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Requiring genetic knowledge: a principled case for support

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Should people be required to know information about themselves that arises from their genetic test? This question is highly relevant given the NHS's plans to sequence 100,000 whole genomes before 2017. The approach to this issue in the USA generated significant opposition to requiring knowledge, on the basis that it interferes with autonomy. This piece presents a different perspective, arguing that requiring knowledge may not undermine the legal conception of autonomy, giving reason to doubt that it would be unlawful to require people to have genetic information about themselves. Following this, the piece presents an alternative principled position that might support a legal recognition of the interest in not having information about oneself; namely that of preventing personal harm. However, this approach runs into difficulties if the reasons for requiring knowledge are also based on preventing personal harm. The argument considers how interests might be balanced in this competing harms context.

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INTRODUCTION

The ability to analyse a person's genes has developed rapidly in the past decade. Traditionally, a genetic test was performed to answer a specific question about a person's risk to a single genetic condition. It is now almost as cheap and easy to sequence all of a person's genes in one go. This means that as well as looking at parts of the genome that are related to the reason for the test, scientists can also look for things unrelated to the reason for testing. This technique is called whole genome sequencing (WGS). It is currently largely confined to research and commercial contexts, but this is set to change, because in December 2012 David Cameron announced the UK's plan to sequence 100,000 whole genomes within the NHS before 2017. To deliver the project, in July 2013 the Department of Health created a company, Genomics England, which will establish the largest genetic database in the world and pave the way for genome sequencing to become a routine part of NHS care.

The vision is that mainstreaming genetic medicine will improve healthcare.[1] The creation of a data set containing the information from a critical mass of genome

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1. On the Genomics England website, Sir Mark Caulfield, Chief Scientist to the project, claims that 'the work of GeL could be to transform the NHS provision of diagnostic tests and then care to a whole range of patients. This could . . . achieve earlier diagnosis and more effective intervention for patients most at risk from developing very serious illnesses.' See http://www.genomicsengland.co.uk/prof-mark-caulfield-reflects-on-the-impact-the-100k-genome-project-could-have-on-the-nhs/ (accessed 16 July 2014).

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sequences will provide scientists with a research resource that will ultimately lead to more personalised medical care, which could save lives. However, the information generated by a whole genome sequence can relate to future health generally, rather than solely to current medical treatment. Imagine that a person is being treated for lung cancer. Because of this they are offered a whole genome sequence. In the course of analysing the person's genome on the basis of the lung cancer, scientists discover that they possess genetic traits indicating an elevated risk of suffering from breast cancer in the future.[2] How should they manage the disclosure of this risk to the patient?[3]

In essence, there are three possible options. First, we might not return any information to the patient, other than that which relates to the reason why the test was performed. This is the approach taken by UK Biobank with regard to the genetic data they collect from participants in the research context and by two of the few studies that currently sequence whole exomes in the UK.[4] Secondly, the patient could be required to receive their genetic information. In this context, specific criteria may be attached to particular conditions warranting disclosure. Until recently, this was the approach adopted by the American College of Medical Genetics and Genomics (ACMG). The third approach is to allow the patient to choose what information they receive. In March 2013, the ACMG published a report recommending that in whole genome sequencing in clinical care, information about 24 genetic mutations (the 'minimum list')[5] that can cause cancer or cardiac conditions should be returned without 'offering the patient a preference as to whether or not to receive the minimum list of incidental findings'.[6] However, a year later, on 1 April 2014, the ACMG retreated from this position and agreed that an 'opt out' could be offered.[7]

Following the publication of its original recommendations in March 2013, the ACMG was heavily criticised for adopting a position that the College itself considered to be an interference with autonomy, in favour of preventing personal physical harm.[8] However, analysis of the value of overriding autonomy in favour of preventing harm was hampered by the fact that the College did not offer any clarification of what they believed autonomy to consist in.[9] This is problematic because

2. Many possible examples could be posed that are not limited to cancer.

3. There is also significant uncertainty about how we should manage disclosure to the tested person's relatives. See my forthcoming empirical work on this issue: T Heaton and V Chico 'Attitudes towards the sharing of genetic information with at-risk relatives: Bayesian ordinal regression with random effects'.

4. See the following projects: Deciphering Developmental Disorders (DDD) study, http://www.ddduk.org/ (accessed 17 September 2014); Specialist Pathology: Evaluating Exomes in Diagnostics (SPEED) Study, University of Cambridge, http://bioresource.nihr.ac.uk/rare-diseases/study-specialist-pathology-evaluating-exomes-in-diagnostics/ (accessed 23 April 2014). Whole exome sequencing refers to the technique that selectively sequences the protein coding regions of the genome.

5. RC Green et al 'ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing' (2013) 15 Genet Med 565–574 at 567.

6. Ibid, at 568.

7. See https://www.acmg.net/docs/Release_ACMGUpdatesRecommendations_final.pdf (accessed 27 May 2014).

8. Green et al, above n 5, at 568.

9. Or for that matter what it considered the potential harms to be. Did these solely concern not being able to access treatment for the particular genetic condition? Or also not being able to minimise related risks that other treatments might pose for someone with that (asymptomatic) genetic condition? See below for a discussion of these two types of harm.

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the principle exists in diverse conceptualisations. Given the ACMG's own opinion that their recommendations interfered with autonomy, much of the criticism of the recommendations focused on this apparent interference.[10] These critiques also do not acknowledge the multi-faceted nature of the concept of autonomy, and do not engage in deeper analysis of how autonomy is construed and functions in the context of knowing information about oneself.[11] Thus the conceptual foundation of the position, which holds that requiring genetic knowledge about oneself interferes with autonomy, is unclear. Furthermore, despite the retraction of the required knowledge position in the USA, other jurisdictions *do* require incidental findings to be fed back in clinical whole exome sequencing.[12] As Genomics England's 100,000 Genomes Project gathers pace, decisions about what information should be fed back to patients will have to be made. This piece seeks to add a new voice to this debate, which relies on a deeper analysis of how autonomy might be conceptualised in this context. This analysis will demonstrate that requiring knowledge may not undermine the legal (or for that matter some theoretical) conception(s) of autonomy adopted in English medical law. Following this, the work will argue that if required knowledge does not interfere with autonomy, the reliance on the prevention of harm justification for requiring genetic knowledge is strengthened.

