Background document sent to all participants in the workshop

Index

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Joint meeting on familial genomic information

Background

The question of how genomic and genomic test results that are relevant to more than one family member should be managed, has been a topic of debate for several decades in healthcare. However, the difficulties of balancing duties of care where the information revealed is both personal, and at the same time familial, is a continuing challenge for healthcare professionals.

Such issues arise in at least half of all cases discussed at the UK Genethics Forum – a multidisciplinary discussion forum for healthcare professionals, which has held 70 meetings over more than two decades. Professional guidelines such as those from the General Medical Council have long recommended a balancing exercise between one patient's confidentiality and the prevention of harm to another. However, the complex governing legal framework (including common law and legislation relating to patient confidentiality, privacy, human rights, personal data and professional responsibilities) provides conflicting accounts of how this might be achieved. The seminal 2020 judgment of the High Court in *ABC v St George's Healthcare NHS Trust* sets an important precedent by establishing a legal duty to consider disclosure of confidential information without consent if another person is at risk of serious harm in certain circumstances. But many working in healthcare, including hospital legal teams who may be called upon to advise, remain uncertain about the implications of this judgment for clinical practice.

Genomic information and families

Ever since the first chromosomal genomic tests (karyotyping) entered NHS practice in the 1970s, practitioners have at times been faced with questions about *what* might need to be disclosed to family members, *when* this might be appropriate, and *who* should be involved in this communication. Considerations of what constitutes 'familial information' and if, when and how this should be communicated to others are the subject of our meeting.

The speed and cost of genomic testing have improved exponentially – over the last 2 decades in particular – such that a genomic code (genome) can be mapped in detail to see whether variants within help to explain an individual's clinical signs or symptoms, or a family history of a condition.

A genomic diagnosis in one person can, depending on the circumstances, suggest that others might also have inherited the condition or trait. Sometimes the family history and/or clinical presentation of disease will strongly suggest that a relative also has the genomic variant in question, even if they have not (yet) been tested. At other times healthcare professionals may identify relatives who may not know they have an increased risk of a genomic condition. Healthcare professionals can find it difficult to know how to preserve the confidentiality of one patient and at the same time alert a family member of their risk of a particular condition.

As the three (hypothetical) clinical cases below illustrate (cases 10, 14 and 15 from JCGM guidance),[1] findings in one individual may point to family members who might benefit from being alerted about their risks, because much genomic information will be common to close relatives. Indeed, genomic testing may only be requested because of wider knowledge about a condition within a family.

[1] Cases copied from guidelines from the Joint Committee on Genomics in Medicine. Royal College of Physicians, Royal College of Pathologists and British Society for Genomic Medicine. Consent and confidentiality in genomic medicine: Guidance on the use of genomic and genomic information in the clinic. 3rd edition. Report of the Joint Committee on Genomics in Medicine. London: RCP, RCPath and BSGM, 2019.

Once a genomic diagnosis is made, healthcare professionals will often suggest that an individual communicates their genomic results with the relatives for whom it may be relevant. However, for a variety of reasons, this may be difficult for some patients, and studies suggest that a significant group of relatives – identified by healthcare professionals as requiring information – do not find out about their heritable risk.

Struggles in sharing information

Case 10: Struggles in sharing information

Saleem is a 41-year-old man with Lynch syndrome (a cancer predisposition syndrome that increases the risk of bowel and various other cancers). He is very ill with advanced colorectal cancer. Saleem has several siblings with whom he is not in regular contact. He provided their details when giving his family history but is reluctant to tell his siblings about his diagnosis of Lynch syndrome. He does not appear to be withholding this information maliciously, but because of the lack of contact, he finds it difficult to approach them. The clinical genetics department has offered Saleem help to make contact with his siblings, but Saleem is adamant that he will do this, he would just like to 'get over his treatment first'.

