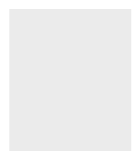


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ISSUE DESCRIPTION



COMMITTEE	World Health Organization
ISSUE	Ensuring Transparency Regarding Genetic Testing
SUBMITTED BY	Krisztina Nánási, Chair of the World Health Organization
APPROVED BY	Vilmos Eiben, President of the General Assembly

Introduction

Genetic testing, which is a relatively new and a rapidly emerging field, is the process of a laboratory test to examine one's DNA for variations or mutations which could cause diseases. It can be a helpful tool considering the biological basis of health conditions that someone may develop or is already affected by. Another widely used way of genetic testing is search of ancestry and family trees. While this may sound very simple and harmless, there have previously been problems with the revelation of people's DNA, for instance at an American company called 23andMe. This incident resulted in millions of people's data getting in the hand of unprivileged individuals of such information. Standing by this, the revealed genetic information is private and is directly related to an individual's identity. Not only is confidentiality an issue for health care, insurance coverage, and employment, but information from a genetic test can affect an entire family. Disclosure of such genetic results can be critical in all aspects of an individual's life more importantly to life altering decisions, therefore it needs addressing and discussion to prevent complications in the future and to ensure fair treatment for all.

Definition of Key Terms

Genetics - It could be defined as the study of genes, including the ways they act in a cell and the ways in which they are transmitted from parent to offspring. Modern genetics focuses on the chemical substance that genes are made of, called the deoxyribonucleic acid (DNA), and the ways in which it affects the chemical reactions that constitute the living processes within the cell.

DNA - Deoxyribonucleic acid is a molecule which carries the genetic information that codes for the development, traits and functions of an organism. It is present in nearly all living organisms.

Genotype - all the genetic information present in an individual

Genomic - a set of genes in a cell or organism

Biometric Personal Data - It is a type of personal information that can be used to uniquely identify an individual. It is usually collected as a part of a digital identity verification process. Biometric data can include fingerprints, voiceprints, iris scans, and facial recognition systems.

Amniotic Fluid - the fluid that surrounds a fetus during the pregnancy

General Overview

HISTORY OF GENETIC TESTING

Since breakthroughs in the 1980s, DNA testing has evolved rapidly, fuelled by advancements in technology and research methodologies. The very first application of this testing occurred in the forms of DNA fingerprinting discovered by British geneticist, Sir Alec Jeffreys. This rather new, practical invention was initially used in forensic investigations, and later in many other scientific fields to identify individuals. Around the same time, the introduction of other techniques also revolutionized the field which helped scientists to amplify small DNA samples. From then on up until now, DNA testing has expanded. In the meantime, scientists are still working on precisising this process and bringing accessibility to everyone in every region. This will eventually allow everybody, especially those who are involved in the field, to understand our structure on a more complex level. Nowadays, there are many companies offering direct-to-consumer tests, while clinical tests are more and more common in medical fields.

HOW IS IT DONE?

There are many different types of genetic tests available for individuals, and most of them require a sample of blood, hair, skin, amniotic fluid, or other tissue. The sample is sent to a laboratory, where technicians look for specific changes in chromosomes, DNA, or proteins, depending on the suspected disorders, often using DNA sequencing. The laboratory reports the test results in writing to a person's doctor or genetic counsellor. In most cases, the results arrive in a few weeks.

THE MAIN TYPES OF GENETIC TESTING

As there are nearly uncountable types of genetic tests, they could be categorized in a lot of ways. This situation is caused by the mere fact that there is no single DNA test that is able to detect all genetic conditions.

The categorization of genetic tests according to suspected state of an individual can be:

