# Generating ideas for the Law Commission's 14th Programme of law reform

## Consultation response from the ConnecteDNA Research Team, studying donor conception in the age of direct-to-consumer genetic testing

The project is being conducted by a multi-disciplinary team led by Dr Lucy Frith, University of Liverpool with Professor Marie Fox, Dr Caroline Redhead and Dr Leah Gilman (University of Liverpool), Professor Nicky Hudson (De Montfort University, Leicester), Dr Petra Nordqvist (The University of Manchester), Dr Fiona MacCallum (University of Warwick) and Dr Jackson Kirkman-Brown (University of Birmingham)

**Foreword**

The ConnecteDNA project is a collaboration between researchers at the University of Liverpool, The University of Manchester, De Montfort University, the University of Warwick and the University of Birmingham. The project has been awarded funding by UK Research and Innovation Economic and Social Research Council to explore how people involved in donor conception use, and are impacted by, the rise in online DNA testing (sometimes called direct-to-consumer genetic testing or DTCGT).[1]

We are pleased to submit this response to the Law Commission's public consultation regarding ideas for the 14th Programme of Law Reform. We welcome this consultation, and the invitation to contribute our ideas. In offering our suggestions below, we have taken account of the criteria which will be applied in agreeing the 14th Programme with the Lord Chancellor, and we would draw the Commissioners' attention to the closeness of fit between our research and the initial ideas for law reform suggested by the Law Commission under the 'family law' heading.[2] Direct-to-consumer genetic testing is also an area that the House of Commons Science and Technology Committee, in its First Report of Session 2021-22 (Report), has recommended requires legal and regulatory scrutiny and reform.[3]

We note that the Law Commission welcomes comments on its initial project ideas. We support the suggestion that DTCGT is an area the Law Commission should consider including in the 14th Programme and we would be well-placed and willing to offer support to the Commission's work in this area, for the reasons we set out below.

**Background: DTCGT in the context of donor conception**

The aim of the ConnecteDNA project is to examine the use of DTCGT by donor (egg, sperm and embryo) conceived adults, donors and parents of donor-conceived people. The Donor Conception Network describes 'donor conception' as the use of eggs, sperm or embryos (or both eggs and sperm) from donors to help with conception when one or both partners in a heterosexual couple are infertile.[4] Donor gametes may also be used in order to reduce the risk of passing on a genetic condition to any child conceived, to aid family building for women without a male partner and lesbian couples, or in conjunction with surrogacy.[5] It may take place via reproductive treatment centres (egg/sperm banks and fertility clinics) or (in some cases of sperm donor conception) through private arrangements outside of medical centres.

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[1] Indicative data (which we have not verified) suggests that the databases of the biggest DTCGT providers hold the data of around 40 million individuals: https://www.dataminingdna.com/who-has-the-largest-dna-database/

[2] See the reference to information about an individual's origins, particularly in the context of assisted conception: https://www.lawcom.gov.uk/14th-programme-kite-flying-document/#Family

[3] https://committees.parliament.uk/publications/6347/documents/69832/default/. Dr Lucy Frith, the PI for the ConnecteDNA research, submitted evidence to the House of Commons Science and Technology Select Committee inquiry into commercial genetic testing. https://bit.ly/2RXnesN Evidence was also submitted by members of the ConnecteDNA Advisory Board.

[4] See https://www.dcnetwork.org/what-donor-conception

[5] For further information, see the websites of The Donor Conception Network: https://www.dcnetwork.org/what-donor-conception and the Human Fertilisation & Embryology Authority: https://www.hfea.gov.uk/

Donor conception, in the UK, is regulated by the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008) (the 1990 Act).[6] The 1990 Act also established the Human Fertilisation & Embryology Authority (HFEA), which is the UK's independent regulator of fertility treatment and research using human embryos. The HFEA has general oversight over the treatment services and activities governed by the 1990 Act, and specific powers to licence, monitor and inspect fertility clinics. It is constituted as an 'arm's length body' of the Department of Health, meaning it works independently of the Government, but on the Government's behalf.[7]

