

Direct-to-Consumer (DTC) Genetic Testing - Risk and Safeguards

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In 2008, TIME magazine named 23andMe's \$399 saliva test kit "Invention of the Year"

¹. Genetic testing had been commoditized, any layman could get his DNA analyzed to determine his ancestry and his predisposition to certain illnesses. With so much interest in DTC genetic testing, what are the potential risks and what are some safeguards that companies should have?

Consent when processing special categories of data

DTC genetic testing companies have given artificially conceived individuals the ancestry information needed to identify and contact their biological fathers. This is *prima facie* a marvel of modern technology until we realize that most sperm donors were promised anonymity at the time of their donation ². In one case, a poor student chose to donate his sperm purely for the £10 reimbursement, which is hardly enough recompense if he knew what implications future technology was about to bring. ³.

Separately, the comprehensive ancestry tree amassed by these companies have attracted the attention of law enforcement officers, who have attempted to upload DNA found either at the crime scene or gathered through surreptitious means in hopes of identifying

¹ Anita Hamilton, 'TIME's Best Inventions of 2008' (*TIME*, 2 November 2008) <https://web.archive.org/web/20081102044918/http://www.time.com/time/specials/packages/article/0,28804,1852747_1854493,00.html> accessed 21 October 2023

² Meghana Keshavan, "There's no such thing as anonymity': With consumer DNA tests, sperm banks reconsider long-held promises to donors' (*STAT*, 11 September 2019) <<https://www.statnews.com/2019/09/11/consumer-dna-tests-sperm-donor-anonymity/>> accessed 21 October 2023

³ The Guardian, 'Ending sperm donor anonymity will have a profound impact on families' (*The Guardian*, 3 June 2022) <<https://www.theguardian.com/science/2022/jun/03/ending-sperm-donor-anonymity-will-have-a-profound-impact-on-families>> accessed 24 October 2023

suspects ⁴. Individuals, who may have just happened to sneeze at the wrong place at the wrong time, risk having their genetic data uploaded to these databases outside of their own volition.



Figure 1: Tissue discarded by an innocent passerby. ⁵

Consent when processing special categories of data should be the overall top risk because it has a detrimental effect on the efficacy of existing laws. Spitting into a tube could subvert and render otiose the Human Fertilisation and Embryology Act ⁶, which allows the authorities to reject requests when there is an increased likelihood of identifying the donor. Such *de facto* methods will need to be regulated to ensure fairness to *ex-ante* sperm donors.

Taking responsibility and empowering customers with privacy controls

Companies are aware of the aforementioned risks, and they have taken the responsibility to self-regulate and empower their customers with choice. After some initial missteps, 23andMe has disabled their ancestry tree feature unless the user chooses to opt-in ⁷. GEDmatch set up a separate website for law enforcement use and gives users varying

⁴ Rafil Kroll-Zaidi, 'Your DNA Test Could Send a Relative to Jail' (*The New York Times*, 27 December 2021) <<https://www.nytimes.com/2021/12/27/magazine/dna-test-crime-identification-genome.html>> accessed 21 October 2023

⁵ Generated using DALL-E

⁶ Human Fertilisation and Embryology Act 2008, Section 31ZA, Paragraph 6

⁷ Roberta Estes, 'Hide and Seek at 23andMe, DNA Relatives Consent, Opt-In, Opt-Out and Close Relatives' (*DNAeXplained*, 25 October 2014) <<https://dna-explained.com/2014/10/25/hide-and-seek-at-23andme-dna-relatives-consent-opt-in-opt-out-and-close-relatives/>> accessed 22 October 2023

privacy options to choose from ⁸. Hence, *ex-ante* sperm donors can choose stricter privacy settings if they wish to remain anonymous. In addition, the state of Maryland passed a law on Forensic Genealogical searches limiting its use to serious crimes and requiring *inter alia* informed consent from non-suspects and judicial authorization, which is only granted as a last resort ⁹.

I believe such safeguards are a good step in ensuring that *ex-ante* sperm donors' identities remain protected. It is important to note that family members of sperm donors might still be identified as they share a sizable percentage of the genetic data of the sperm donor ¹⁰. With stricter requirements for law enforcement use, innocent bystanders will not get caught in the crossfire and lose control of their own genetic data.

Risk minimization and its effect on a data breach of non-temporal data

Genetic data is immutable. If your password or credit card details are leaked, it is trivial to change the password or issue a new credit card respectively. The same cannot be said for genetic data. GEDmatch practices risk minimization by storing only “tokenized” DNA data ¹¹. Such safeguards ensure that raw genetic data is not leaked if a data breach occurs. When DNA Diagnostics Center (DDC) suffered a data breach in 2021, the regulator as well as affected users were notified within a day ¹². DDC also practiced risk minimization measures, storing genetic data in a separate database that was thankfully unaffected by the aforementioned breach ¹³. This case proves that risk minimization measures do work to safeguard genetic data and reduce the probability of a leak.