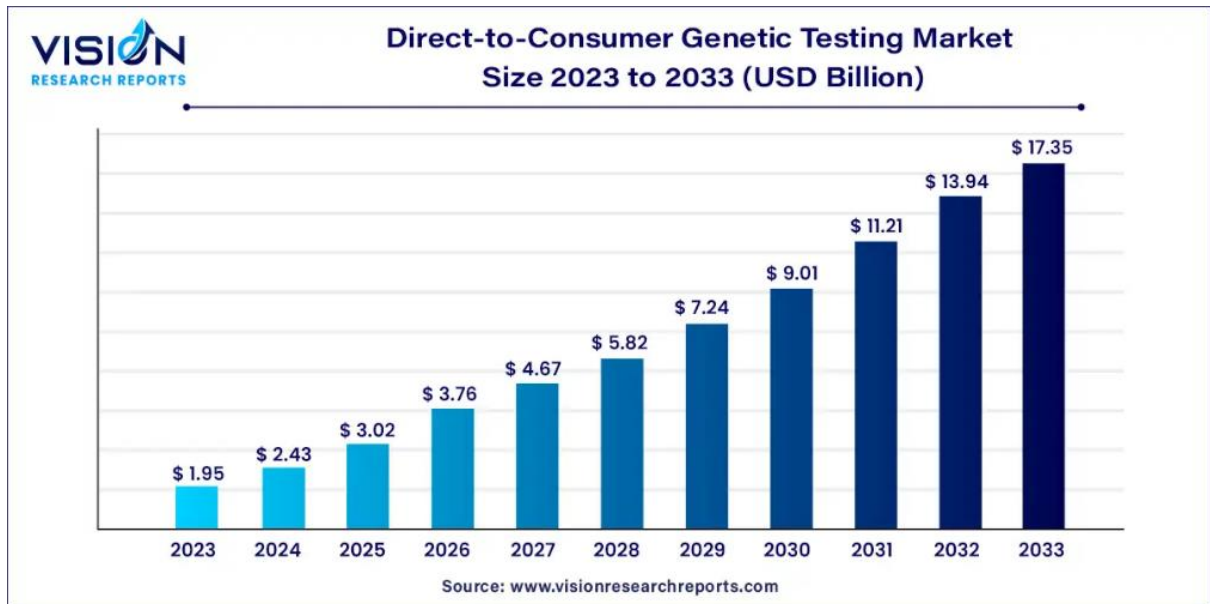
1. **Diagnostic testing** identifies the current disease states or illnesses of an individual. This process occurs during the prenatal or newborn period in one's life, and it could be viewed as the most common one.
2. **Carrier testing** determines whether a person only carries a certain genetic trait - it does not mean they are affected, can be only carriers of either a dominant or recessive feature.
3. **Predictive testing** ascertains whether an individual has a genetic mutation that could lead to or develop into a late-onset disorder.

THE CATEGORIZATION OF GENETIC TESTS ACCORDING TO QUANTITY

According to categorization based on the quantity of the genes examined, there could be single gene, genetic panels and large-scale tests. Out of these, each one looks at the patient's or customer's genes on a deeper level, and with large-scale tests being the ones to contain nearly all the information about one's DNA. Therefore, these could be the most precious to people and would make a greater loss to lose such data. Of course, losing any type and quantity of information about us, especially our DNA, is unpleasant and dangerous.

CLINICAL AND DIRECT-TO-CONSUMER GENETIC TESTS

The difference between the two could be easily explained. Clinical tests can only be ordered by one's health care provider, while DTC tests could be bought in stores or online. This easily accessible test is mainly used for learning more about ancestry and the main reason for that is that DTC tests cannot determine whether they will develop certain diseases. Meanwhile, clinical tests are much more reliable and confidential.



The number of people participating in direct-to-consumer tests has been increasing rapidly in the last decade which has also resulted in the intense growth of the market. These tests have many advantages, however, they always come with risks too. The compromise of genetic privacy could be one of the most serious issues regarding these tests. Many people are unaware of the fact that once they decide to do such an examination, their DNA will be in the hands of other people and as previously seen by some companies, not stored in the safest places. Others, who know about this, might not realize the value of their DNA, that it holds all information of their traits. By losing this data, one could also lose their privacy, which should be highly valued. According to statistics in 2021, roughly 100 million people had taken a DTC test, which has obviously increased up until today. With this many people involved in this field, it also proves that this issue cannot be ignored and has to be taken care of.

THE CONCERNING ISSUE

Having access to the genomic pieces of information of humans is fraught with ethical, legal, social, and cultural issues. Thus, the responsible sharing of such data has been set as a specific goal by the Science Council in the recent past. Of course, being able to access such information and revealing it comes with unbearable risks, such as emotional, financial or social ones. The release of such data can result in genetic discrimination, which is not as common nowadays as it used to be, but persists to be a relevant issue.

The greatest, most concerning issue is transparency and the safe storage of such genomic data of persons. People not knowing about the many disadvantages of this process could be the

result of companies not promoting the risks that come with sharing your DNA, and only displaying the advantages and bright side to this process. Moreover, there have recently been problems at some companies, such as 23andMe, where several customers' data was hacked, resulting in unauthorized people gaining access to many individuals' genetic information and trying to sell them for financial benefits. Unfortunately, these incidents of data breach are very common and are quite impossible to stop completely.