The activities for which the HFEA may grant licences are set out in Schedule 2 to the 1990 Act. Broadly, it can license a range of activities relating to the provision of fertility treatment services and research, at licensed premises. The HFEA's jurisdiction does not, however, extend to commercial DTCGT services, and the organisations offering these services are not subject to equivalent regulation or oversight in the UK. Clearly DTCGT services differ, in many respects, from the activities to which the 1990 Act applies. But what is becoming clear, however, is that the provision of genetic information to consumers who use DTCGT services has the potential to circumvent, and significantly disrupt, the regulatory structures established by the 1990 Act, particularly as regards information provision to donor conceived people.

DTCGT service providers include family history sites, such as Ancestry.co.uk, and medical testing sites, such as 23andme. Many of these companies also offer 'relative finder services'.[8] Despite the different motivations people have for using DTCGT services (e.g., genealogical, health-related, for 'wellness' reasons or to obtain information about ethnicity), it is now easier for people to search for, find, and/or inadvertently discover, information about their genetic origins and relationships through DTCGT. The numbers of people finding out they are donor-conceived through DTCGT are rapidly increasing. For example, one woman discovered she was donor conceived after using 23andme to assess her risk of breast cancer, an eventuality she had not anticipated when she decided to take that test.[9] Similarly, donor relatives can unexpectedly be identified, particularly when results of genetic testing are combined with searches of the broad global community created by social media platforms. Some individuals have found large numbers of donor-siblings, and donors have been traced by their adult donor offspring. Donor-conceived people, recipients of donor gametes and embryos, and donors may become aware of unexpected genetic connections as a result of information revealed by DTCGT.[10] These discoveries can lead to valued relationships[11] but

[6] See https://www.legislation.gov.uk/ukpga/1990/37/contents
[7] See https://www.hfea.gov.uk/about-us/
[8] See, for example, https://www.ancestry.co.uk/genealogy/records
[9] Crawshaw, M. (2018) *Direct-to-consumer DNA testing: the fallout for individuals and their families unexpectedly learning of their donor conception origins*, Human Fertility, 21:4, 225-228
[10] See, for example, BBC2 'DNA Family Secrets' series: https://www.bbc.co.uk/programmes/m000sth9
[11] See, for example Maren Klotz (2015): https://www.tandfonline.com/doi/full/10.1080/01459740.2015.1012615

they can also have harmful consequences, disrupting family life and relationships, exposing family secrets and leading to reassessments of family history and individual identity.[12]

It is important to note, in considering the potential for harmful disruption created by such inadvertent discoveries, that the individuals who discover (or who are discovered through) genetic connections of which they were previously unaware, may not themselves ever have engaged with donor conception. Further, it is possible, or even probable, that those potentially affected will control neither the discovery of the information about these unexpected connections, nor its dissemination. If, for example, a sperm donor's brother, who was unaware that his brother had donated, were to be contacted by someone conceived from his brother's donation, there might be a plethora of potential consequences. The donor's brother would have to consider, for example, whether to put the donor conceived person in contact with his brother, whether to tell their mutual relatives of his discovery or, were his brother to be deceased, whether to inform any surviving spouse and/or children. Any of these potential scenarios clearly calls into question the notion of informed consent in this context, as well as highlighting the pressing need for guidance about access to counselling and/or other support services for users of DTCGT services.

An equally important issue relates to donor anonymity. With effect from 2005, UK legislation has required any donor of gametes or embryos used in the treatment of others to agree to the disclosure of their identity to any person conceived from their donation, should they request it after reaching the age of 18.[13] The regulations underpinning this change did not have retrospective effect and, prior to their entry into force, donors were routinely assured that their anonymity would be protected. Officially therefore, donors whose donation was made before the entry into effect of the 2004 Regulations retain their anonymity. Similarly, donors who have donated since 2005 may well be under the impression that their anonymity is protected until any donor offspring are eighteen. Realistically, however, a donor's anonymity cannot, any longer, be assured.[14] This adds a further dimension to the complex legislative and social context within which DTCGT sits.