1. IMPLICATIONS FOR WHOLE GENOME SEQUENCING IN THE UK

The issue of how we deal with incidental findings in a way that maximises potential health benefits without interfering with fundamental interests is pressing in the UK, given Genomics England's plans. This project may well provide the blueprint for rolling out whole genome sequencing in routine NHS clinical care. Supporters portray revolutionised, personalised patient care.[13] But what if the clinical benefits are, at least initially, unremarkable and the project adopts an approach to incidental findings and data-sharing that raises concern? People may become wary of having their genome

10. See eg M Allyse and M Michie 'Not-so-incidental findings: the ACMG recommendations on the reporting of incidental findings in clinical whole genome and whole exome sequencing' (2013) 8 Trends Biotechnol 439–441; SM Wolf, GJ Annas and S Elias 'Respecting patient autonomy in clinical genomics: new recommendations on incidental findings go astray' (2013) 340 Science 1049–1050; W Burke et al 'Recommendations for returning genomic incidental findings? We need to talk!' (2013) 15 Genet Med 854–859; A Townsend et al 'Paternalism and the ACMG recommendations on genomic incidental findings: patients seen but not heard' (2013) 15 Genet Med 751–752.

11. Above n 10.

12. Personal conversation with Dr Ilse Feenstra, Clinical Geneticist at Radboud University Medical Centre, Nijmegen, The Netherlands. The consent form for exome sequencing in diagnostics at the Radboud University Nijmegen Medical Centre does not offer 'an opt out possibility for feedback of unsolicited findings: if a patient does not want to be informed about relevant unsolicited findings, he/she is not eligible for the test'. T Rigter et al 'Reflecting on earlier experiences with unsolicited findings: points to consider for next-generation sequencing and informed consent in diagnostics' (2013) 34 Human Mutation 1322–1328 at 1324.

13. Above n 1.

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sequenced.[14] In this case, clinical whole genome sequencing might not achieve its full potential. Being able to demonstrate to patients that the approach to feedback minimises any interference with patient's interests is likely to be an important part of the project's success.

The Ethics Committee advising Genomics England will soon make recommendations to the board about the approach to feeding back incidental findings. Currently, Genomics England is recruiting to two pilot projects; one with the Rare Disease NIHR Bioresource at the University of Cambridge and one with the Cancer Research UK stratified medicine programme. The consent forms that will be used in these pilots stem from existing Stratified Medicine and Bioresource research projects. It appears that the approach to feedback of incidental findings is likely to be inconsistent. The pilot project at the NIHR Bioresourse will not be feeding back any incidental findings to research participants. However, the Stratified Medicine Programme looks set to take an approach that may automatically lead to feedback of incidental findings if the person consents to a whole genome sequence. It seems that their approach will be similar to that taken in the Molecular Genetic Analysis and Clinical Studies of Individuals and Families at Risk of Genetic Disease (MGAC), whereby 'if the patient consents' to the study, they may automatically be informed of 'any results we find by chance'.[15] In this approach, consent to participation and consent to receiving results found by chance are not treated separately. Thus the position that will be adopted regarding the feedback of incidental findings in the main phase of the Genomics England project remains unclear. Reflecting this uncertainty last year, the chair of the ethics committee advising Genomics England said that 'no ethical issues are off the table'.[16]

2. REQUIRED KNOWLEDGE: HISTORY AND RATIONALE

We know that originally the ACMG 'did not favor offering the patient a preference as to whether or not to receive the minimum list of incidental findings'.[17] The rationale for this was to prevent physical harm to patients.[18] The minimum list covers those conditions for which the most effective treatments exist.[19] For example, the ACMG recommends feedback of a genetic variant that causes malignant hyperthermia susceptibility. This is a life-threatening condition triggered by exposure to certain anesthetic drugs. In susceptible individuals, these drugs can lead to circulatory

14. The plans for care.data – a database of GP records – were delayed in February 2014 following a public backlash against the use of patient information. Tim Kelsey, NHS England National Director for Patients and Information, said 'We paused it because there was this enormous outcry, and uncertainty about what was happening.' L Donnelly *The Telegraph* 6 June 2014.

15. See participant information sheet for Molecular Genetic Analysis and Clinical Studies of Individuals and Families at Risk of Genetic Disease (MGAC), available at http://oxfordbrc.nihr.ac.uk/wp-content/uploads/2014/02/MGACPIS101213.pdf (accessed 27 May 2014).

16. See http://www.genomicsengland.co.uk/prof-mike-parker-says-no-ethical-issues-are-off-the-table-as-gel-considers-its-approach-to-patient-consent/ (accessed 4 June 2014).

17. Green et al, above n 5, at 568.

18. Ibid, at 568.

19. The ACMG recommends feedback relating to 24 conditions on the basis that they are 'disorders where preventative measures and/or treatments are available'. Ibid, at 576. But see also above n 9.

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collapse and death. Where a person knows about their risk, they may be able to elect not to have an anesthetic, or to have a type of anesthetic that is not associated with sudden death, thereby completely eliminating their risk. The remainder of the ACMG list largely concerns genetic variants that can cause cancer[20] or heart failure, which might lead to a cardiac arrhythmia that could cause sudden death.[21]

For many of the conditions on the list, surgery is available to significantly minimise the risk of the condition manifesting.[22] Specifically inherited forms of thyroid, breast, ovarian and bowel cancer that can be avoided with surgery are on the list. The ACMG also recommends feedback of genetic mutations that cause multiple complex cancers, such as Li–Fraumeni and Lynch syndrome. Comprehensive surveillance protocols have been shown to facilitate early detection of tumours and improve survival rate in these syndromes. In a study of Li–Fraumeni syndrome, researchers found that survival was 100% in a group subjected to a surveillance programme dubbed the 'Toronto protocol', but only 21% for those who did not undergo surveillance.[23] Mortality arising from cardiomyopathies can be significantly reduced by pharmacological intervention.[24] Cardiomyopathies often go undetected for long periods.[25] Thus disclosure of genetic mutations associated with cardiomyopathy may lead to diagnosis of the condition before it becomes symptomatic. This would create an opportunity for the patient to choose whether or not to take medication that might reduce the risk of sudden death, which they would not have had if they had remained ignorant of the genetic risk. However, it might be argued that the harm prevention rationale goes much wider than simply minimising the risk of the condition to which the mutation relates. The ACMG did not explicitly state how harm might be prevented by knowing about the conditions on the minimum list. The primary vision was that people might avoid harm by accessing treatment and screening to minimise the risk that the particular genetic condition might manifest. However, the ACMG may also have had in mind that people will also learn about treatments that are particularly risky for them in light of their genetic mutation, enabling them to make informed decisions whether or not to run these related risks.[26] People with many of the genetic mutations on the minimum list should avoid a multitude of regular medical treatments such as certain

20. Seventeen different types of cancer are listed. Some of these mutations cause multiple cancers such as Li–Fraumeni and Lynch syndromes, while others are linked with one or two cancers, such as breast, ovarian or bowel cancer.

21. Six largely cardiac conditions are listed. Five of these are cardiomyopathies and rhythm disturbances. I am including familial hypercholesterolaemia along with the cardiac disorders because of its implication in atherosclerotic heart disease.

