic Testing IRBNet# 1525218... = I do not consent, I do not wish to participate

End of Block: Informed Consent

Start of Block: Default Question Block

Q2 What is your gender?

- ○ Male
- ○ Female
- ○ Other

Q3 What is your age?

- ○ 18
- ○ 19
- ○ 20
- ○ 21
- ○ 22
- ○ 23
- ○ 24
- ○ 25+

Q4 What is your race?

- ○ White
- ○ Black or African American
- ○ American Indian or Alaska Native
- ○ Asian
- ○ Native Hawaiian or Pacific Islander
- ○ Multiracial
- ○ Other

Q5 Which of the following describes your ethnicity?

- ○ Hispanic/ Latino
- ○ Non-Hispanic

Q6 What is your total family income before taxes?

- ○ Less than $29,999
- ○ $30,000-49,999
- ○ $50,000-69,999
- ○ $70,000-99,999
- ○ $100,000-$119,999
- ○ More than $120,000

Q7 What is your religion?

- ○ Catholic/Christian
- ○ Judaism
- ○ Islam
- ○ Buddhism
- ○ Hinduism
- ○ Non-religious / Atheist
- ○ Other: _____

Q8 What academic year are you?

- ○ Freshman
- ○ Sophomore
- ○ Junior
- ○ Senior

Q9 Is your major in a science-related field?

- ○ Yes
- ○ No

Q10 Is your major in a health-related field?

- ○ Yes
- ○ No

Q11 Which is the closest to your major?

- ○ Teaching
- ○ Business
- ○ Communications
- ○ Architecture
- ○ Health and Nutrition
- ○ Social Sciences
- ○ Humanities
- ○ Art and Fine Arts
- ○ Nursing
- ○ Biology
- ○ Chemistry
- ○ Physics
- ○ Math and Statistics

Q12 How do you perceive your knowledge of genetics?

- ○ Poor
- ○ Fair
- ○ Average
- ○ Above Average
- ○ Excellent

Q13 Which of the following Biology classes have you taken?

- [ ] High school biology
- [ ] BIO 100 (Biology for a Modern Society)
- [ ] BIO 102 (Biology Concepts for Teachers)
- [ ] BIO 111 or 112 (General Biology)
- [ ] BIO 113 (Microbiology for Health Sciences)
- [ ] BIO 214 (Genetics)
- [ ] BIO 215 (Cell Biology)
- [ ] BIO 313 (Microbiology)
- [ ] BIO 448 (Biometry)
- [ ] BIO 452 (Advanced Genetics)
- [ ] BIO 453 (Human Genetics)
- [ ] BIO 454 (Genomes)
- [ ] BIO 457 (Molecular Biology)

Q14 How would you report your health?

- ○ Poor
- ○ Fair
- ○ Average
- ○ Above average
- ○ Excellent

Q15 Have you heard of or know about genetic testing?

- ○ Yes
- ○ No

Skip To: Q17 If Have you heard of or know about genetic testing? = No

Q16 How did you find out about genetic testing?

- [ ] Parents
- [ ] Siblings
- [ ] Extended relatives
- [ ] Friends
- [ ] Healthcare provider
- [ ] Mass media
- [ ] Classes
- [ ] Other: _____

Q17 Has anyone in your family had genetic testing?

- ○ Yes
- ○ No

Q18 How do you perceive your knowledge of direct-to-consumer (DTC) genetic testing (i.e. 23andMe, Ancestry, etc.)?

- ○ Poor
- ○ Fair
- ○ Average
- ○ Above Average
- ○ Excellent

Q19 Please rate how useful you believe genetic testing is for someone your age.

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10

Q20 Have you taken a direct-to-consumer (DTC) genetic test?

- ○ Yes
- ○ No

Skip To: Q25 If Have you taken a direct-to-consumer (DTC) genetic test? = No

Q21 Which brand's DTC test(s) did you take?

- ☐ 23andMe (Ancestry)
- ☐ 23andMe (Health Traits)
- ☐ Ancestry
- ☐ FamilyTreeDNA
- ☐ Promethease
- ☐ Other: _____

Q22 Which of the following reflect your experience with genetic testing? Please select all that apply.

- [ ] The educational materials provided by the company about genetic testing were adequate
- [ ] Having personal genomic testing made me feel like I have more control over my health
- [ ] I learned something to improve my health from my genetic testing that I didn't know before
- [ ] The information I received has influenced how I will manage my health in the future
- [ ] What I learned about my genetics can help reduce my chances of developing a disease
- [ ] Genetic testing was a beneficial experience
- [ ] I am disappointed that my results did not tell me more information
- [ ] Other: _____

Q23 Would you talk to a genetic counselor or physician about your testing results?

- ○ Yes, I already have
- ○ Yes, if I found something that concerned me
- ○ Maybe
- ○ No, I am not concerned by my results

Q24 Please rate your level of regret to being genetically tested.