Key points

- Many patients acknowledge the need to inform their family members about genetic risks but some find it difficult to do so.
- Consent conversations need to make it explicit that genetic tests may generate information of relevance to family members. It may be helpful to encourage patients to discuss their intention to have genetic testing with their family, in advance of receiving the results.
- Clinicians are often left in a difficult situation when a patient intends to disclose information about a genetic risk but is struggling to do so. Offering support such as written information to pass onto relatives, relevant online resources, or liaison with relatives' GPs may be appropriate.

The same Guidance recommends that healthcare professionals should routinely discuss with patients the importance of family communication about genomic findings and help them to identify the relatives that might benefit from that information. The draft record of discussion form included as Appendix 1.2 in this Guidance (Appendix 1 here) provides a template form that prompts a healthcare professional to discuss various aspects of genomic testing, including supporting discussions about sharing genomic information with other family members.

It is worth noting that both a genomic diagnosis and exclusion of a genomic diagnosis may have implications for relatives' risk assessment. Case 2 explores how knowledge of a family history may be relevant in the context of prenatal testing.

Case 14: Early pregnancy with a chance of a serious genetic condition

Caroline is seen in the genetics clinic when she is 10 weeks pregnant. Multiple boys in her family have died young due to an X-linked condition (ie one in which males, with a single X chromosome, are affected but females, with two X chromosomes, are usually unaffected because they only carry one copy of the altered gene and have a normal copy on their other X chromosome). Caroline does not know which of her relatives have had genetic testing. Caroline currently does not want anyone in her family to know about her pregnancy, as if she knew that she was pregnant with a boy with the X-linked condition she would plan to have a termination of pregnancy, and she thinks that her family would not support this. However, in order to provide an accurate carrier test and potentially a prenatal test to Caroline, the genetics service would need to access the exact details of the disease-causing X-linked variant in an affected relative of Caroline.

Key points

- The public interest in keeping Caroline's pregnancy confidential (and in maintaining trust between patient and physician) may be more important than the requirement for consent to the disclosure of a test result from a family member. However, there is also a clear public interest in maintaining a confidential health service in which people are not deterred from having genetic testing by concerns that their confidential information might be disclosed.
- Consent conversations for genetic testing should ideally encompass the issue that results may be used to inform the care of other family members, and this discussion should be documented at the time of testing.
- It may be appropriate to view the details of the X-linked variant as being confidential on a familial level, such that this information could be used to allow Caroline's carrier testing. The personal details of the relative(s) in whom the X-linked variant has been identified should not be disclosed to Caroline.

Respecting confidential information is an important aspect of clinical practice and is vital in securing public trust and confidence in healthcare. Yet providing the tested person with a right of veto over communicating such information without requiring an assessment of the wider benefits and risks to familial members may be unsound. This forms the basis for the third case (case 15) which deliberately reflected the facts in the *ABC vs St George's* case which is the focus for this meeting.

Case 15: A 50:50 chance of inheriting Huntington's disease

Henry has recently received a diagnosis of Huntington's disease. This serious hereditary condition has no cure and early death (aged 40–60) is likely. Henry's daughter, Jane, knows that her father is ill, but not that his condition is heritable. She is pregnant and mentions this to Henry's clinicians. They wonder whether Jane has a right to know that she has a 1 in 2 or 50:50 chance of developing Huntington's disease (which may have significant implications for her own health and reproductive choices). Henry refuses consent for Jane to be told his diagnosis, as he is worried that she might terminate her pregnancy.

Key points

- Here, clinicians need to balance the harms of potentially disclosing Henry's diagnosis against his wishes, with the benefits to Jane of having access to information about her potential risk of developing Huntington's disease.
- The decision of whether to disclose this information to Jane is challenging and should be discussed with experienced colleagues. The balancing act involved in reaching a decision should be clearly documented in the medical notes.
- The genetic risk of Huntington's disease can be considered as familial information rather than information that is confidential to Henry.
- If clinicians decide to disclose the information to Jane, this should be done in a way that protects Henry's confidentiality as far as possible, for example making Jane aware that she may be at risk of developing Huntington's disease and that testing is available, without disclosing information such as the details of Henry's clinical history and date of diagnosis. However, the fact that Jane may correctly deduce these more personal details about Henry should not necessarily prevent disclosure of the genetic information.
- A similar case is currently being discussed in the courts.[11] Although this has not yet been concluded, the Court of Appeal has already stated that, depending on the circumstances of the case, clinicians may have a duty to consider the interests of at-risk relatives (see section 2.2.2).