22. Although the ACMG now offers the opportunity to opt out of receiving incidental findings, it still *recommends* disclosure in relation to the 24 conditions on the list on the basis of the ability of disclosure to prevent harm. See https://www.acmg.net/docs/Release_ACMGUpdatesRecommendations_final.pdf (accessed 16 July 2014).

23. A Villani et al 'Biochemical and imaging surveillance in germ line TP53 mutation carriers with Li–Fraumeni syndrome: a prospective observational study' (2011) 12 Lancet Oncol 559–567.

24. PA Heidenriech, TT Lee and BM Massie 'Effect of beta-blockade on mortality in patients with heart failure: a meta-analysis of randomized clinical trials' (1997) 30 J Am Coll Cardiol 27–34; M Packer et al 'Comparative effects of low and high doses of the angiotensin-converting enzyme inhibitor, Lisinopril, on morbidity and mortality in chronic heart failure. ATLAS Study Group' (1999) 100 Circulation 2312–2318.

25. BJ Maron 'Hypertrophic cardiomyopathy' (2002) 106 Circulation 2419–2421.

26. Hereinafter I will refer to this conception of harm as 'related risks'.

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painkillers and antibiotics because they are dangerous for people with that condition even if it is asymptomatic. People with some of the mutations on the minimum list should take extra precautions when undergoing routine conditions such as dental work, because their asymptomatic condition puts them at higher risk or morbidity and mortality.[27] If the person is asymptomatic and they are not given the relevant information from their genome sequence, they might run a risk that they would not have chosen to run if they had known the relevant information.

The charity Cardiac Risk in the Young lists 166 drugs that should not be taken by people with long QT syndrome because they can further prolong the QT interval significantly, increasing the risk of sudden cardiac death. Among many other drugs, the list includes antibiotics, antidepressants, antihistamines, anti-migraines and drugs for high blood pressure. If the patient makes a choice about taking these drugs in ignorance of crucial information about the risk they are running, this interferes with their ability to be autonomous.[28] When refusing information from the whole genome sequence, they are not only refusing to know whether or not they need treatment for the genetic condition to which the information from the sequence pertains; the interference with their autonomy is much more encompassing, because the genetic information that they refuse could be relevant to a multitude of routine medical treatments, which are not directed at treating the genetic condition itself. It may be very difficult, if not impossible, for clinicians to allow the patient to go ahead and run a high risk because the patient says they do not want to know this risk. However, if the incidental information has not been fed back to the patient, other clinicians who treat the patient in future episode may also not be aware of it. Furthermore, a successful negligence action on the basis that the patient was not informed of a relevant risk that therefore undermined their autonomy cannot be ruled out.

The incidental finding in question might relate to an increased risk for a condition for which general population screening is offered. In this case, decisions about whether to have the available screening or not might be made in ignorance of relevant information about a significantly increased risk. On the other hand, the particular incidental finding might lead to the individual being offered extraordinary pre-symptomatic screening or treatment that is not routinely available to the general

27. Some medical risks that might be relevant for people with genetic mutations on the ACMG minimum list are as follows. Pregnancy is a very high-risk state for people with Marfan syndrome, because the rise in blood pressure can trigger an aortic dissection. This information might be considered relevant in offering any assisted conception service. Patients with (asymptomatic) cardiomyopathy should avoid a number of drugs, such as some antidepressants, and common non-steroidal, anti-inflammatory drugs such as ibuprofen. These are contraindicated because they are associated with increased risk of death and cardiovascular morbidity. GH Gislason et al 'Increased mortality and cardiovascular morbidity associated with use of nonsteroidal anti-inflammatory drugs in chronic heart failure' (2009) 169 Arch Intern Med 141–149.

28. See eg *Chester v Afshar* [2005] 1 AC 134 for how failure to disclose relevant risks might interfere with autonomy. Another paper could be written considering how the law might respond to a patient's claim that their autonomy was interfered with when they weren't informed of a risk of treatment, where information about that risk arose in their WGS but eventuated because their genetic mutation put them at an elevated risk in a related treatment. Of course the patient refused to know about the risk, but there is no evidence that a patient's refusal to know about the risk will protect a clinician who does not disclose relevant risks in a negligence action.

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population. This will not happen where the patient is not aware of the incidental finding. On this basis, where information about incidental findings is refused, the patient's choice leads to them not being offered an intervention that they would be offered if they had not remained in ignorance.

Given that incidental genetic information could prevent serious morbidity and mortality, we can assume that most people will want to know about it. However, the autonomy of people who want feedback is not contentious.[29] Furthermore, where the person wants the information, the ability of disclosure to maximise the aim of harm prevention is likely to be evidenced by an intention to access preventive treatment or avoid risks based on that information. Indeed, if information exists, a person might be keen to have it so that they can access treatment that may only have limited chance of success.[30] But some people make seemingly odd decisions to refuse treatment and if the ultimate aim of disclosure is harm prevention, the purpose of mandatory disclosure to these people is not clear, because, on the face of it, disclosure may not lead to harm preventing action.[31] In order to achieve the end of preventing harm, we would also need to override refusals of medical treatment and prevent people from running high risks. As in the UK, medical law in the USA champions patient autonomy, so that in the context of consent to medical treatment, autonomy is the supreme legal principle and cannot be displaced on the basis of concerns that refusing treatment is unwise and harmful.[32] Thus one of the difficulties for the ACMG was that although it recommended interference with autonomy in the refusal of medical information context, it could not recommend interference with autonomy in the refusal of medical treatment context.[33] From the perspective of the ACMG's aim to prevent physical harm, it is problematic if refusals of medical information and refusals of medical treatment are treated differently. The ACMG's original position and the critique of it seemed to assume that decisions to refuse medical information have the same capacity to interfere with autonomy as decisions to refuse medical treatment, albeit their position seemed to be that the interference could be justified in the former but not in the latter. However, it might be argued that refusals of information are not the same as refusals of treatment from an autonomy perspective. On the contrary, the crucial importance of information in establishing autonomy in the legal context might support the view that refusals of medical information cannot be made in the name of autonomy while refusals of medical treatment can.[34] If knowledge of relevant information is an

29. It is possible to argue that their choice has been removed, but that argument is not one that is made in this paper.

30. L Koch 'IVF – an irrational choice?' (1990) 3 Issues Reproduct Genet Engng: J Int'l Feminist Analysis 235–242.

31. See below for a detailed discussion of predictions of refusal of medical treatment.

32. Mental Capacity Act 2005 s 1 (4).

33. Although knowledge of relevant risks is an important aspect of legal autonomy in consent to medical treatment – see, in particular, *Chester v Afshar* [2005] 1 AC 134 – if a patient demands treatment that their doctor does not want to provide because they consider it too risky, the law does not recognise a person's autonomy to have been breached where their demand for treatment is overridden. See eg *Re J (A Minor) (Wardship: Medical Treatment)* [1990] 3 ALL ER 930; *R v Cambridge Health Authority ex p B* [1995] 2 ALL ER 129. Given that, in the law, there is a clear distinction between how not respecting refusals and demands for treatment might interfere with patient autonomy, this part of the discussion focuses on refusal of treatment.