⁸ GEDmatch, 'GEDmatch & Community Safety' (*GEDMatch*) <<https://www.gedmatch.com/community-safety/>> accessed 22 October 2023

⁹ Maryland Statutes Criminal Procedure 2022, Title 17 - Forensic Genealogy

¹⁰ Keshavan (n 2)

¹¹ GEDmatch, 'Terms of Service & Privacy Policy' (*GEDMatch*) <<https://www.gedmatch.com/terms-of-service-privacy-policy/>> accessed 24 October 2023

¹² Office of the Maine AG, 'Data Breach Notifications' (*Office of the Maine AG*, 29 October 2021) <<https://apps.web.maine.gov/online/aewiewer/ME/40/0d530517-178f-4144-abc5-ac77b10c30af.shtml>> accessed 24 October 2023

¹³ Alicia Hope, 'DNA Testing Firm Data Breach Exposed Sensitive Information of More Than 2.1 Million People' (*CPO Magazine*, 9 December 2021) <<https://www.cpomagazine.com/cyber-security/dna-testing-firm-data-breach-exposed-sensitive-information-of-more-than-2-1-million-people/>> accessed 24 October 2023

Advertising with integrity and comprehensibility

Genetic variations and their corresponding effects are an area of active research. It is tempting for companies to advertise new tests for susceptibility to certain diseases even though the research results are not fully conclusive or supported by additional studies. In 2013, the FDA ordered 23andMe to discontinue marketing of their test kit until they could “analytically or clinically validate” it ¹⁴. The FDA were also concerned about the customers’ ability to comprehend and how they intended to use that information ¹⁵.

This risk is ranked lowest because the worst-case scenario would be psychological harm or worry about the increased risk of developing a certain disease. *Grieves v FT Everard* has established that anxiety at the thought of increased risk of suffering from a certain disease would not be sufficient as a cause of action under tort ¹⁶. There might even be positive benefits as customers might adopt a healthier lifestyle.

General duty of care and taking sensible precautions

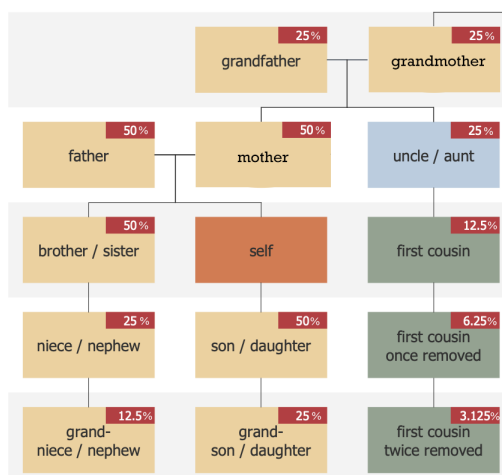


Figure 2: Chart illustrating genetic kinship. ¹⁷

¹⁴ George J Annas and Sherman Elias, ‘23andMe and the FDA’ (2014) 370(11) *New England Journal of Medicine* 985 (PMID: 24520936) <<https://doi.org/10.1056/NEJMp1316367>>

¹⁵ Annas and Elias (n 14)

¹⁶ *Grieves v FT Everard & Sons Ltd* (2007) 3 WLR 876

¹⁷ Dimario, Cousin tree (with genetic kinship) (Wikimedia Commons, 27 April 2010) <[https://en.m.wikipedia.org/wiki/File:Cousin_tree_\(with_genetic_kinship\).png](https://en.m.wikipedia.org/wiki/File:Cousin_tree_(with_genetic_kinship).png)> accessed 28 October 2023

If a close family member decides to do genetic testing, a large fraction of an individual's genetic information, which is a special category of data under the GDPR requiring explicit consent ¹⁸, might also be inadvertently processed. At a genetic conference in 2012, two Native American women shared that they would never do a genetic test without first consulting the entire tribe, as they would be “making the decision for everybody” ¹⁹. We have also earlier explored a case where family members of sperm donors might be identified by the artificially conceived recipient.

Genetic data is as much “personal data” as it is “family data”. There are some parallels with Lindqvist. Lindqvist shared her colleague's personal data to facilitate ‘confirmations’ in her parish ²⁰. Hence, the blog entries contained multiple individual's personal data, of which only she had consented to the sharing. The commission took the position that publishing that data on the internet could not be considered ‘a purely personal or household activity’ ²¹. If we were to apply that to genetic testing, it would probably be alright for an individual to decide to do genetic testing. However, he should probably exercise duty of care, consult the opinion of family members before deciding to share that information in a publicly accessible ancestry tree. Individuals should also adopt the precautionary principle and ask themselves, even though they can share that information, is it really wise to do so?

¹⁸ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L119/1, Article 9

¹⁹ Kroll-Zaidi (n 4)

²⁰ Elizabeth Brownsdon, ‘Websites and data protection—the Lindqvist case’ (2004) 4(3) Privacy and Data Protection

²¹ Case C-101/01 *Bodil Lindqvist* [2013] ECR I-12971, paragraph 47

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