A report from the then Chief Medical Officer for England, *Generation Genome*, published in 2017,[2] emphasised that healthcare professionals should recognise the principles of solidarity and altruism in genomic medicine. The report suggested that confidentiality of genomic information might at times need to be viewed through a new lens, one that makes the distinction between individual clinical information about a disease or condition (phenotypic information) and the inherited variation(s) that led to the clinical findings. Whilst professional guidelines such as those from the General Medical Council[3] cite the disclosure of genomic information as a specific instance in which disclosure might be justified in the public interest (if doing so would protect people from serious harm or death) it might, in certain cases, also be possible to disclose other shared information without any breach of confidence.

[2] Davies, S.C. Annual Report of the Chief Medical Office 2016, Generation Genome *London: Department of Health (2017)*
https://assets.publishing.service.gov.uk/media/5a82b85fe5274a2e87dc2a4a/CMO_annual_report_generation_genome.pdf

[3] General Medical Council. Confidentiality: good practice in handling patient information. Paragraph 75. https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---confidentiality-good-practice-in-handling-patient-information----70080105.pdf

In practice, as case 14 suggests, it may not always be necessary to disclose to relatives that a specific patient has been diagnosed with, say, inherited breast cancer. They can be informed that in a particular family there is an inherited tendency to cancer that could be usefully tested for in family members who are worried about their risk. On some occasions, this approach might raise concerns that discussing the test would identify a particular family member and constitute a breach of her or his confidentiality, but this need not be the case – particularly in large or multi-generational families where others have the familial disease in question. If a woman who is concerned about her family history could be offered an appropriate genomic test without identifying the individual in whom the familial cause was first identified, this side-steps raising any concerns about protecting that person's confidentiality.

The disclosure of genomic/genomic information is contingent on such information being available for use by healthcare professionals in the appropriate care of family members and it is here that, in practice, the biggest hurdles are often found. Even where healthcare professionals know that a relative has been tested in a laboratory in another part of the country, there may be caution about releasing this information without specific consent from the tested person, for fear of a breach of confidence. The guidance from the Joint Committee on Genomics in Medicine attempts to encourage healthcare professionals to incorporate the principles of altruism, reciprocity and solidarity in their approaches to familial communication. It emphasises that the assumption that confidentiality towards individuals is always paramount is as inappropriate as the assumption that disclosure is always permissible, and that each case requires a decision that is tailored to the context of a particular situation. Indeed, it is possible that in some very specific situations, a legal duty to inform relatives may arise in the future.

Relevant legal frameworks

Several areas of law provide for the use and disclosure of genomic information in the healthcare context. These include the common law of confidentiality, the tort of negligence, human rights law and data protection law. As background to our discussions, these legal frameworks are briefly sketched below, followed by a summary of the seminal case of *ABC v St George's Healthcare NHS Trust and Others* and another relevant prior ruling in *Smith & Anor v University of Leicester NHS Trust*.

Common law of confidentiality

In law, the starting presumption is that a person who received information from another party in confidence cannot take advantage of it without some form of legal authority or justification. This presumption covers cases where a healthcare professional might disclose confidential information about one person to another.

In a healthcare context, there are four forms of legal authority and justification for disclosing confidential information:

- with the consent of the patient (whether implied or explicit)
- where a legal obligation to disclose exists (such as disclosure by court order)
- where there is an overwhelming public interest in disclosure (such as where it is necessary to prevent a crime)

- where authority is granted under The Health Service (Control of Patient Information) Regulations 2002

Establishing such a legal justification may not be sufficient in itself for lawful disclosure, since other legal regimes governing information, including data protection law and human rights law will also, at times, need to be considered.