34. The law regularly allows refusals of treatment on the basis of autonomy: *Re B (Consent to Treatment: Capacity)* [2002] 1 FLR 1090; *St Georges Healthcare NHS Trust v S* [1999] Fam. 26; *Re C (Adult: Refusal of Treatment)* [1994] 1 WLR 290.

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unassailable condition of the legal interpretation of autonomy, making a decision to refuse information that will pervade our ability to be self-governing in managing and choosing in relation to our health is difficult to support from an autonomy perspective. Even if the person has the information relevant to the choice whether or not to refuse information, the fact that this information could be relevant to a number of specified and unspecified, identified and unidentified future health choices means that the person will encounter many future health decisions where they would not meet the legal definition of autonomy because of their ignorance of relevant information. From a legal perspective, it is arguable that there is an inextricable link between information and autonomy such that it is doubtful whether choices that reject the receipt of relevant information are, in fact, autonomous.

3. WHY REQUIRING KNOWLEDGE MIGHT NOT INTERFERE WITH AUTONOMY

On a theoretical level, the reliance on principles to make moral decisions has been criticised. Holm argues that the four principles approach presented by Beauchamp and Childress[35] is lacking because there is more to morality than principles, and because the approach lacks an explicit mechanism for solving the problems that arise when principles conflict.[36] Despite theoretical criticism of the principled approach, medical care in England is often organised around the principles of autonomy, beneficence, non-maleficence and justice. Legal judgments in medical dilemmas are also often based on these principles.[37] In the legal context, there is a common view that autonomy enjoys a dominant position.[38] Given this, it is likely that most health professionals will want to adopt a position that does not interfere with patient autonomy. The law respects autonomy by requiring patients to consent to medical interventions even when they are undoubtedly good for them. Intervention without consent interferes with autonomy in a way that attracts legal recognition in the tort of battery. However, battery requires a physical element. Where the unwanted intervention takes the form of information, there is no interference with autonomy that would attract legal recognition. This might be because the law is not concerned with protecting people's autonomy in the context of their refusal to receive information about themselves, or because the construction of autonomy that the law adopts does not recognise that a refusal of personal, relevant information is autonomous at all. The discussion here focuses on the latter position, arguing that the concept of autonomy adopted in English law might not support a refusal of information about oneself, even though this concept of autonomy might support a refusal of treatment based on that information.

Theories of autonomy might import content into choices themselves or into the procedure by which choices are arrived at. Philosophers such as Nietzsche, Dworkin,

35. T Beauchamp and J Childress *Principles of Biomedical Ethics* (New York: Oxford University Press, 4th edn, 1994).

36. S Holm 'Not just autonomy – the principles of American biomedical ethics' (1995) 21 J Med Ethics 332–338. For a similar critique, see K Danner Clouser and B Gert 'a critique of principalism' (1990) 15 J Med & Phil 219–236.

37. See, in particular, *Chester v Afshar* [2005] 1 AC 134 and *Re B (Consent to Treatment: Capacity)* [2002] 1 FLR 1090.

38. Above n 34. However, there are many who criticise this. See eg C Foster *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law* (Oxford: Hart Publishing, 2009).

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Berlin and Gaus[39] adhere to an individualistic content-neutral notion of autonomy, where the central value is the ability to determine one's way of life for oneself; being able to choose as one pleases irrespective of an ideal or moral position. However, this is not the only way in which autonomy might be construed. Kant's interpretation of autonomy incorporated the ability to give the moral law to oneself. On this interpretation, the impulses that Nietzsche et al consider autonomous would not be autonomous if they were at odds with the moral law. Given that the concept of autonomy is subject to such diverse conclusions, we might expect the law to provide a detailed consideration of the concept when it is relied on to underpin judgments. However, the courts have consistently failed to define the concept. Donnelly argues that this is because 'where the right of autonomy is recognised, the law has relied on the requirement for capacity to act as gatekeeper for the application of the right'.[40] According to Donnelly, by relying on capacity to deal with difficult cases on an individual basis, the law has been able to lend its support to autonomy with little analysis of what the principle actually means, or how it conflicts with other principles.[41] Despite the vague nature of autonomy in English medical law, in essence there seems to be a commitment to a content-neutral interpretation of the concept. Lord Donaldson articulated the legal position in 1992 when he said:

> An adult patient who . . . suffers from no mental incapacity has an absolute right to choose whether to consent to medical treatment, to refuse it or to choose one rather than another of the treatments being offered . . . This right of choice is not limited to decisions which others might regard as sensible. It exists notwithstanding that the reasons for making the choice are rational, irrational, unknown or even non-existent.[42]

The English common law has explicitly recognised this commitment to respecting the capacitated patient's choice, whatever that choice might be, on numerous occasions.[43] Furthermore, this commitment to a content-neutral interpretation of autonomy in relation to the clearly capacitated has been put on a statutory footing with respect to those whose capacity, and therefore autonomy, is in doubt.[44] One of the principles that

39. F Nietzsche *On the Genealogy of Morals* tr W Kaufmann and RJ Hollingdale in *On the Genealogy of Morals and Ecce Homo* (New York: Random House, 1967); G Dworkin *The Theory and Practice of Autonomy* (Cambridge: Cambridge University Press, 1988); I Berlin 'Two concepts of liberty' in *Four Essays on Liberty* (London: Oxford University Press, 1969); GF Gaus 'The place of autonomy within liberalism' in J Christman and J Anderson (eds) *Autonomy and the Challenges to Liberalism* (Cambridge: Cambridge University Press, 2005).
40. M Donnelly *Healthcare Decision-Making and the Law* (Cambridge: Cambridge University Press, 2010) p 89.
41. Ibid, p 2.
42. *Re T (Adult: Refusal of Treatment)* [1993] Fam. 95 Lord Donaldson at 102.
43. *Re B (Consent to Treatment: Capacity)* [2002] 2 FLR 1090; *Chester v Afshar [2005] 1 AC 134*; *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB).
44. In some cases, the patient's capacity has been questioned with little clear basis. See, in particular, *Re B (Consent to Treatment: Capacity)* [2002] 1 FLR 1090; *St Georges Healthcare NHS Trust v S* [1999] Fam. 26; *Re C (Adult: Refusal of Treatment)* [1994] 1 WLR 290; *Re W (Adult: Refusal of Treatment)* [2002] EWHC 901. I am very grateful to the insightful anonymous reviewer who helpfully pointed out that the MCA's main interest is truncated capacity/autonomy, which might reduce the authority with which it can speak about untruncated autonomy, thereby leading me to also consider judicial treatment of the clearly capacitated.