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10

Q25 Which of the following reasons, if any, apply to why you participated or considered participating in genetic testing? Please select all that apply.

- ☐ I wanted to know if I was at risk for a certain disease
- ☐ I wanted to contribute my data to scientific research
- ☐ I wanted to test my sensitivity to certain medications
- ☐ I wanted to find out about my genetic ancestry
- ☐ I wanted to know my carrier status for different disorders
- ☐ I wanted to find out more about my genetic traits
- ☐ I was curious about how genetic testing works
- ☐ I am interested in genetics in general
- ☐ I took the test for fun
- ☐ A healthcare professional advised the test
- ☐ My family wanted me to take the test
- ☐ The test was available to me for free
- ☐ I wanted to find relatives
- ☐ Other: _____

Q26 When considering genetic testing, which of the following is/were a barrier to being tested? Please select all that apply.

- [ ] I was worried about the results of the test
- [ ] I did not think the results were valid
- [ ] I did not think the results were useful
- [ ] I was concerned about the privacy of my data
- [ ] I was skeptical of genetic testing in general
- [ ] I was concerned about the cost of genetic testing
- [ ] I was concerned about the time involved in testing
- [ ] I was concerned about the test not being recommended by a healthcare professional
- [ ] I was not interested in my genetic data
- [ ] I was not interested in the genetics at all
- [ ] Genetic testing goes against my religion and/or morals
- [ ] I was worried about my genetic information being used to discriminate against me

Q27 Please rate your confidence in the quality of results DTC genetic testing provides.

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10

Q28 Please rate your confidence in the accuracy of the results DTC genetic testing provides.

- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10

Q29 Please rate your opinion on the cost of genetic testing.

- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10

End of Block: Default Question Block

Appendix 2: IRB Approval Form

Office of Research Integrity
Institutional Review Board (IRB)
2000 University Avenue
Muncie, IN 47306-0155
Phone: 765-285-5052
Email: orihelp@bsu.edu

DATE:	February 25, 2020
TO:	Taylor Johnson
FROM:	Ball State University IRB
RE:	IRB protocol # 1525218-1
TITLE:	Perceptions of College Students on Direct-to-Consumer Genetic Testing
SUBMISSION TYPE:	New Project
DECISION:	APPROVED
PROJECT STATUS:	EXEMPT
DECISION DATE:	February 25, 2020
REVIEW TYPE:	Exempt Review

The designated reviewer for the Institutional Review Board (IRB) reviewed your protocol and determined the procedures you have proposed are appropriate for exemption under the federal regulations. As such, there will be no further review of your protocol, and you are cleared to proceed with the procedures outlined in your protocol. As an exempt study, there is no requirement for continuing review. Your protocol will remain on file with the IRB as a matter of record. All research under this protocol must be conducted in accordance with the approved submission and in accordance with the principles of the Belmont Report.

Exempt Categories:

	Category 1: Research conducted in established or commonly accepted educational settings, that specifically involves normal educations practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
x	**Category 2:** Research that only includes interactions involving educational test (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside

	the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the humans subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).
	Category 3: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).
	Category 4: Secondary research for which consent is not required.
	Category 5: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
	Category 6: Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
	Category 7: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 46.111(a)(8).
	Category 8: Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (1)Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d); (2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117; and (3) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to participants as part of the study plan. Note: This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Ball State Specific Exempt Categories

	Category 9: Research involving publicly observable online behavior. Any online behavior that requires a person's permission to access is considered private and does not fall under this category. Information that cannot be accessed by the general population would also be considered private.

	Category 10: Research involving BSU students who are under 18 but have legal authority over their FERPA protected information. Only studies that fall into another exempt category except for sampling from BSU students who are under 18 can be considered exempt in this category.

Editorial Notes:

1. Approved.

While your project does not require continuing review, it is the responsibility of the P.I. (and, if applicable, faculty supervisor) to inform the IRB if the procedures presented in this protocol are to be modified or if problems related to human research participants arise in connection with this project. **Any procedural modifications must be evaluated by the IRB before being implemented, as some modifications may change the review status of this project.** Please contact Sena Lim at (765)285-5034 or slim2@bsu.edu if you are unsure whether your proposed modification requires review or have any questions. Proposed modifications should be addressed in writing and submitted electronically to the IRBNet as a "Modification/Amendment" for review. Please reference your IRB protocol number 1525218-1 in any communication to the IRB regarding this project.

In the case of an adverse event and/or unanticipated problem, you will need to submit written documentation of the event to IRBNet under this protocol number and you will need to directly notify the Office of Research Integrity (http://www.bsu.edu/irb) **within 5 business days.** If you have questions, please contact Sena Lim at (765)285-5034 or slim2@bsu.edu.

Reminder: Even though your study is exempt from the relevant federal regulations of the Common Rule (45 CFR 46, subpart A), Ball State has elected to hold you accountable to these regulations to encourage best research practices. You and your research team are not exempt from ethical research practices and should therefore employ all protections for your participants and their data which are appropriate to your project.