Data protection law

Information that is disclosed in confidence may also be subject to the Data Protection Act 2018 and UK General Data Protection Regulation where it amounts to 'personal data'. Data concerning health fall are among special categories of personal data that are subject to more stringent regulation. Personal data is defined under Article 4(1) as:

> *'**any information relating to an identified or identifiable natural person**… who can be identified, **directly or indirectly**… **by reference to an identifier such as a name**, ID number…or to one or more factors specific to the **physical, physiological, genomic,** mental, economic, cultural or social **identity of that person'.***

Anonymous data fall outside the scope of the UK GDPR but one of the challenges of data protection law is the broad interpretation of 'personal data' which means it is frequently considered to apply to data that are not obviously connected to an individual. While this protects individual data subjects it also generates challenges, including uncertainty about whether multiple members of a family may be able to claim genomic test information as their 'personal data'. This ambiguity and associated uncertainty about how the rights and interests of multiple family members in the same data should be reconciled (for example, what should be done if one person seeks deletion of the data) remain unresolved.[4] In terms of data protection requirements that are particularly relevant to this area, an important provision of the data protection regime is a prohibition against disclosure of information if it is likely to cause serious harm to another. In practice, health services and healthcare professionals often rely on this provision when handling requests for disclosure. However, it also allows disclosure in certain circumstances such as when it is in the public interest to do so, or to protect the rights of the data subject or others.

Duty of care in negligence

A key legal framework influencing practice in this area is the tort of negligence, which governs the liability of professionals (and vicariously, healthcare institutions) for a failure to meet acceptable standards of care. In order to bring a claim in negligence, it must be shown that a duty of care existed; that this duty was breached; and that there is a causal relationship between the duty owed and the harm suffered.[5] A novel duty of care may be established through *Caparo's* tripartite test of foreseeability, proximity and fairness.[6] Certain relationships, such as the doctor-patient relationship, give rise to a well-established duty of care. The breach of a duty of care by a healthcare professional may lead to a professional negligence claim, or, where serious harm or death occurs as a result of negligent behaviour by the healthcare professional, a gross negligence manslaughter claim. Prior to

[4] Mitchell C & Hall A, GA4GH GDPR Brief: familial genomic data and the GDPR. 7 Jun 2021. https://www.ga4gh.org/news_item/ga4gh-gdpr-brief-familial-genomic-data-and-the-gdpr/

[5] *Donoghue v Stevenson* [1932] UKHL 100.

[6] *Carparo Industries PLC v Dickman* [1990] UKHL 2

the final judgment in the case of *ABC v St George's* (described below), there was no established legal duty to consider disclosure of genomic risk information to non-patient relatives. Some suggested that a composite duty of care to consider the interests of genomic relatives should be introduced (i.e. to consider both the risks and benefits of disclosing genomic risk information, and to weigh these against the duty of confidentiality owed to the patient to keep medical (including genomic) information secret), arguing that this would be in line with professional guidance for HCPs.[7] We summarise the establishment of a limited novel duty along these lines in *ABC v St George's,* further below.

Human Rights Law

Human Rights law, notably rights derived from the European Convention on Human Rights, which are incorporated in UK law by the Human Rights Act 1998, are also of potential importance. Article 8 of the Convention provides individuals with a right to respect for their private and family life. This has been interpreted broadly as a right to privacy and a right to have information about one's own health (as acknowledged by Irwin LJ in *ABC,* see further below). Any interference with this right should be justified and proportionate. In the clinical context, a human rights claim is commonly brought alongside a tort claim but the courts show a reluctance to consider these claims as substantively different or additional to a claim in negligence.[8] Some scholars argue this is unfortunate because the human rights claims are the appropriate vehicle for vindication of what is often truly at stake in this context, a violation of autonomy.[9]

It is not just Article 8 rights that may be engaged in such cases. The internationally recognised right to health could reinforce and augment the legal recognition of family members' rights to have information about their health. The right to health has been recognised by many countries and in international law.[10,11] For example, the WHO's Constitution states that, 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.'[12] Access to meaningful information is a critical determinant of the right to health (the highest attainable standard of health) and requires a reliable system of knowledge production.[13] Such public interest arguments could be extended to familial interests in genomic data, especially where knowledge of a genomic diagnosis might guide future treatment or management.