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underpins the Mental Capacity Act 2005 (MCA) is that 'A person is not to be treated as unable to make a decision merely because he makes an unwise decision',[45] reaffirming the position that the ends of choices are not required to accord with any particular value position for that choice to be considered autonomous. The law articulates this value-neutral position by holding that the duty to respect autonomy supersedes any duty to prevent harm.

Although English law adheres to a conception of autonomy that is content-neutral on the basis that it does not require that a choice achieves particular ends, it does require certain procedural standards. Procedurally, for a choice to be autonomous, it must be free of internal or external constraints that might affect the choice's ability to represent the person's true or 'authentic' preferences.[46] External constraints on authentic preferences might be coercion, indoctrination or *ignorance of relevant facts*.[47] English medical law reflects this and adopts a position whereby *knowledge of relevant information* is central to the capacity to make autonomous decisions.

The need to have relevant information before making autonomous decisions has a long history in English medical law. It has been argued that where the courts have wanted to prevent a person who is ostensibly capable of autonomy from making a decision, they have withheld information from that person in order to find that they are not autonomous.[48] In *Re L*, a 14-year-old girl was severely burnt when she fell into a bath. Her life was at risk unless she had treatment that might include a blood transfusion. L refused this and the surgeon caring for her did not think it appropriate to inform her of the 'horrible' death, caused by resulting gangrene, that she would endure if she continued to refuse the transfusion.[49] Sir Stephen-Brown held that L had not been given all the information that would be relevant to the decision whether or not to accept a blood transfusion and accordingly her decision was not autonomous.[50] The importance of knowing relevant information has fairly recently been reaffirmed in *Chester v Afshar*. Mr Afshar failed to inform Miss Chester of a 0.9–2.0% risk of nerve damage, which was a risk of back surgery. Lord Steyn, with whom the majority agreed, felt that the purpose of informed consent was to give due respect to the autonomy of each patient.[51] He continued that the 'right of autonomy . . . ought to be vindicated by a narrow and modest departure from traditional causation principles'.[52] The Mental Capacity Act also recognises the inextricable link between information and autonomy, stating that a person is unable to make a decision for himself if he is unable 'to understand the information relevant to the decision, retain that information and to use or weigh that information as part of the

45. MCA 2005 s 1 (4).
46. G Dworkin 'Autonomy and behaviour control' (1976) 6 Hastings Center Rep 23.
47. Ibid, at 27 (my emphasis).
48. A Grubb 'Refusal of treatment (child): competence *Re L (Medical Treatment: Gillick Competency)*' (1999) 7 Med L Rev 58–61.
49. *Re L (Medical Treatment: Gillick Competency)* [1999] 2 FCR 524 at 526.
50. Ibid, at 527.
51. *Chester v Afshar* [2004] UKHL 41 Lord Steyn at 18.
52. Ibid, Lord Steyn at 24. Furthermore, the English courts have recently held that patients who are not given adequate information about possible alternative treatments will not have sufficient information to make an autonomous choice. See *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB).

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process of making a decision'.[53] This entrenched relationship between information and autonomy makes the exercise of patient autonomy contingent on the ability to understand and use relevant information and necessarily, therefore, on the receipt of relevant information.[54] Consent, and the autonomy that it protects, is vitiated if that consent is ill informed.[55] Thus knowledge of relevant information is a procedural requirement of autonomy.

Refusals of medical information create something of a conundrum in this procedural autonomy context. This is because the relevant procedure might be adhered to in refusing the medical information; that is, the patient has the information that is relevant to the decision to refuse the information. However, the act of refusing information in this instance means that the patient may not adhere to the procedural conditions in future choices, because information that is relevant to that choice exists but the patient does not know it because of the earlier refusal of information.[56]

From a theoretical perspective, we can find support for the position that a person can act in a procedurally independent manner in renouncing her procedural independence such that she has acted authentically, and autonomously restricted her autonomy.

According to Dworkin:

> . . . a person might decide to renounce her independence of action or thought because he wants (genuinely) to be that sort of person. A person might do whatever his mother, or his government, tells him to do, and do so in a procedurally independent manner.

He continues, saying that the person who

> . . . wishes to be restricted in various ways, whether by the discipline of the monastery, regimentation of the army, or even by coercion, is not, on that account alone, less autonomous.

Dworkin maintains that all choices to some extent foreclose other choices and that such foreclosures need not be viewed as forfeitures of autonomy. However, others have argued that it is crucial to procedural autonomy that the individual retain control over her choices, such that choices that appear to be independent but forgo future independence cannot be justified by recourse to the principle of autonomy.[57] In the context of knowledge of personal health information, Harris and Keywood argue that

53. MCA 2005 s 3 (1) (a), (b) and (c). The provisions of the MCA 2005 do not only relate to the ability to make decisions about medical treatment. The Act covers decision making in a wider context, including any decisions that relate to a person's welfare or property and affairs: s 16 (1) (a) and (b).

54. J Harris and K Keywood 'Ignorance, information and autonomy' (2001) 22 Theoret Med 415–436 at 418.

55. Ibid, at 418.

56. There is significant authority in English law that the patient has a right to know information relevant to their medical treatment. In *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871, the House of Lords felt that disclosing the risks of medical treatment is part of the doctor's ordinary duty of care. In recent years there has been a move towards a more patient-centred assessment of the content of the doctor's duty to provide information. However, there is no similar legal duty not to disclose information that the patient does not want.

57. Harris and Keywood, above n 54; R Rhodes 'Genetic links, family ties, and social bonds: rights and responsibilities in the face of genetic knowledge' 23 (1998) J Med & Phil 10–30.

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an element of continuing control is crucial to a choice's consistency with the concept of autonomy.[58] They contrast the person who sells herself into slavery and the person who enters a monastic order. They argue that although both choices seem to autonomously surrender autonomy, only the latter choice is consistent with autonomy. This is because the monk retains the choice to leave, if the monastic experience is not all he thought it would be. In this way, the monk maintains control over the course of his life while the slave does not.[59]

So where does the choice to refuse personal genetic information fit into this perspective on continuing control? In the monastic choice, autonomy is maintained because when the person experiences the nature of the choice in which future choices are limited, they can then choose to end that experience. In the context of the choice not to have genetic information, it might be argued that the patient retains control because they can always choose to have the information about genetic risks in the future. However, as argued earlier, when you remain ignorant of information about your health that might be relevant to future decisions, it might not be clear, in the absence of knowing the essence of the factual quality of that information, the decisions to which that information might be relevant. This information may permeate your healthcare choices in a general sense. You might be uninformed about treatments you might need, or unaware that you are at increased risk in drug or interventional treatments, or unaware of screening opportunities, or you might be unaware that pregnancy is particularly risky for you. Thus the information about a genetic mutation may have a much wider healthcare choice relevance than simply creating an opportunity to know whether you need a specific treatment for the genetic condition or not. When you don't know what the information is, or what it might be relevant to, you cannot experience the purported autonomy-limiting experience and then choose to reject it in the same way as the person who chooses to enter the monastic order. Harris and Keywood argue that ignorance of crucial information is inimical to autonomy in a way that other autonomy-limiting choices are not. For where the individual is ignorant of information that bears upon rational life choices, she is not in a position to be self-governing.[60] It might be argued that, from a legal perspective, decisions regarding knowledge of medical information about oneself are unique in requiring specific content, so that future decisions can meet the procedural conditions required by the law. Thus decisions regarding receipt of that information take on a substantive requirement that is absent from other choices which do not lead to an inability to fulfil the procedural conditions required for autonomous choice.