One of the most serious problems with the release of one's genetic information is connected to Jews and other ethnic group origins who could easily be identified by this and then be discriminated against again, as seen a few decades ago. Furthermore, the data of more well-known people is also known to be at risk, such as, for instance, the British Royal family or the founders of Google. Moreover, by having access to such confidential genomic information, employers and insurers could easily make interest by knowing whether their client will perhaps pass away early or suffer from a debilitating illness. While they could make profit out of it, many other people could lose their job or status as a result of it. This is exactly the reason why such information about our DNA is supposed to be strictly confidential, however, in our advanced world, it is becoming harder and harder to achieve each day. In the long term, one's genetic information could be more revealing about them than anything else, so it is in Favor of everyone to keep such data private.

Furthermore, until 2020, involving the private companies which offer direct-to-consumer tests, there was an absence of appropriate regulations directed at these exact companies, which, in addition, made it even harder to enforce any laws. As time has passed, regulations have been brought in by each nation, legislating their companies on their preferred level. However, as we look at all the regions' regulations on these tests or companies, they seem to vary. These laws cover aspects such as medical device safety, laboratory quality assurance, medical supervision, genetic counselling, and informed consent. Yet, most of these laws only apply to genetic testing within the conventional health care system. Applying these laws to a commercial product may not be sufficient to protect citizens from potentially harmful tests. So the need for further regulations is growing, while they would be extremely tough to apply considering the international and dynamic character of DTC genetic testing services.

What is more, the aforementioned firm, 23andMe has claimed that they are committed to protecting customer data and are consistently focused on maintaining the privacy of their customers after the incident. Based on this unsuccessful attempt and their share prices' drastic

drop, the company is unlikely to survive. But still, there are numerous companies in this same field working legally on the same serious level as 23andMe had been. The probability that they will get hacked too and more information will be leaked is in the skies, so to say that it is time governments did something about this issue is not an understatement.

Major Parties Involved

Estonia: Estonia's government deeply supports the tests of its residents' genomes, as they offer all citizens testing as part of their simple health care system. It is promised that the information from the test will be translated into personal reports for everyone. The main goal is to prevent health problems by warning participants about any probable condition they might develop, and to suggest taking preventative drugs.

The United States of America: In the U.S., the Genetic Information Nondiscrimination Act strictly prohibits group health plans and health insurers from denying coverage to a healthy person in the case when the results of a genetic test predict a possible disease in the future. The law also forbids employers taking one's genetic data into consideration when hiring, firing, making job placements or during promotion decisions. Besides this, the greatest and most recent hacking of a genetic testing company, 23andME has taken place in the country and is now going through a huge downfall. Unfortunately, this is not the only American company having problems with its security. Standing by this, the USA might be considered one of the most involved parties.

Germany: The testing of genomes in the country is governed by the Genetic Diagnostics Act, which clearly states that genetic tests can only be carried out under medical supervision in the hope of ensuring the proper interpretation of the results and well-informed decision making. The law emphasizes that counselling and informing patients is essential, along with the protection of individuals from misuse or misunderstanding of their data. Over and above that, the government has banned secret paternity tests from being carried out without the consent of those involved. The main reason for this is to ensure that fathers are not able to test their children for evidence that they are the real biological fathers without the mother's consent. This is necessary to prevent the breakup of families in the country

France: Genetic testing's legal status in France is strictly regulated by privacy and data protection laws. Due to concerns about the potential misuse and privacy violations of genomic data, direct-to-consumer tests are prohibited unless conducted with medical

oversight. Furthermore, tests for non-medical purposes, such as ancestry or personal traits, also face restrictions, which are due to a change of law stating that from January 2023, no citizen will be able to purchase and no company will be able to sell DTC tests legally.

Russian Federation: Russian law states that in connection with the implementation of international agreements, the processing of special categories of personal data, such as race or intimate life, is allowed and can be processed without the consent of the subject along with the compulsory state fingerprinting registration. It also applies to the processing of information characterizing the physiological and biological traits of a person, on the basis of which it is possible to establish one's biometric personal data. Within the framework of this genographic program, the government also plans to include the population of neighbouring countries which are the main source of migration.