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[7] Edward Dove at al., 'Familial genomic risks: how can we better navigate patient confidentiality and appropriate risk disclosure to relatives?', (2019) Journal of Medical Ethics 45(8), 504-507.https://doi.org/10.1136/medethics-2018-105229.

[8] Irwin LJ was 'unconvinced that the Convention adds anything to the common law or can provide a basis for action if the common law does not do so'. See *ABC* para 65.

[9] Foster C, Gilbar R. Is there a New Duty to Warn Family Members in English Medical Law? ABC V ST George's Healthcare NHS Trust and Others [2020] EWHC 455. Medical Law Review. 2021 May 1;29(2):359-72.

[10] International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316, at 49 (Dec. 16, 1966).

[11] Special Rapporteur on the Right to Health, Addendum to the Report of the Special Rapporteur, U.N. Comm'n on Human Rights, Mission to the World Trade Organization, ¶ 15 , U.N. Doc. E/CN.4/2004/49/Add.1 (Mar. 1, 2004)

[12] Constitution of the World Health Organization, preamble, available at https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf.

[13] Trudeau Lemmens and Candice Telfer, 'Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency' (2012) *American Journal of Law & Medicine* 38(1), 63-112, p.100.

However, a right to health has not been directly incorporated in UK law and such arguments are yet to be heard before the domestic courts in England and Wales.

Legal cases relating to the duty of healthcare professionals to keep genomic data confidential in England and Wales

Relevant precursors to the *ABC* case

There are very few legal cases concerning the disclosure of genomic or genomic data, but *Smith & Anor* predated the *ABC* case and provides some background context.

Case where diagnosis in a family member was not communicated to a family member [*Smith & Anor v University of Leicester NHS Trust* [2016] EWHC 817 (QB) (15 April 2016)]

Two brothers (Y and Z) claimed that Leicester NHS Trust was in breach of its duty of care for failing to diagnose their illness earlier than it did. Leicester NHS Trust had been caring for their first cousin once removed (X) who suffered from a long-standing genomic disease. In 2003, X's consultant had requested a diagnostic test for X. This was not carried out until 2006, when it was confirmed that X had a genomic disease. The test report stated that family members of X should be referred to genomic counselling. In 2006, Z was diagnosed with the disease following his admission to hospital. Y was tested and found to have the same genomic disease.

Y and Z therefore claimed that *had* X's condition been diagnosed in 2003 when his consultant requested a biochemical test that might have led to a genomic test, their own diagnoses would have been made earlier and, consequently, they would have had significantly better outcomes.[14]

Leicester NHS Trust claimed that it did not owe Y and Z a duty of care and that it would not be fair, just or reasonable if one were imposed. Their defence relied on insufficient proximity, as Y and Z were not their patients. If upheld, they argued, the alleged duty would be too onerous and against public policy since it would effectively require them to inform third parties of a diagnosis identified in a patient of theirs.

Held

Case dismissed.

- The court viewed this alleged duty of care to be a novel claim and that it would not be fair and reasonable on policy grounds to impose a duty on Leicester NHS Trust concerning individuals who were not their patients. To extend this duty to cousins went beyond existing law pushing the common law of negligence too far.

ABC v St George's Healthcare NHS Trust and Others [2020] EWHC 455

The case of *ABC v St George's Trus*t is the leading case that specifically considers familial interests in genomic information. It was first heard in brief in 2015 by the Queen's Bench and subsequently in

[14] In this case however, X did not attend for the biochemical blood test that might have resulted in a genomic test being offered.

the Court of Appeal in 2017. The appeal was allowed and the case was finally heard at a full trial in 2020.

1. First Instance Decision [2015] EHWC 1394 (QB)

The defendant NHS Trusts applied to strike out a claim for negligence for a healthcare professional's failure to disclose to his patient's daughter that their patient (her father) had the heritable condition of Huntington's disease.