If English law's procedural autonomy requirements support the argument that a choice to have a test that leads to the creation of information should incorporate knowledge of that information, does this mean that we could rely on the principle of autonomy to require someone to have a diagnostic test in order to generate personal information? It might be argued that relevant information only becomes such when it exists, when we know its factual quality and in what context it might or might not be relevant. Requiring someone to know information about themselves that they do not want to know and requiring someone to submit to a test that is designed to generate personal information could be distinguished on the basis that the former involves intervening in the informational sphere but does not entail interruption of physical integrity, while the latter involves some interference with physical integrity. Some

58. Harris and Keywood, above n 54, at 419–420.
59. Ibid, at 419–420.
60. Ibid, at 419–420.

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commentators believe that protection of the informational sphere is as important as protection of the physical sphere.[61] However, English law does not reflect this position. It has a long tradition of providing robust protection against unwanted physical contact through the tort of battery, but not providing the same level of protection in the event of interference in the informational sphere. The tort of battery has been relied on to prevent health professionals from interfering with a patient's bodily integrity without patient consent.[62] Battery's protection against unwanted physical interference does not extend to protecting people from unwanted information. Thus while refusals of interventions that infringe bodily integrity, even if they might lead to the generation of new information, can be supported on the basis of autonomy, refusals of medical information that do not involve breaching physical integrity cannot be supported on the same basis.

From this perspective, a person could choose not to have the test and thus not receive any information. However, if they choose to have the test, English law provides no mechanism for protecting them from knowing the personal information that exists and is known by others. It is at the point of the test that the patient is asked to weigh up the benefits and burdens of having the test and knowing the information that the test might reveal.[63] It is part and parcel of making this decision that the patient decides whether or not to generate information about themselves. The argument that the patient can refuse the test on the basis of autonomy but not the information was reflected in the ACMG's original position, which provided that 'Patients have the right to decline clinical sequencing if they judge the risks of possible discovery of incidental findings to outweigh the benefits of testing.' Thus if patients want to protect themselves from genetic information that they do not want, they can find support for their choice to refuse the test on the basis of autonomy.[64] However, once patients have decided to generate information, this becomes relevant to choices and there is significant reason to doubt whether it would undermine their autonomy to require them to have that information.

4. DISCLOSURE OF INCIDENTAL FINDINGS AND THE PREVENTION OF PERSONAL HARM

If requiring personal knowledge does not breach the interest in autonomy, the need to offer a justification for disclosure is arguably reduced. However, although it might be argued that disclosing information to a person who does not want to know would not be legally recognised as an interference with their autonomy, it might be argued that unwanted disclosure could attract legal recognition on the basis that it caused harm. Requiring a person to know about her risk of future illness against her will could conceivably cause psychological harm, as the person struggles to cope with that information, which they cannot unknow.

61. See eg G Laurie *Genetic Privacy: A Challenge to Medico-Legal Norms* (Cambridge: Cambridge University Press, 2002).

62. *Re B (Consent to Treatment: Capacity)* [2002] 2 FLR 1090, for supportive comment, see also *Airedale NHS Trust v Bland* [1993] AC 789 Lord Keith at 857 and Lord Browne-Wilkinson at 882.

63. Green et al, above n 5, at 568. This is also the approach taken in relation to clinical exome sequencing at the Radboud University Nijmegen Medical Centre. Above n 12.

64. This approach is not without problems, especially in the clinical context. But this argument is not considered here.

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This redefines the problem in requiring knowledge. As we know, the ACMG perceived the tension to be between autonomy and harm prevention. Their view was that requiring knowledge was an interference with autonomy, but that it could be justified on the basis of preventing harm in the form of the manifestation of a genetic condition.[65] Because autonomy is treated (rightly or wrongly) as the supreme principle in English medical law, harm prevention does not justify interfering with autonomy. However, if requiring knowledge in the face of a refusal interferes with the interest in non-maleficence as opposed to the interest in autonomy, the tension between the interests at stake shifts, because the question becomes 'Does the potential to prevent physical harm in the form of the manifestation of a genetic condition, or avoidance of risks related to possessing that genetic mutation, justify risking causing psychological harm?' In the context of the legal articulation of medical principles, this sets up a level playing field, which makes it more difficult to determine what duties might be owed than if the tension existed between autonomy and harm prevention, where there is a clear hierarchy.[66]

It might be argued that we should take more care to avoid causing harm to people than we should to prevent harm to them. However, there is no certainty regarding whether harm will be caused (psychological) or prevented (physical) by the disclosure of unwanted genetic information. It might be argued, then, that we should focus on how the risk of harm might be minimised as opposed to how that harm might arise. Here, the physical harm v psychological harm interpretation presents a further an equivocality that is absent from the autonomy v physical harm interpretation. Where information is given to a person against their will, the ACMG assumed that the interference with autonomy was implicit in the disclosure. Prevention of physical harm is not similarly absolute at the point of disclosure; disclosure creates an *opportunity* to avoid physical harm, which will depend on a number of factors over and above having the information, such as the choice to submit to harm-preventing action, the likelihood of success in harm-preventing action and the choice not to run related risks. Thus, in addition to the general view that autonomy leads the hierarchy of principles in English medical law, the fact that autonomy *will* be interfered with while physical harm *might* be prevented adds weight to the argument that autonomy should trump non-maleficence if giving a person information is deemed to infringe autonomy.[67] However, when we are dealing with risks of harm where the level of each risk is uncertain, prioritisation becomes difficult.[68] It is to this question of setting priorities in minimising harm that this piece now turns.

At first sight, it might be argued that refusal of medical information is likely to be associated with an intention not to rely on that information to reduce risk, whether by having treatment to reduce the risk that the genetic condition will manifest or relying on the information to avoid related risks. We know that the ACMG sought to justify feedback in the face of a refusal, on the basis that knowledge could prevent physical harm.[69] Irrespective of whether requiring someone to have

65. Green et al, above n 5, at 568.
66. In the legal sense at least.
67. The argument here is, of course, that there is significant doubt about whether it does.
68. For the conditions on the ACMG list, the presence of the genetic mutation still leaves significant uncertainty as to whether the condition will manifest. For example, 55–65% of women who inherit a harmful BRCA1 mutation and 45% of women who inherit a harmful BRCA2 mutation will develop breast cancer by age 70: see http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA (accessed 18 July 2014).
69. Green et al, above n 5, at 586.