Thus the growth in the use of DTCGT has the potential to be highly disruptive to current legal and regulatory practices in the UK (and more widely). There has been considerable discussion, media interest and anecdotal evidence about the potential harms linked to these lacunae in the law, especially where the individuals affected were neither involved with donor conception nor users of DTCGT services. We note, although it is not the focus of our research, that the provisions in the Adoption and Children Act 2002 (and associated Regulations) restricting the disclosure of information in relation to a person's adoption may also be circumvented by DTCGT.[15] The issues raised will thus also link to those likely to be experienced by adopted persons and anyone connected to them. There has been no large-scale research into either the social consequences of DTCGT, or the regulatory position. There is therefore

[12] Frith, L. Blyth, E. Crawshaw, M. van den Akker, O. (2017) Secrets and disclosure in donor conception. Sociology, Health & Illness. https://onlinelibrary.wiley.com/doi/10.1111/1467-9566.12633

[13] The Human Fertilization and Embryology Authority (Disclosure of Donor Information) Regulations 2004 https://www.legislation.gov.uk/uksi/2004/1511/contents/made

[14] See Darroch and Smith (2021) https://onlinelibrary.wiley.com/doi/epdf/10.1111/fcre.12553

[15] See Adoption and Children Act 2002, s56 et seq: https://www.legislation.gov.uk/ukpga/2002/38/contents

an urgent need both for a review of the law in this area, and for research to inform any proposed reforms.[16] Our project will address the latter. The 14th Programme should address the former.

**The recommendations of the House of Commons Science and Technology Committee Report on DTCGT: a snapshot**

DTCGT is relevant to a number of areas of law, most notably to laws relating to privacy and consent, and to consumer protection legislation. The House of Commons Science and Technology Committee (Committee) Report on DTCGT (Report),[17] which builds on the work of the Committee's predecessor select committee and a proposal from the Nuffield Council on Bioethics,[18] presents a review of the oral and written evidence submitted to the Committee. The Report makes a number of recommendations for legal and regulatory reform:

1. that the Government should require direct-to-consumer tests to be subject to greater pre-market assessment by an external body, to cover clinical performance as well as analytical performance;

2. that the Government should work with Genomics England and the NHS to define clear technical standards for direct-to-consumer genomic testing;

3. that the Government should consider the case for amending the current regulation of direct-to-consumer genomic tests to revise the requirements on information and support provided to consumers;

4. that the Government should review the adequacy of the UK's data protection framework for direct-to-consumer genomic testing, including the risks and opportunities presented by technological developments and growing numbers of consumers using direct-to-consumer genomic tests. The Committee suggested that the Government should aim for the data protection framework governing genomic data in the UK to be world-leading;

5. that the Government should consider if any restrictions should be placed on the types of genomic tests that should be available directly to consumers for use on asymptomatic children and for prenatal testing; and

6. that the Government should consider the scope of regulation of direct-to-consumer genomic testing, specifically with respect to companies selling testing products to UK consumers but conducting testing outside of the UK, and companies offering analysis of genomic data obtained by third parties

[16] Phillips, A. (2016) Only a Click Away – DTC Genetics for Ancestry, Health, Love…and More: A View of the Business and Regulatory Landscape. Applied and Translational Genomics. 8, 16-22.
[17] See: file:///M:/DTCGT/Documents/Law%20Commission/Parliament%20report%202021.pdf
[18] See: https://www.nuffieldbioethics.org/assets/pdfs/Nuffield-response-to-ST-Committee-inquiry-on-commercial-genomics-April-2019-FINAL.pdf

The Report focused primarily on testing used for medically related purposes such as, for example, to identify rare genetic conditions that could otherwise take significant time and effort to identify, or to alert people to their specific health risks, allowing them potentially to mitigate those risks through changed behaviours or personalised screening.[19] Our research focuses primarily on the issues related to the 'relative finder' function of these services. We suggest that both uses of DTCGT are equally important components of a law reform project.