United Arab Emirates: Since the end of 2021, the UAE Genome Project has been in progress. Its main aim is to establish strategic partnerships with top medical research centres and make sustainable investments in health care services. In order to identify genetic footprints and prevent the most prevalent diseases in the country, the government is trying to innovate modern techniques related to profiling and genetic sequencing. The UAE also pursues the achievement of personalized treatment for each patient based on genetic factors.

Israel: Israel was one of the first countries to establish a regulatory framework for the conduction of genetic testing, genetic counselling, and for the handling and use of identified genetic information. Accredited by the Ministry of Health, genetic tests must be done in labs. The law also forbids discrimination for employment and insurance purposes based solely on genetic test results, along with taking a strict approach to genetic testing on minors. Under the Genetic Information Law as of 2019, commercial DNA tests are not permitted to be sold directly to the public, but can be obtained with a court order, due to data privacy.

INTERNATIONAL POLICIES WITH DTC

Region/Location	Countries	Laws/Regulations
European Union	Belgium, France, Italy, Germany, United Kingdom	Provisions were added to the Charter of Fundamental Rights of the EU (2000) and the Convention on Human Rights and Biomedicine (1997). The provisions added were about insurers and how they are not allowed to require genetic tests for insurance purposes and genetic info, that exists from family members is not allowed to be processed by insurers. Laboratories have voluntary accreditation and get inspected every five years.
Asia	South Korea, Taiwan, India	South Korea has applied regulations prohibiting discrimination when it comes to a person's genetic components, and this applies to education, insurance, and employment. Taiwan passed the Personal Information Protection Act in 2012. India has acts that apply to individual data and insurance companies cannot have exclusions that are about genetic disorders.
South America	Chile, Argentina	Chile has regulations regarding clinical settings, but nothing when it comes to education, insurance, or employment. Argentina discusses the prohibition of using genetic information for discriminatory purposes but does not include either physical or blood tests.
Middle East	Israel	DNA testing is required in Israel for couples to either seek legal marriages or citizenship applicants. They are the only Middle Eastern Country to have anti-genetic discrimination legislation and prohibit insurers from requesting genetic testing or even asking if their customers have done genetic testing.
Africa	Morocco and Tunisia	<i>"Policy Requirements, Procedures and Guidelines for the Conduct and Review of Human Genetic Research in Malawi."</i> This states how genetic information poses risks to harmful consequences in social life such as education, health insurance, and immigration, and that this could lead to further separation and discrimination for individuals and families.

Timeline of Events

Mid-19th Century - The works of Gregor Mendel with hereditary material result in new discoveries.

1955 - Determination of exactly 46 human chromosomes

Spring of 2000 - The first American company starts to offer DNA testing for ancestry purposes.

November 17, 2004 - The UN health agency approves the first international standard for genetic testing.

May 25, 2018 - The General Data Protection Regulation (GDPR) is implemented in the European Union.

September 12, 2021 - The WHO suggests the first-choice screening method for cervical cancer to be DNA testing.

July 12, 2022 - WHO's science council issues the need to accelerate access for genomics testing in less-developed countries too.

September 2023 - America's Federal Trade Commission takes action against two direct-to-consumer DNA testing companies, CRI Genetics and 1Health/Vitagene for failing to keep DNA data secure.

October 6, 2023 - Data breach of 6.9 million users' genetic information (23andMe)

Previous Attempts to Solve the Issue

So far there have not been many attempts that could solve this still emerging issue. However, as of 25 May 2018, the General Data Protection Regulation (GDPR) was enacted by the European Union. It is a set of rules that helps individuals take control of their data that is collected, used and stored digitally or in a filing system, and moreover restricts a company's use of personal data. A more recent version of this is the Guidance for Human Genomic Data released by the WHO in November 2024. It also issues the secure collection, using and sharing of such personal information. This piece of document serves as the official source of navigation of complex issues surrounding data governance. Moreover, it aims to promote equity, safeguarding rights along with fostering transparency. The guidance recommends that publicly available policies such as the criteria for collection, access, use and protection should be described deeply and how such policies were developed to customers. These policies should describe how the right to privacy is protected and who is responsible for ensuring respect to this right throughout the data life cycle. In addition, it also suggests the right communication between the parties and the information of the involved client's rights related to their genomic data.