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information about themselves is an interference with their autonomy, providing a justification for a particular position opens that justification to scrutiny. It might be argued that, on the face of it, the ability of knowledge to lead to harm prevention in the context of a person's refusal of that knowledge is questionable. It is not the information that has the capacity to minimise the harm, but what you do with that information. From the perspective of the aim to prevent harm, not respecting the decision to refuse information would have to be accompanied by not respecting a refusal of the intervention that might prevent the harm, or interfering with a choice to run related risks.[70] However, there is reason to doubt that those who are given health information against their wishes will refuse to act to minimise risks to their health. Despite the intuitive appeal of the argument that refusals of genetic information will be associated with refusals of corresponding treatment, studies have consistently shown that that we cannot accurately predict how we will respond to future events.[71] In fact, our forecasts of our own future reactions are distorted, making our predictions 'typically inaccurate'.[72]

The inability to accurately predict our future emotional responses, and consequently decisions that are based on these emotional responses, is described in the psychological literature on affective forecasting. Affective forecasting does not describe a minority position in which a person's thinking is disordered or unconsidered; it is part of normal mental activity.[73] If our predictions of our actions are 'typically inaccurate',[74] the concern (outlined above) that refusal of information makes harm prevention unlikely may be unfounded, such that harm prevention in the form of avoiding a genetic condition or not engaging in high related risks can be presented as possible or probable even in the face of a desire not to have information.

Research into affective forecasting assesses accuracy by measuring both predicted and experienced responses, which allows a systematic study of errors. Mis-predictions of future responses occur because of impact bias, which leads people to overestimate the intensity and duration of their emotional reactions.[75] Central to impact bias theory are focalism, which leads us to underestimate the extent to which other events will influence our thoughts and feelings, and the failure to anticipate how quickly we will make sense of things that happen in a way that speeds emotional recovery. Although people are generally (though not always) accurate at knowing the valence of their emotional reaction to an experience – of knowing, that is, whether an experience will evoke a positive or negative emotional reaction – they are remarkably inaccurate at predicting the intensity and the duration of those emotions. This is so even for

70. That is, would we want to prevent risky pregnancy?

71. TD Wilson et al 'A source of durability bias in affective forecasting' (2000) 78 J Personality & Soc Psychol 821–836; DT Gilbert et al 'Immune neglect: a source of durability bias in affective forecasting' (1998) 75 J Personality & Soc Psychol 617–638; TD Wilson and DT Gilbert 'Affective forecasting: knowing what to want' (2005) 14 Current Directions Psychol Sci 131–134.

72. JA Blumenthal 'Law and the emotions: the problems of affective forecasting' (2004) 80 Ind L J 155–238 at 166.

73. R Rhodes and JJ Strain 'Affective forecasting and its implications for medical ethics' (2008) 17 Camb Q Healthcare Ethics 54–65 at 55.

74. Ibid, at 166.

75. Wilson et al, above n 71.

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relatively straightforward emotional experiences, such as winning the lottery or suffering severe injuries.[76]

Studies show that people are particularly prone to mis-predicting the negative emotions that they will feel when given adverse medical results. One study asked a group of people how they thought other people would feel when they received positive or negative HIV results. The judging group significantly over-predicted the distress that people with positive results experienced.[77] In a different study, women who were about to take a pregnancy test were asked to predict their emotional responses to the test results. Women who received bad news actually felt better than they expected.[78] This evidence raises doubts about people's fears that they will suffer lasting psychological harm on the basis of knowing information about an increased risk of illness. Any early distress that people experience upon learning adverse results, which might include the increased risk of a genetic condition, might subside as the person's psychological immune system kicks in.[79] If people who receive bad medical news do not suffer any long-term psychological harm, they are unlikely to be able to demonstrate harm that attracts legal recognition. In the legal context, psychological harm will only be recognised when it constitutes a medically recognised psychiatric condition.[80] Nevertheless, it might be argued that even though disclosure of unwanted genetic information is not likely to cause legally recognised harm, there is no reason to disrespect a person's wishes if they do not stand to gain some benefit. The ACMG clearly felt that the benefit from knowing one's risk was the ability to prevent physical harm. If the distortions of affective forecasting that lead people to wrongly predict their emotional responses to negative information also lead people to wrongly predict the choices that are inevitably guided by these emotional responses, the ACMG's argument that knowledge will prevent harm may also apply in cases of disclosures against the person's wishes.

One of the central factors affecting our inability to accurately predict our emotional response to illness is that our anticipation of illness is different from the experience of it. This creates a particular problem where people are required to make a decision about receiving information based on a prediction of how they will react to and make decisions based on the risk that an illness will occur. It seems that errors in judgement that arise through affective forecasting are rife in predicting responses to future occurrences where, at the time of the prediction, the person *does have* the relevant information about the future occurrence. Take, for example, surveys of people at risk of having the gene that causes Huntington's disease. Before a genetic test was available, the majority of the at-risk population said they would have the test if it was

76. P Brickman, D Coates and R Janoff-Bulman 'Lottery winners and accident victims: is happiness relative?' (1978) 36 J Personality & Soc Psychol 917–927.

77. EM Sieff, RM Dawes and G Loewenstein 'Anticipated versus actual reaction to HIV test results' (1999) 112 Am J Psychol 297–311.

78. BA Mellers 'Choice and relative pleasure of consequences' (2000) 126 Psychol Bull 910–924.

79. For a more detailed account of the psychological immune system, see Blumenthal, above n 72, at 175–176; DT Gilbert, E Driver-Linn and TD Wilson 'The trouble with Vronsky: impact bias in the forecasting of future affective states' in LF Barrett and P Salovey (eds) *The Wisdom in Feeling: Psychological Processes in Emotional Intelligence* (New York: Guilford Press, 2002) pp 114–143.

80. *Alcock v Chief Constable of South Yorkshire Police* [1992] 1 AC 310, Stocker LJ at 365.

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available.[81] However, when a test became available, the uptake rate was much lower than expected.[82] The people eligible for testing did not have any additional information about the nature of the test or the condition, but they were now experiencing the opportunity to have the test, as opposed to predicting their response to experiencing the opportunity to have the test. In a similar vein, assume that A has had a genetic test that reveals that she carries an APC-inactivating mutation.[83] In carriers of APC-inactivating mutations, the risk of colorectal cancer by age 40 is almost 100%. A knows that a colostomy will significantly reduce her chances of developing colon cancer, but she is consumed by the fear of living with a colostomy and chooses not to have this operation. She is told that having the operation now is much more likely to prevent mortality than if she has it upon developing cancer. A predicts that even if the cancer manifests she will refuse the operation because of her fear of living with a colostomy. However, when the cancer does occur, and she is offered a colostomy again, now she is faced with the decision in the context of experiencing the cancer, its symptoms and treatment and her impending death. Given this, she decides to have the colostomy operation. Her fear of, and subsequent focus on, the singular issue of having a colostomy proved to be exaggerated in the context of concomitant factors that arose in actual experience of the illness.