**The ConnectedDNA Research Project**

The ConnecteDNA project will examine the social, ethical and regulatory implications of DTCGT technologies, and consider how these 'unofficial,' and largely unregulated, systems for accessing information about donor conception sit alongside, and/or interact with, the 'official' systems (e.g. the Donor Conceived Registry, a centrally held database for donors and donor conceived people in the UK). It focuses on the UK context but will have implications for practice across other jurisdictions. The aim of our research is to examine the use of direct-to-consumer genetic testing (DTCGT) by donor (egg, sperm and embryo) conceived adults, donors and parents of donor-conceived people.

This is an inter-disciplinary project. The team members have expertise in sociology, law and socio-legal studies, family psychology, reproductive science and bioethics. Our Advisory Board will comprise people with expertise in fields relating to donor conception and/or DTCGT, including policy-makers, lawyers, counsellors, academics, geneticists, members of relevant support and community organisations and clinic managers. We are therefore well equipped to address the multi-faceted nature of DTCGT as an emerging social, and socio-legal, phenomenon.

We are funded by the UKRI for a three year period from February 2021, with a total research budget of almost £750,000. During this period, we will carry out a variety of research activities to inform the development of a set of recommendations for the governance of DTCGT services, and produce suggested practice guidance. Our recommendations will be relevant both for those involved in donor conception and more generally.

The focus of this project is on donor conception, rather than the concerns about the use of DTCGT for medical reasons (false positives and negatives, inadequate consent procedures and problems interpreting results). However, the findings of our research, particularly in relation to the legal and social consequences of the 'relative finder' services, will be potentially relevant for all users of DTCGT, particularly as this service is often offered as a package together with the other services offered. Our research will also have broad general relevance in the context of changes to the ways in which people are now accessing information and healthcare. It is important to note, as highlighted in the Background section above, that the issues we will be investigating can (and do) affect a much larger pool of people than those who have engaged with donor conception or DTCGT. Our findings will provide guidance for

[19] See page 9 of the Report:
file:///M:/DTCGT/Documents/Law%20Commission/Parliament%20report%202021.pdf

service users, professionals and policy makers who are navigating an increasingly complex terrain where there is little advice or guidance available.

**Concluding comments: evidencing the need for law reform in the areas of law relevant to DTCGT**

There is *real value and importance* in reviewing and proposing reforms to the patchwork of laws relevant to this area, both as they relate to the regulation of DTCGT companies and as they regulate information sharing in the context of donor conception. The harms that will arise from an insufficiently coherent legislative framework are potentially significant in each case, albeit for different reasons. With the exponential rise in the use of donor conception[20] and the number of people taking DTCGT tests predicted to grow to over 100 million people worldwide by 2021,[21] the *impact* of law reform in this area is potentially significant, and it is *urgently required*.

There is *Government support* for legal and regulatory reform in this area. Our advisory board membership suggests significant *stakeholder engagement and support* for research to underpin legal and regulatory change. Our suggestion is that reform *should be considered more widely than in relation only to the medical uses of DTCGT*. The law must be able to balance the particular rights and interests of donors and donor-conceived people who are curious about their origins and identity, as well as offering appropriate consumer protection to *all* users of DTCGT services.

If the Law Commission decides to take forward a project related to DTCGT in the 14th Programme, we would welcome the opportunity to collaborate with the Law Commission's team. The lawyers in our team have a wealth of academic knowledge and practising experience. Alternatively, we would be pleased to share our findings to the extent that they are compatible with the aims of the Law Commission's project.

**The ConnecteDNA Research Team**
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[20] De Geyter, C et al. (2018) The European IVF-monitoring Consortium (EIM) for the European Society of Human Reproduction and Embryology (ESHRE), ART in Europe, 2014, Human Reproduction, Volume 33, Issue 9, September, 1586–1601.

[21] Regalado, A. (2018) 2017 was the year consumer DNA testing blew up: More people took genetic ancestry tests last year than in all previous years combined. MIT Technology Review. https://www.technologyreview.com/s/610233/2017-was-the-year-consumer-dna-testing-blew-up/