Besides these attempts, nations themselves have also made further regulations trying to solve this unfolding issue. Some European countries tried resolving this issue by banning private DRC tests completely and strictly regulating clinical tests, for instance France and Switzerland. These restrictions seem to have been working, however in the long term it could seem too strict and unnecessary to ban all ways of genetic testing, which is still a potentially great and labour-breaking technology despite its dangers. In the U.S., neither clinical nor DTC tests are regulated in any way, however the government has shown their attention in the 23andMe accident. In 2013, the U.S. Food and Drug Administration (FDA) warned the company to discontinue

marketing its health-related genetic tests in the country until it completed the agency's regulatory review process, which they only managed to complete nearly two years later. Their later launched program, which was also the DRC testing, seemed to meet FDA requirements for being scientifically and clinically valid, so the grant of this project led to their first direct-to-consumer test available. Since these and another few of the FDA's activities in the past, there has not been anything done publicly to solve the issue of the hacked genomic pieces of data. So as seen, shutting this technology out completely or letting it in fully are not likely to be the perfect solution, and that is the exact reason why nations need to find the "aurea mediocritas".

Possible Solutions and Approaches

With the completion of the Human Genome Project, it has been showcased that "correct", "usual" and "normal" no longer have meaning when it comes to a person's genetic makeup, and the reason for that is the individuals' very different genotypes from each other. Scientists continue to work on ways to understand the structure of human genetic makeup on a deeper level, which could allow important advances in the prevention, detection and treatment of many disorders.

A basic and well-working solution could obviously be offering more detailed education to the people, especially about the dangers of direct-to-consumer tests' lack of safety. In the long run, this could mean the downfall of such companies. As all the safety problems come from direct-to-consumer tests, reducing or regulating the use of them could lead to less people giving away their genomic information just out of curiosity of their ancestry or else. Improving the security of already existing companies with many people's genomic information is also essential and cannot be neglected.

The cooperation between such organizations could also lead this issue towards a better future, discussing and sharing technologies and privacy methods. Moreover, if governments get involved with these companies' policies more, it could also help us solve this issue. Screenings, providing a safer surface to store information or higher quality devices, places to store data could prevent these unethical and uncomfortable situations, such as with 23andMe. People could be provided with insurance for the possibility of losing their data, or at least they should be given an opportunity to underwrite such a policy.

QUESTIONS TO CONSIDER

- ❖ How would the WHO manage to fund genetic testing and education in underdeveloped countries?
- ❖ How could the WHO reduce discrimination due to genetic test results in relation to employment and health insurances?
- ❖ In which ways could countries support each other involving hacking problems connected to genetic testing?
- ❖ How could countries reduce or regulate the use of unnecessary direct-to-consumer tests?
- ❖ Where does liability fall in case of a breach, to what extent should companies be held responsible?

Bibliography

<https://www.mayoclinic.org/tests-procedures/genetic-testing/about/pac-20384827>

<https://www.genome.gov/genetics-glossary/Genetic-Testing>

<https://pubmed.ncbi.nlm.nih.gov/articles/PMC2564466#:~:text=Genetic%20information%20is%20private%20and,can%20affect%20an%20entire%20family.>

<https://medlineplus.gov/genetics/understanding/testing/genetic-testing/>

<https://www.politico.eu/article/europe-eyes-new-rules-for-wild-west-of-dna-testing/>

<https://news.un.org/en/story/2004/11/121202>

<https://www.psychologytoday.com/intl/blog/the-lost-family/202012/extraordinary-year-milestones-in-dna-testing> <https://www.evergreen-life.co.uk/health-wellbeing-library/when-did-dna-testing-start/>

<https://iris.who.int/bitstream/handle/10665/379554/9789240102149-eng.pdf?sequence=1>

<https://www.robinskaplan.com/newsroom/insights/the-evolution-and-practical-application-of-genetic-testing>

<https://www.cdc.gov/genomics-and-health/counseling-testing/genetic-testing.html>

<https://www.nytimes.com/2024/10/05/business/23andme-dna-bankrupt.html>

<https://www.bbc.com/future/article/20240212-dna-testing-what-happens-if-your-genetic-data-is-hacked>

<https://www.biospace.com/direct-to-consumer-genetic-testing-market-rising-rapidly-at-cagr-24-43-percent>

<https://www.bbc.com/news/articles/c4gm08nlxr3o>

https://isogg.org/wiki/Regulation_of_genetic_tests#:~:text=around%20the%20world.-,France,selling%20DNA%20tests%20in%20France

<http://d-scholarship.pitt.edu/46315/1/Zogu%2C%20S.%20MPH%20Essay%202024.pdf>

<https://customercare.23andme.com/hc/en-us/articles/211831908-23andMe-and-the-FDA>