One of the particular problems associated with predicting decisions based on predicted emotional responses to learning adverse medical information about yourself is that fear might become a focal point, which plays a significant part in those predictions. Fear is an emotion that is particularly susceptible to over-prediction, and learning of an adverse medical prognosis and undergoing invasive medical intervention are both events that evoke fear.[84]

Predicted fears that are distorted by focalism might not be instrumental in actual experiences of illness and choice. Fear is not normally a lasting emotion. The psychological immune system enables people to overcome fear[85] and the ways in which they do this are likely to be specific to the individual. However, before fear can be overcome, the individual needs to experience it, because it is only then that they know what they need to do to overcome it. Experiencing the prediction of fear is not the same as experiencing fear, and experience of the prediction may not lead the individual to know how they will overcome that fear. The provision of relevant information has been shown to be a significant factor in reducing fear of medical

81. D Craufurd et al 'Uptake of pre-symptomatic predictive testing for Huntington's disease (letter)' (1989) 2 Lancet 603–605; G Evers-Kiebooms and M Decruyenaere 'Predictive testing for Huntington's disease: a challenge for persons at risk and for professionals' (1998) 5 Patient Educ & Counselling 15–26; MR Hayden 'Predictive testing for Huntington's disease – 15 years later', presentation during the International Congress of Human Genetics (Vienna, 15 May 2001); KA Quaid and M Morris 'Reluctance to undergo predictive testing: the case of Huntington's disease' (1993) 45 Am J Med 41–45; A Tibben et al 'Understanding the low uptake of pre-symptomatic DNA-testing for Huntington's disease (letter)' (1992) 340 Lancet 1416.

82. Above n 81.

83. This mutation is on the ACMG's recommended feedback list.

84. M Schmid et al 'Tomophobia, the phobic fear caused by an invasive medical procedure – an emerging anxiety disorder: a case report' (2009) 3 J Med Case Reports 131; TN Wise, MJ Marcangelo and DL Anderson 'Anxiety and anxiety disorders in medical settings' in DJ Stein, E Hollander and BO Rothbaum (eds) *Textbook of Anxiety Disorders* (Washington, DC: American Psychiatric Publishing, 2nd edn, 2009); BO Olatunji et al 'Development and initial validation of the medical fear survey – short version' (2012) 19 Assessment 318–336.

85. Above n 79.

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intervention.[86] Once in receipt of information about a specific risk, the person will be able to access further information, support and counselling that might diminish fear, proving the vague fear of the unknown that they felt when asked if they wanted to know incidental findings to be unfounded. From this perspective, the argument that requiring knowledge in the face of refusal would not lead to harm prevention becomes doubtful, because the predictions of refusal of treatment are based on exaggerated emotional responses that are 'typically inaccurate'.[87]

When a person is predicting whether they would submit to a medical intervention at the point of consenting to the receipt of incidental findings in a whole genome sequence, the prediction of future choices arguably becomes even more precarious, because it is not only a prediction, but a prediction of a future situation that is unlikely to occur. Most people who have clinical whole genome sequencing will not possess any of the mutations associated with the 24 genetic conditions on the minimum list. Thus, in effect, they are being asked to make a hypothetical decision about a situation that is unlikely to arise, and we might expect people to invest minimal time and effort in thinking about their preferences in unlikely hypothetical scenarios. Where the person's prediction is characterised by a lack of relevant information – crucially, whether they will have to make choices to which the prediction relates at all – the individual's prediction about where their focus might lie if and when they make choices might be mistaken and would not in fact be a focus if the person had the relevant information. If focalism can lead to errors in predicting emotional responses where it is known that the relevant situation will, or is likely to, arise in the future, errors might be even more likely where there is significant uncertainty as to whether the situation will arise at all.

Furthermore, at the time of consenting to the whole genome sequence, the person will be asked whether or not they want to know about mutations relating to many different genetic conditions in one consent episode, adding to the difficulties in accurate prediction. The 24 conditions on the minimum list raise different risks, require different types of treatment and will evoke predictions of different emotional reactions. If judgements about emotional reactions to singular illness situations are often erroneous, multiplying the situations that the person is required to consider in one episode is likely to further impair judgement.

Given that predictions of emotional responses to adverse medical information are prone to exaggeration through fear, it might be argued that the greatest opportunity to prevent harm will be realised by requiring a person to know incidental information depicting an increased genetic risk. This is because her prediction that she will suffer an adverse psychological response upon knowing the medical information is likely to be exaggerated, as are her predictions that fear will leave her unable to act on that information to minimise the risks to her health.

CONCLUSION

The ethics committee advising Genomics England will soon have to tackle the very difficult issue of what information to feed back to patients who have their whole genome sequenced through the project. The advice that the committee gives will

86. DPH Stark and A House 'Anxiety in cancer patients' (2000) 83 Br J Cancer 1261–1267 at 1265; M Lowry 'Knowledge that reduces anxiety' (1995) 10 Prof Nurse 318–320.
87. Blumenthal, above n 72, at 166.

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depend on the principles that it conceives to be at stake and the reflection of those principles in English medical law. This paper considers the concept of required knowledge in the context of English medical law. In the USA, the required knowledge position was short-lived, because the tension was presented as being between autonomy and personal harm prevention. If required knowledge is seen to be an interference with autonomy in the UK, the superior status of that principle in English law might lead the committee to reject the required knowledge position. Taking the cue from other jurisdictions in which the required feedback position is adopted, this piece challenges the position that requiring knowledge interferes with autonomy in the sense in which it is conceived in English medical law. It is argued that information is central in autonomous decision making in English law, giving us significant reason to question whether a choice that rejects relevant information ought to be recognised as autonomous.

It is argued here that a principled position against required knowledge might be based on the fact that it might cause psychological harm. However, if preventing harm is the reason to respect choices not to have relevant information, this needs to be balanced against the harm prevention reason for requiring knowledge of that information. Given that both interests arise from the same principle; namely non-maleficence, there is no clear hierarchy, as there would be if required knowledge did interfere with autonomy. This piece offers an argument about how harms might be balanced in this competing harms context, which is based on an assessment of the likelihood that each harm will arise. We see that knowing unwanted information is not necessarily more likely to lead to harm than not knowing it, further strengthening the case for Genomics England to consider the required feedback position.

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