Facts

The claimant's father had been convicted of manslaughter for killing the claimant's mother. He was mentally unwell and so relied on the grounds of diminished responsibility and consequently, was subject to a hospital and restriction order. He was then diagnosed with Huntington's disease, a degenerative, heritable and eventually fatal genomic disorder. There was a 50% chance that his daughter (the claimant) would also have the condition. Later she disclosed that she was pregnant. There was therefore a 25% chance that the child she was carrying would inherit the condition. The healthcare professionals wanted to disclose this fact to the daughter, but her father refused to give consent for this disclosure. However, she was accidentally told about this after her baby was born and was later tested and found to have inherited the condition. She brought a claim in negligence that, had she known about her father's condition she would have wanted to be tested, and if positive, would have terminated her pregnancy on the basis that she would not be able to bring up the child. She also brought claims for psychiatric harm suffered as a result of the defendant trust's failure to inform her and argued that if her daughter had the disease, she would incur additional expense.

The key question was whether the defendant trusts were negligent. This required the claimant to demonstrate that she was owed a duty of care and that that duty had been breached and that she had suffered damage as a result. A secondary question was whether they had violated her rights under Article 8 of the European Convention on Human Rights (ECHR). The defendant trusts argued that owing her such a duty of care would not be fair, just and reasonable.

Held

Claim dismissed.

The claim was dismissed in favour of the defendants on the basis that there is no reasonably arguable duty of care owed to the claimant. There was no special relationship between the claimant and the defendant as she was not a patient of theirs, nor was there any evidence of assumption of responsibility for her by the trust. A balance had to be struck between the value of the claimant knowing about her father's condition and his Article 8 ECHR right to confidentiality, and the court found in favour of protecting her father's right to confidentiality.

2. Court of Appeal

The claimant (daughter) appealed against this decision on 16th May 2017.The appeal drew on the clinical guidance developed by the JCMG and BSGM 'Consent and Confidentiality in Genomic

Practice, Guidance on Genomic Testing and Sharing Genomic Information' (2011).[15] She submitted that this guidance made clear that professional obligations existed towards those who, although not in an existing doctor-patient relationship with a healthcare professional, had vital interests in genomic information that the healthcare professional had obtained. According to her claim, those professional obligations formed the basis for an extension of the legal duty of care to individuals affected in that way.

Held

Appeal was allowed.

The Court of Appeal held that there *may* in this context be a duty to inform. They determined that the claimant's harm was foreseeable and that there was arguably sufficient proximity between the claimant and her father's treating healthcare professionals to justify the existence of a duty of care. The court rejected the argument that to recognise such a duty would lead to conflicting professional duties for healthcare professionals and would undermine patient trust in doctor confidentiality, and, instead, thought it would encourage proper balancing of these competing interests. The appeal was allowed, and the case remitted for trial in the High Court.

3. High Court Trial 2020

ABC v St George's Healthcare NHS Trust [2020] EWHC 455 (QB)

The claimant brought a claim against three NHS trusts, contending that the defendants breached a duty of care owed to her and/or acted contrary to her rights under Article 8 of the European Convention on Human Rights in failing to alert her to the risk that she had inherited the gene for Huntington's disease in time for her to terminate her pregnancy. The second defendant was the NHS Trusts' mental health trust which was responsible for the family therapy, which both herself and her father attended.

Held

The court held that the claimant was owed a duty of care by the defendant mental health NHS Trust but no actionable breach of the duty was found. The claim was dismissed.

As a patient of the family therapy team that both herself and her father attended, her relationship with the defendants was deemed analogous to a doctor-patient relationship, and therefore a duty of care was established between herself and the mental health trust providing the family therapy.

The defendants suggested that the argument that the family therapy team had assumed responsibility for informing her about her father's diagnosis was a novel claim, and one that did not exist in law. Nevertheless, the judge Mrs Justice Yip (Yip J) decided that her relationship with the family therapy team (the second defendant) was sufficient to establish a duty of care. By recognising the possibility of her suffering psychological harms and a loss of opportunity to terminate her pregnancy, the court acknowledged the potential responsibility of the mental health trust for these

[15] JCMG and BSGM Consent and Confidentiality in Genomic Practice: guidance on genomic testing and sharing genomic information (2011). This guidance was revised in 2019, both versions are available at https://bsgm.org.uk/healthcare-professionals/confidentiality-and-genomic-information/

outcomes. However, the court believed that the Trust had acted reasonably in balancing the competing considerations of disclosure and confidentiality, and ultimately in deciding not to make the disclosure.

Significantly, Yip J deemed that it was fair, just and reasonable to impose a legal duty on the daughter's mental health trust to balance her interest in being alerted to a possible genomic risk against the interests of her father and the public interest in keeping this confidential. Yip J concluded that this balancing act was justified because the duty of confidentiality is not absolute and, in some circumstances, appropriate and necessary to override.

Additionally, the Yip J did not feel that imposing such a duty to override confidentiality where there is a serious threat to a patient's health or threat of death would negatively impact the doctor-patient relationship. In fact, existing professional guidance reinforced this view. The requirement for close proximity between heathcare professional and patient in order for a legal duty to be recognised was a sufficient safeguard, and for this reason the imposition of a legal duty would not require the greater use of resources than were called for by existing guidance. Finally, the judge concluded that by recognising a legal duty in a situation where guidance had already recognised its existence, meant that the courts had not overstepped their function. The claimant's Article 8 ECHR rights were relevant, but that interference was justified and proportionate. Her human rights claim was therefore also dismissed.

Appendix 1

Record of discussion form from JCMG and BSGM *Consent and Confidentiality in Genomic Practice: guidance on genomic testing and sharing genomic information* (2019).

A1.2 Record of discussions form to summarise clinical consent

RECORD OF DISCUSSIONS regarding testing and/or storage of genetic material

I have discussed genomic/genetic testing with my health professional and I understand that:

Family implications

1. The results of my test *may* have implications for other members of my family. I acknowledge that my results may sometimes be used to inform the appropriate healthcare of others. This could be done in discussion with me, or in such a way that I am not personally identified in this process.

Uncertainty

2. The results of my test *may* reveal genetic variation whose significance is not yet known. Deciding whether such variation is significant may require sharing of information about me including (inter)national comparisons with variation in others. I acknowledge that interpretation of my results may change over time as such evidence is gathered.

Unexpected information

3. The results of my test *may* reveal a chance of a disease in the future, and nothing to do with why I am having this test. This may be found by chance, while focusing on the reason for my test, and I may then need further tests to understand what this means for me. If these additional findings are to be looked for, I will be given more information about this.

DNA storage

4. Normal laboratory practice is to store the DNA extracted from my sample even after the current testing is complete. My sample might be used as a 'quality control' for other testing, for example, that of family members.

Data storage

5. Data from my test will be stored to allow for possible future interpretations.

Health records

6. Results from my test and my test report will be part of my patient health record.

Note of other specific issues discussed (*eg referral to particular research programmes, insurance*):

Further reading:

- Confidentiality and sharing genomic information with relatives. Lucassen A, Parker M. Lancet 2010 May 1;375(9725):1507-9.
- Genomic information: a joint account? Parker M, Lucassen AM.BMJ. 2004 Jul 17;329(7458):165 (c)
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- M. Parker and A.M. Lucassen. Concern for families and individuals in clinical genomics **J Med ethics** 2003, 29 70-73
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- Consent-and-confidentiality-in-genomic-medicine-July-2019.pdf (rcpath.org)
- https://societyandethicsresearch.wellcomeconnectingscience.org/project/abc-versus-st-georges-nhs-trust/
- Vicky Chico https://journals.sagepub.com/doi/10.1177/0968533216653440?icid=int.sj-abstract.similar-articles.1
- Michael Fay https://journals.sagepub.com/doi/abs/10.1177/0968533216664113
- Colin Mitchell et al https://pubmed.ncbi.nlm.nih.gov/28943725/